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Application Proof of

RemeGen Co., Ltd.*

榮昌生物製藥(煙台)股份有限公司

(the “Company”)

(A joint stock company incorporated in the People’s Republic of China with limited liability)

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RemeGen Co., Ltd.*

榮昌生物製藥(煙台)股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

[REDACTED]

Number of [REDACTED] under : [REDACTED] H Shares (subject to the
the [REDACTED] [REDACTED])
Number of [REDACTED] : [REDACTED] H Shares (subject to
adjustment)
Number of [REDACTED] : [REDACTED] H Shares (subject to
adjustment and the [REDACTED])
Maximum [REDACTED] : HK\$[REDACTED] per H Share, plus
brokerage of 1%, SFC transaction levy
of 0.0027%, and Stock Exchange
trading fee of 0.005% (payable in full
on application in Hong Kong dollars
and subject to refund)
Nominal value : RMB1.00 per H Share
Stock code : [●]

Joint Sponsors, [REDACTED], [REDACTED] and [REDACTED]

Morgan Stanley



华泰国际
HUATAI INTERNATIONAL

J.P.Morgan

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We are incorporated and a substantial majority of our business and assets are located in the PRC. Potential investors should be aware of the differences in the legal, economic and financial systems between the PRC and Hong Kong, and the fact that there are different risk factors relating to investment in PRC-incorporated companies. Potential investors should also be aware that the regulatory framework in the PRC is different from the regulatory framework in Hong Kong, and should take into consideration the different market nature of the H Shares. Such differences and risk factors are set out in the sections headed “Risk Factors” and “Regulatory Overview” in this document and in Appendix IV, Appendix V and Appendix VI to this document.

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* For identification purpose only

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

EXPECTED TIMETABLE⁽¹⁾

[REDACTED]

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SUMMARY

This summary aims to give you an overview of the information contained in this document and is qualified in its entirety by, and should be read in conjunction with, the more detailed information and financial information appearing elsewhere in this document. As this is a summary, it does not contain all the information that may be important to you and we urge you to read the entire document carefully before making your investment decision. There are risks associated with any investment. Some of the particular risks in investing in the [REDACTED] are set out in the section headed “Risk Factors” in this document. You should read that section carefully before you decide to invest in the [REDACTED]. In particular, we are a biopharmaceutical company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules.

OVERVIEW

We are a commercial-ready biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics for the treatment of autoimmune, oncology and ophthalmic diseases with unmet medical needs in China and globally. Our vision is to become a leading player in the global biopharmaceutical industry.

Since our inception in 2008, we have been dedicated to the research and development of biologics with novel targets, innovative design and breakthrough potential to address global unmet clinical needs. Through more than ten years of meticulous efforts, we have built a fully-integrated, end-to-end therapeutics platform encompassing all the key biologic drug development functionalities, including discovery, pre-clinical pharmacology, process and quality development, clinical development, and manufacturing in compliance with global good manufacturing practice (GMP). Leveraging our strong research and development (R&D) platforms, we have discovered and developed a robust pipeline of more than ten drug candidates. Among our drug candidates, five are in clinical development stage targeting 17 indications and more than five are in the investigational new drug (IND) application filing preparation stage. Two of our clinical-stage candidates, telitacicept (RC18) and disitamab vedotin (RC48), are in registrational trials targeting six indications in China and the U.S. Our new drug application (NDA) for telitacicept in China for systemic lupus erythematosus (SLE) was accepted by the National Medical Products Administration (NMPA) in November 2019 and was granted priority review the following month. We expect to receive approval from the NMPA to market telitacicept in China for SLE in the fourth quarter of 2020.

SUMMARY

The following chart illustrates our pipeline and summarizes the development status of our clinical-stage drug candidates and selected IND-enabling stage candidates as of the Latest Practicable Date:

Drug Candidates	Target (Modality)	Indication	Status (Clinical Sites Indicated on Status Bar)					NDA/BLA submission date	Commercial Rights			
			Pre-clinic.	IND	Ph I	Ph II	Pivotal/Ph III					
Autoimmune Diseases Telitacept (RC18)*	BlyS/APRIL (fusion protein)	Systemic Lupus Erythematosus	China					NDA Filed	October 2019	Global		
		Systemic Lupus Erythematosus	US									
		Neuromyelitis Optica Spectrum Disorder	China									
		Rheumatoid Arthritis	China									
		IgA Nephritis	China									
		Sjogren's Syndrome	China									
		Multiple Sclerosis	China									
		Myasthenia Gravis	China					In registrational trial ⁽⁶⁾				
Oncology Disitamab Vedotin (RC48)*	HER2 (ADC)	HER2-Expressing ² Gastric Cancer	China					3	Q3 of 2020	Global		
		HER2-Expressing Urothelial Cancer	China					4	1H of 2021			
		HER2-Expressing Urothelial Cancer	US					5				
		HER2-Expressing Gastric Cancer	US					6				
		HER2 Low-Expressing ² Breast Cancer	China						In registrational trial ⁽⁶⁾			
		HER2 Low- to Non-Expressing ² Urothelial Cancer	China									
		HER2-Expressing Biliary Tract Carcinoma	China									
		HER2-Expressing Non-Small-Cell Lung Cancer	China									
		RC88	Mesothelin (ADC)	Multiple Solid Tumors	China							Global
		RC98	PD-L1 (mAb)	Multiple Solid Tumors	China							Global
		RC108	c-MET (ADC)	Multiple Solid Tumors	China							Global
RC118	Confidential (ADC)	Multiple Solid Tumors	China						Global			
RC138	Confidential (HiBody)	Multiple Solid Tumors	China						Global			
RC148	Confidential (HiBody)	Multiple Solid Tumors	China						Global			
RC158	Confidential (HiBody)	Multiple Solid Tumors	China						Global			
Ophthalmology RC28*	VEGF/FGF (fusion protein)	Wet Age-Related Macular Degeneration	China					7		Global		
		Diabetic Macular Edema	China					8				
		Diabetic Retinopathy	China					9				

* Denotes our core drug candidates.

Abbreviations: 1H = first half; ADC = antibody drug conjugate; HiBody = a novel bifunctional antibody; mAb = monoclonal antibody; Q3 = third quarter

Notes:

- (1) The U.S. Food and Drug Administration (FDA) has provided clearance for us to proceed with the Phase III clinical trial of telitacept for SLE in the U.S in January 2020 and granted telitacept Fast Track designation in April 2020.
- (2) HER2-expressing refers to a human epidermal growth factor receptor 2 (HER2) status of tumor cells identified with a test score of IHC 1+ or above. HER2 low-expressing refers to a HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+/FISH-. HER2 non-expressing refers to HER2 status of tumor cells identified with a test score of IHC 0.
- (3) In China, we are (i) finalizing a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) gastric cancer (GC), and (ii) conducting a Phase I clinical trial to evaluate disitamab vedotin in combination with PD-1 inhibitor for the treatment of HER2 over-expressing GC.
- (4) In China, we are conducting (i) a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) urothelial cancer (UC), and (ii) a Phase Ib/II trial to evaluate disitamab vedotin in combination with PD-1 inhibitor for the treatment of UC.
- (5) The FDA has provided clearance for us to proceed with the Phase II clinical trial of disitamab vedotin in the U.S in April 2020.
- (6) We have initiated pre-IND discussion with the FDA to obtain their consents for disitamab vedotin's Phase II clinical trial in GC in the U.S.
- (7) We have completed a Phase I trial of RC28 in wet age-related macular degeneration (wet AMD) in August 2019 in China, of which the primary endpoint of safety was met. In July 2018, we obtained the NMPA's approval for us to conduct Phase I, II and III trials of RC28 according to our clinical development plan and progress, and the NMPA has not raised any objections towards our clinical trials of RC28 since then. We are currently conducting a Phase Ib trial of RC28 to further evaluate its efficacy and safety for the treatment of wet AMD.
- (8) We plan to initiate a Phase II trial for RC28 in diabetic macular edema in the second half of 2020 in China.
- (9) We plan to initiate a Phase II trial for RC28 in diabetic retinopathy in the second half of 2020 in China.
- (10) Registrational trial, or pivotal trial, means the clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval.

SUMMARY

Our pipeline features three highly-differentiated core drug candidates, and we are developing them for autoimmune, oncology and ophthalmic diseases, respectively:

- **Telitacept (RC18)** is a first-in-class new drug application (NDA)-filed late-stage innovative TACI-Fc fusion protein targeting two important cell-signaling molecules, B-cell lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL), implicated in B cell-mediated autoimmune diseases. For details on its mechanism of action, please refer to the paragraph headed “Business — Our Core Drug Candidates — Telitacept (RC18) — Mechanism of Action.” We are carrying out a broad clinical development program for this drug candidate targeting a variety of B cell-mediated autoimmune diseases with unmet or underserved medical needs.

SLE is the lead indication of telitacept. In SLE, we have completed a Phase IIb registrational study in China, where telitacept showed robust efficacy and a favorable safety profile, and has supported best-in-class potential in treating SLE. The primary endpoint of this trial was the proportion of patients achieving SRI-4 response at week 48. Telitacept treatment groups at multiple doses in this trial had significantly higher SRI-4 response rates (70% to 79%) than the placebo group (32%), which indicates significant reduction in SLE disease activity in the telitacept treatment groups. In general, telitacept was well tolerated by patients in this trial, with a serious adverse event (SAE) rate ranging from 13% to 16% across the treatment groups for dose levels ranging from 80mg to 240mg, comparing to the placebo group which had an SAE rate of 16%. For more details on this trial, please refer to the paragraph headed “Business — Our Core Drug Candidates — Telitacept (RC18) — Summary of Clinical Trial Results.” Based on the results of this trial, we submitted our NDA to the NMPA for conditional approval of telitacept for SLE in October 2019. The NMPA accepted our NDA in November 2019 and granted it priority review based on the significant unmet medical need in December 2019. The approval will be conditional on a commitment to complete a confirmatory Phase III trial in SLE post the commercial launch, and we are currently enrolling patients in this Phase III trial. We expect to receive marketing approval in China and commence commercialization activities in the fourth quarter of 2020.

In addition to SLE, we are actively developing telitacept for six other B cell-mediated autoimmune diseases in late-stage clinical trials in China, including (i) two registrational studies in neuromyelitis optica spectrum disorder (NMOSD) and in rheumatoid arthritis (RA), (ii) two Phase II studies in indications with large patient populations but few efficacious treatments available, including IgA nephropathy (IgAN) and Sjögren’s syndrome (SS), and (iii) two additional Phase II studies in hard-to-treat rare diseases, including multiple sclerosis (MS) and myasthenia gravis (MG).

Based on the encouraging clinical trial results in China and our clearly defined U.S. clinical development strategy, telitacept has the potential to become the first created-in-China first-in-class biologic drug to be approved for marketing in the

SUMMARY

U.S. Among other efforts, we obtained the FDA’s consent for entry into a registrational trial for the treatment of SLE in the U.S. in January 2020, and the FDA granted telitacicept Fast Track designation in April 2020. We expect to initiate the global Phase III clinical trials in SLE covering multiple jurisdictions, including the U.S., Europe and other countries, in the first half of 2021.

- **Disitamab vedotin (RC48)** is a late-stage anti-HER2 antibody-drug conjugate (ADC) targeting prevalent cancers with significant unmet medical needs, and it is the first domestically-developed ADC in China to have entered clinical development. For details on its mechanism of action, please refer to the paragraph headed “Business — Our Core Drug Candidates — Disitamab vedotin (RC48) — Mechanism of Action.” We are implementing a differentiated development and commercial strategy for disitamab vedotin, targeting prevalent HER2-expressing indications that are currently underserved, including both (i) HER2-expressing cancer (IHC 1+ or above) indications beyond breast cancer (BC), such as gastric cancer (GC) and urothelial carcinoma (UC) (both currently in registrational trials in China), and (ii) HER2 low-expressing cancer (IHC 2+/FISH- or IHC 1+) indications, such as HER2 low-expressing BC (currently in a registrational trial in China). These therapeutic areas represent a less crowded but underserved field for HER2-targeted therapies, and a broad addressable patient population for disitamab vedotin.

Based on its design advantages, disitamab vedotin has demonstrated superior anti-tumor activity and good tolerability in a registrational study in GC and a Phase II study in UC. In our Phase II registrational trial for GC, disitamab vedotin delivered an independent review committee (IRC)-assessed confirmed objective response rate (ORR) of 24.4%, median progression-free survival (PFS) of 4.1 months and median overall survival (OS) of 7.6 months in 127 patients with HER2 over-expressing (IHC 2+ or IHC 3+) GC or GEJ cancer post to second lines of prior chemotherapy treatment as of June 22, 2020. In the initial Phase II study with 43 HER2 over-expressing (IHC 2+ or IHC 3+) second line UC patients, disitamab vedotin generated best ORR of 60.5%, confirmed ORR of 51.2%, and median PFS of 6.9 months. For more details on these trials, please refer to the paragraph headed “Business — Our Core Drug Candidates — Disitamab vedotin (RC48) — Summary of Clinical Trial Results.” We plan to file NDAs with the NMPA for disitamab vedotin in the third quarter 2020 for GC and in the first half of 2021 for UC.

Leveraging the promising efficacy and safety data observed in our clinical trials in China so far, we are actively exploring overseas trial opportunities for disitamab vedotin. In the U.S., disitamab vedotin has received orphan drug designation from the FDA for GC as treatment for a rare disease, and the FDA has cleared its IND application for a Phase II study in the U.S. for UC. We plan to initiate U.S. studies of disitamab vedotin in UC and GC patients in 2021.

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- **RC28** is a potential first-in-class vascular endothelial growth factor (VEGF)/fibroblast growth factor (FGF) dual-targeting fusion protein for the treatment of eye diseases. Compared to single-target VEGF inhibitors, RC28 has the potential to more effectively inhibit the abnormal blood vessel growth implicated in various eye diseases through both VEGF and FGF pathways, and potentially allows for a better dosing profile. RC28 has demonstrated good safety in a Phase I dose escalation study in patients with wet age-related macular degeneration (wet AMD) in China. We have initiated a Phase Ib study in wet AMD and plan to initiate Phase II clinical studies in diabetic macular edema (DME) and diabetic retinopathy (DR) in the second half of 2020 in China.

As of the Latest Practicable Date, with respect to our three core drug candidates, we own three issued Chinese patents, six pending Chinese patent applications, two issued U.S. patents, one pending U.S. patent applications, four pending Patent Cooperation Treaty (PCT) applications, and 36 issued patents and 15 patent applications in other jurisdictions.

Our fully-integrated platform is driven by a proprietary R&D engine, which consists of three specialized platforms, including (i) an antibody and fusion protein platform, based on which we are internally developing telitacept, RC28 and RC98 (a clinical-stage PD-L1 antibody); (ii) an ADC platform, based on which we are internally developing disitamab vedotin, RC88 (a clinical-stage anti-mesothelin ADC) and two IND-enabling stage ADCs (RC108 and RC118); and (iii) a bifunctional antibody (HiBody) platform, based on which we are internally developing three IND-enabling stage HiBody compounds (RC138, RC148 and RC158). Furthermore, we actively seek and leverage partnership opportunities with preeminent academic and research institutions in the discovery and development of our drug candidates. For further details, please refer to the paragraph headed “Business — Collaboration Agreements” in this document.

Our Co-Founder, Chief Executive Officer (CEO) and Chief Scientific Office (CSO), Dr. Fang, is one of the few founders in China’s biopharmaceutical industry with a successful track record of progressing novel biological drugs from discovery through development and commercialization. A Harvard-trained scientist, Dr. Fang is a visionary leader in translating biomedical discovery into therapeutics. He invented many molecules in our pipeline and is the key driving force for our continual innovation. Furthermore, we have assembled an experienced senior management team with an average of more than 20 years of industry experience (mostly in the U.S.) and proven track records of innovative drug R&D, clinical development and commercialization.

Another key driver of our success has been our strong clinical development capability and insights in regulatory affairs. Led by our Chief Medical Officer, Dr. Ruyi He, our clinical development function has approximately 200 employees and carries out our global clinical development plan through both rigorous trial design and trial operational excellence. More importantly, our clinical development team discovers and explores often unanticipated clinical opportunities, which has organically stimulated the growth and expansion of our clinical development programs. Leveraging Dr. He’s nearly 20 years of unique policy-making and managerial experience at the FDA in the U.S. and the NMPA in China, we have accumulated substantial expertise in and familiarity with regulatory review requirements and approval

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processes in China, the U.S. and beyond. Since our inception, we have submitted ten IND applications for five drug candidates and have obtained approvals for all applications, including two applications which received clearance from the FDA in the U.S. for telitacicept and disitamab vedotin. In addition, we have submitted an NDA in China for our telitacicept and have obtained priority review status.

Our global GMP-compliant manufacturing facilities in Yantai, Shandong Province house six 2,000L disposable bag bioreactors for a total capacity of 12,000L. With these capabilities and experiences, we have established a successful track record of manufacturing five drug candidates in-house. We are building new manufacturing facilities and plan to expand our total production capacity to 36,000L by the end of 2021. To support our near-term launch of telitacicept, we have assembled the sales leadership team and expect to build a strong sales and marketing team of around 100 members with rich sales experience in the autoimmune areas in the second half of 2020, which is expected to further expand to 200 members in the second 12-month period after the commercial launch.

We build and operate our fully-integrated platform with a global vision. In addition to designing and implementing our global clinical development programs for our innovative drug candidates, our regulatory affairs and commercialization teams have invested significant resources in seeking regulatory filings, marketing approvals and eventually successful commercial launches for these products in major markets both in and outside China. We also have been actively seeking strategic partnership opportunities with global leading pharmaceutical companies to maximize the clinical and commercial value of these potential first-in-class and/or best-in-class drug products.

OUR COMPETITIVE STRENGTHS

- First-in-class registrational-stage fusion protein telitacicept with impressive therapeutic efficacy in B cell-mediated autoimmune diseases.
- Late-stage anti-HER2 antibody-drug conjugate disitamab vedotin targeting prevalent cancers with significant unmet medical needs.
- Potential first-in-class VEGF/FGF dual-targeting fusion protein (RC28) targeting ophthalmic diseases with huge market potential.
- A proprietary R&D engine pursuing breakthrough science to generate innovative and best-/first-in-class therapeutics.
- Integrated in-house capabilities well position the Company for biomedical innovation from bench to bedside.
- A visionary management team with rich industry experience and scientific expertise and backed by leading healthcare investors.

SUMMARY

OUR STRATEGIES

- Rapidly advance the development and commercialization of our existing pipeline products, primarily focusing on obtaining marketing approvals and launching commercial sales of our core products.
 - Obtain marketing approval and launch telitacicept for the treatment of SLE in China in fourth quarter of 2020.
 - Advance the clinical development of disitamab vedotin towards commercialization across a variety of solid tumor types.
 - Advance clinical development of RC28 in various ophthalmic diseases.
 - Continuously advance clinical trials of other products by leveraging our outstanding in-house clinical research and development capabilities.
- Execute our well-planned and organized global strategy.
 - Actively carry out global multi-center clinical trials for our core products.
 - Implement a global registration strategy to achieve commercialization of our products globally.
 - Actively seek commercial partnerships with global pharmaceutical companies to maximize the clinical and commercial value of our pipeline products.
 - Expand our global footprint and enhance our all-around drug discovery and development capabilities.
- Scale up manufacturing capacity to meet the needs of global clinical studies and commercial sales.

SUMMARY HISTORICAL FINANCIAL INFORMATION

This summary of key financial information set forth below has been derived from, and should be read in conjunction with, our consolidated audited financial statements, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix I to this document, as well as the information set forth in the section headed “Financial Information.”

Summary Consolidated Statements of Profit or Loss

During the Track Record Period, as we did not obtain regulatory approval for the commercial sale of any of our drug candidates, we had not generated any revenue from sales of any drug candidate. We recognized revenue of RMB11.3 million, nil, nil and nil in 2018, 2019 and the three-month periods ended March 31, 2019 and 2020, respectively, all of which was generated from our provision of contract research and pre-clinical development services to Rongchang Zibo, our related party. We were not profitable and incurred operating losses during the Track Record Period. We had loss of RMB269.9 million, RMB430.3 million, RMB87.8 million and RMB99.6 million in 2018, 2019 and the three-month periods ended March 31, 2019 and 2020, respectively. Substantially all of our losses resulted from our research and development expenses, administrative expenses and finance costs.

SUMMARY

The following table sets forth selected components of our consolidated statements of profit or loss for the periods indicated:

	Year Ended December 31,		Three months ended March 31,	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Revenue	11,321	–	–	–
Cost of sales	(8,932)	–	–	–
Gross profit	2,389	–	–	–
Other income and gains	15,377	38,481	2,551	7,316
Selling and distribution expenses	–	(621)	–	(1,306)
Administrative expenses	(29,125)	(68,434)	(8,420)	(20,336)
Research and development costs	(216,438)	(352,066)	(69,137)	(75,210)
Impairment losses on financial assets, net	(196)	134	–	(79)
Other expenses	(1,900)	(3,985)	(325)	(1,008)
Finance costs	(40,055)	(43,789)	(12,430)	(8,970)
Loss before tax	(269,948)	(430,280)	(87,761)	(99,593)
Income tax expenses	–	–	–	–
Loss for the year/period	<u>(269,948)</u>	<u>(430,280)</u>	<u>(87,761)</u>	<u>(99,593)</u>

Summary Consolidated Statements of Financial Position

The following table sets forth selected information from our consolidated statements of financial position as at the dates indicated:

	As at December 31,		As at March 31,
	2018	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Total non-current assets	466,208	551,737	647,080
Total current assets	64,884	137,574	498,455
Total assets	<u>531,092</u>	<u>689,311</u>	<u>1,145,535</u>
Total non-current liabilities	32,331	64,327	59,295
Total current liabilities	996,939	856,953	680,024
Net current liabilities	932,055	719,379	181,569
Total liabilities	1,029,270	921,280	739,319
Net (liabilities)/assets	<u>(498,178)</u>	<u>(231,969)</u>	<u>406,216</u>

SUMMARY

We recorded net liabilities of RMB498.2 million and RMB232.0 million as of December 31, 2018 and 2019, respectively, and recorded net current liabilities of RMB932.1 million, RMB719.4 million, RMB181.6 million and RMB258.4 million as of December 31, 2018 and 2019, March 31, 2020 and April 30, 2020, respectively, mainly attributable to our borrowings and interest payables to RC Pharma in an amount of RMB858.3 million, RMB588.1 million, RMB523.7 million and RMB494.4 million under current liabilities as of December 31, 2018 and 2019, March 31, 2020 and April 30, 2020, respectively. For more details, please refer to the paragraphs headed “Financial Information—Indebtedness” in this document. We plan to repay the borrowings from RC Pharma by using a portion of net [REDACTED] from the [REDACTED]. For more details, please refer to the section headed “Future Plan and [REDACTED]” in this document. As a result, we expect to improve our liquidity position in the future.

Summary Consolidated Statements of Cash Flows

Our primary uses of cash are to fund the development of our drug candidates, our clinical trials, our payment for the construction of research and manufacturing facilities and for the purchase of equipment, administrative expenses and other recurring expenses. Our net cash used in operating activities was RMB128.0 million, RMB282.7 million, RMB58.1 million and RMB117.9 million in 2018 and 2019, and the three-month periods ended March 31, 2019 and 2020, respectively, primarily due to the significant research and development expenses, administrative expenses and finance costs we incurred during the Track Record Period without generating any revenue from sales of our drug candidates. Our operating cash flow will continue to be affected by our research and development expenses. During the Track Record Period and up to the Latest Practicable Date, we primarily funded our working capital requirements through proceeds from private equity and debt financing. Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. Our Directors are of the opinion that, taking into account of the financial resources available to us, including cash and cash equivalents, available credit facilities, the estimated net [REDACTED] from the [REDACTED] and government grants, we have sufficient working capital to cover at least 125% of our costs, including research and development costs, business development and marketing expenses, and administrative and operating costs for at least the next 12 months from the date of this document. Even without taking into account the estimated net [REDACTED] from the [REDACTED], by taking into account our current financial position (i.e. cash and cash equivalents, Pre-[REDACTED] proceeds in transit, and unutilized credit facilities as of March 31, 2020), our Directors believe that we can remain financially viable for approximately 16 months from March 31, 2020, assuming our cash burn rate going forward will be similar to the cash burn rate level for the three-month period ended March 31, 2020. Our cash burn rate refers to the average monthly amount of (i) cash operating costs (including repayment of lease liabilities), and (ii) interest paid, and amounted to RMB17.6 million, RMB40.0 million, and RMB33.9 million in 2018, 2019 and the three-month period ended March 31, 2020, respectively.

SUMMARY

The following table sets forth our cash flows for the periods indicated:

	Year ended December 31,		Three months ended March 31,	
	2018	2019	2019	2020
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(Unaudited)</i>	
Cash outflow from operating activities before movements in working capital	(205,850)	(338,438)	(64,866)	(77,205)
Changes in working capital	77,801	55,545	6,806	(40,894)
Interest received	21	147	3	239
Net cash flows used in operating activities	(128,028)	(282,746)	(58,057)	(117,860)
Net cash flows used in investing activities	(77,172)	(95,100)	(19,519)	(121,926)
Net cash flows from financing activities	206,289	407,322	77,904	493,539
Net increase in cash and cash equivalents	1,089	29,476	328	253,753
Cash and cash equivalents at end of the year/period	5,069	34,545	5,397	287,603

KEY FINANCIAL RATIOS

The table below sets forth the key financial ratios of our Group as at the dates indicated:

	As at December 31,		As at March 31,
	2018	2019	2020
	%	%	%
Current ratio ⁽¹⁾	6.5	16.1	73.3
Quick ratio ⁽²⁾	3.5	12.4	68.4

Notes:

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories and divided by current liabilities as of the same date.

For more information on our key financial ratios, please refer to the paragraphs headed “Financial Information – Key Financial Ratios.”

RISK FACTORS

There are certain risks relating to an investment in our H Shares. A detailed discussion of the risk factors is set forth in the section headed “Risk Factors”. A summary of certain of these risk factors is set forth below. Any of the following developments may have a material and adverse effect on our business, financial condition, results of operations and prospects:

SUMMARY

Our business faces risks including those set out in the section headed “Risk Factors”. As different investors may have different interpretations and criteria when determining the significance of a risk, you should read the “Risk Factors” section in its entirety before you decide to invest in the [REDACTED]. Some of the major risks that we face include:

- We have incurred significant net losses since inception, and expect to continue to incur net losses for the foreseeable future and we may not be able to generate sufficient revenue to achieve or maintain profitability. Potential investors may lose substantially all their investments in us given the high risks involved in our business.
- We had net liabilities and net cash outflows in operating activities during the Track Record Period.
- We have a limited operating history, particularly as a standalone company, and have only recently begun commercializing our drug candidates, which may make it difficult to evaluate our current business and predict our future performance.
- Our business and financial prospects depend substantially on the success of our clinical-stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals or achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.
- If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.
- We have limited experience in manufacturing therapeutic biologic products on a large commercial scale, which is a highly exacting and complex process, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.
- Our drug candidates, once approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for their commercial success.
- Our success depends, in part, on our ability to obtain and maintain patent, trade secret and other intellectual property and regulatory exclusivity. We may not be able to ensure that we will be able to do so successfully.
- The success of our drug candidates depend on ensuring that we do not infringe, misappropriate or otherwise violate the patent, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of such third party. We may not be able to ensure that we will be able to do so successfully.

You should read the entire section headed “Risk Factors” in this document before you decide to invest in the [REDACTED].

SUMMARY

RECENT DEVELOPMENTS

As we continue to advance the development of our pipeline and expand our clinical development programs, we expect to incur increasing research and development expenses and administrative expenses, which will lead to an increase in our total losses for the year ending December 31, 2020.

IMPACT OF THE COVID-19 OUTBREAK

In December 2019, a novel strain of coronavirus causing coronavirus disease 2019 (COVID-19), was reported in Wuhan, China. The spread of COVID-19 subsequently evolved into a global pandemic and continues to affect China, where we manage our business and are conducting pre-clinical studies and clinical trials, as well as the U.S., Europe and other countries, where we intend to carry out our global clinical development plan. The outbreak of COVID-19 since the end of 2019 has not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in our clinical trials. We have employed various measures to mitigate any impact the COVID-19 outbreak may have on our ongoing clinical trials in China, including cooperating with clinical trial sites to offer personal protection equipment such as masks to our enrolled patients, engaging frequent communications with our principal investigators to identify and address any issues that may arise. Although we experienced minor delays in the patient enrollment process and data entry for certain of our clinical trials in China at the beginning of the COVID-19 outbreak, since then the situation has improved due to the enhanced containment policies implemented by the PRC government and the gradual control of the COVID-19 outbreak in China. As of the Latest Practicable Date, we had resumed the normal patient enrollment and data entry for our clinical trials in China. With respect to our global clinical development plan, (a) we expect to initiate global Phase III clinical trials of telitacicept for SLE in the first half of 2021 to cover multiple jurisdictions, including the United States, Europe and other countries, and (b) we expect to initiate a Phase II trial of disitamab vedotin in UC in the U.S. in the first quarter of 2021, while to initiate a bridging trial in GC patients in the first half of 2021 in the U.S. to seek expedited approval. We are currently conducting preparation works for the aforementioned clinical trials, and had not initiated the patient enrollment process for these clinical trials as of the Latest Practicable Date. We currently do not expect a delay in the aforementioned global clinical development plan of telitacicept and disitamab vedotin. We expect the situation to continue to improve with the sustained implementation of containment policies for the COVID-19 outbreak, and we do not expect it to have any material long-term impact on our clinical trials or our overall clinical development plans. Based on the foregoing, we currently expect that our ongoing clinical trials will not be significantly affected by the outbreak of COVID-19.

We believe that the COVID-19 outbreak will not significantly affect our ability to carry out our obligations under existing contracts or disrupt any supply chains that we currently rely upon. As of the Latest Practicable Date, our top five suppliers in 2019 and other major domestic suppliers had all resumed normal operations, and none of our overseas suppliers had reported any disruption to their business operations as a result of COVID-19.

SUMMARY

We have resumed our normal operations since February 9, 2020 in accordance with applicable regulations. As of the Latest Practicable Date, we had no suspected or confirmed COVID-19 cases on our premises or among our employees. To prevent any spread of COVID-19 in our offices and production facilities, we have adopted a thorough disease prevention scheme to protect our employees from the spread of COVID-19. The measures we have implemented include, among others, regularly sterilizing and ventilating our offices and production facilities, checking the body temperature of our employees daily, keeping track of the travel history and health conditions of employees, and providing face masks and disinfectant to employees attending our offices and facilities.

Our Directors believe that, based on information available as of the date of this document, while the extent to which the COVID-19 outbreak will affect our operations cannot be predicted at this stage, the outbreak of COVID-19 would not result in a material impact on our business operations because (i) we currently expect that our clinical trials will not be significantly affected by the outbreak of COVID-19; (ii) none of our major customers and suppliers is located in Hubei Province (the epicenter in China before the outbreak was contained) or any other regions under government lockdown; (iii) our supply chain has not experienced any material disruption since the outbreak of COVID-19; (iv) none of our headquarters, offices and other facilities are located in Hubei province or any other region under government lockdown; (v) we have resumed our normal operations since February 9, 2020; (vi) substantially all of our employees reside outside of locations under government lockdown; and (vii) the PRC government has brought down the new reporting COVID-19 infection cases to low digit numbers as of the Latest Practicable Date.

It is uncertain when and whether COVID-19 could be contained globally. The above analyses are made by our management based on currently available information concerning COVID-19. We cannot guarantee you, however, that the COVID-19 outbreak will not further escalate or have a material adverse effect on our results of operations, financial position or prospects. For example, with the ongoing COVID-19 outbreak around the world, we cannot assure you that our global clinical development plan covering multiple jurisdictions including the United States, Europe and/or other countries, will not be adversely affected. If the COVID-19 continues to spread in the United States, Europe and/or other countries, we may need to adjust or even postpone our current global clinical development plan. For more details, please refer to the paragraphs headed “Risk Factors – Risks relating to Our Operations – We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control” in this document. We are constantly monitoring the COVID-19 outbreak situation as well as various regulatory and administrative measures adopted by local governments to prevent and control the pandemic. We will continue to monitor and evaluate any impact of the COVID-19 outbreak on us and adjust our precautionary measures according to the latest developments of the outbreak.

Our Directors confirm that, save as disclosed above, there has been no material adverse change in our financial, operational or trading position or prospects since March 31, 2020 and up to the date of this document and there is no event since March 31, 2020 which would materially affect the information shown in our consolidated financial statements included in the Accountants’ Report in Appendix I to this document.

SUMMARY

SHAREHOLDER INFORMATION

Mr. Wang, Dr. Fang, Mr. Lin Jian (林健), Dr. Wang Liqiang (王荔強), Mr. Wang Xudong (王旭東), Mr. Deng Yong (鄧勇), Mr. Xiong Xiaobin (熊曉濱), Mr. Wen Qingkai (溫慶凱), Ms. Yang Minhua (楊敏華) and Mr. Wei Jianliang (魏建良), Rongda, RongChang Holding Group LTD. and I-NOVA Limited (together, the “Concert Parties”) have acted in concert in the management, decision-making and all major decisions of our Group during the Track Record Period. The Concert Parties have entered into a concert party agreement to confirm such arrangement, and have agreed to act in concert and reach consensus on any proposal presented to the general meeting of the Shareholders of our Company for voting. In the event they fail to reach such consensus, each of the Concert Parties shall exercise their respective indirect voting rights in accordance with majority vote amongst themselves. As of the Latest Practicable Date, the Concert Parties are entitled to exercise voting rights of approximately 56.35% of the total issued share capital of our Company. Immediately upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised), the Concert Parties will be entitled to exercise voting rights of approximately [47.90]%. Therefore, the Concert Parties are considered as our Controlling Shareholders upon [REDACTED]. For details, please refer to the paragraph headed “History, Development and Corporate Structure – Concert Party Arrangement” in this document.

We have completed the Pre-[REDACTED] Investments by way of increase and subscription of registered capital in 2019 and 2020. Our Pre-[REDACTED] Investors include dedicated healthcare funds, biotech funds and funds focusing on investments in the biopharmaceutical sector. For details, please refer to the paragraph headed “History, Development and Corporate Structure – Pre-[REDACTED] Investments” in this document.

COMPLIANCE

During the Track Record Period and as of the Latest Practicable Date, we did not experience any non-compliance that, in the opinion of our Directors, is likely to have a material adverse effect on our business, financial condition or results of operations. During the Track Record Period, there were two incidents of non-compliance of certain PRC laws and regulations which constitute systemic non-compliance under Guidance Letter HKEX-GL63-13 issued in July 2013 and last updated in March 2019 by the Stock Exchange. For details, please refer to the paragraph headed “Business – Legal Proceedings and Compliance – Compliance” in this document.

DIVIDEND

No dividend have been declared or paid by entities comprising our Group. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our board of directors and subject to our Articles of Association and the PRC Company Law, and will depend on a number of factors, including the successful commercialization of our drugs as well

SUMMARY

as our earnings, capital requirements, overall financial condition and contractual restrictions. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. As confirmed by our PRC Legal Advisor, according to the PRC law, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above.

THE [REDACTED]

The [REDACTED] by us consists of:

- the offer by us of initially [REDACTED] H Shares, or [REDACTED], for subscription by the public in Hong Kong, referred to in this document as the [REDACTED]; and
- the offer by us of initially [REDACTED] H Shares, or [REDACTED], outside the United States (including to professional, institutional and other investors within Hong Kong) in offshore transactions in reliance on Regulation S and in the United States to QIBs in reliance on Rule 144A or another exemption from the registration requirements under the U.S. Securities Act, referred to in this document as the [REDACTED].

The number of [REDACTED] and [REDACTED], or together, the [REDACTED], is subject to reallocation as described in the section headed “Structure of the [REDACTED]”.

APPLICATION FOR [REDACTED] ON THE STOCK EXCHANGE

We have applied to the Listing Committee for the granting of the [REDACTED] of, and permission to deal in the [REDACTED] to be issued by us pursuant to the [REDACTED] (including any H Shares which may be issued pursuant to the exercise of the [REDACTED]).

SUMMARY

[REDACTED] STATISTICS⁽¹⁾

	Based on the [REDACTED] of HK\$[REDACTED] per [REDACTED]	Based on the [REDACTED] of HK\$[REDACTED] per [REDACTED]
Market capitalization of our Shares ⁽²⁾	HK\$[REDACTED]	HK\$[REDACTED]
Unaudited pro forma adjusted consolidated net tangible assets per Share ⁽³⁾	HK\$[REDACTED]	HK\$[REDACTED]

Notes:

- (1) All statistics in this table are on the assumption that the [REDACTED] are not exercised.
- (2) The calculation of market capitalization is based on [REDACTED] Shares expected to be in issue immediately after completion of the [REDACTED].
- (3) The pro forma adjusted consolidated net tangible assets of the Group attributable to owners of the Company per [REDACTED] is calculated after making the adjustments referred to in “Financial Information—Unaudited Pro Forma Adjusted Consolidated Net Tangible Assets” and on the [REDACTED] Shares expected to be in issue immediately after completion of the [REDACTED].

USE OF [REDACTED]

We estimate that the aggregate net [REDACTED] to our Company from the [REDACTED] (after deducting [REDACTED] commissions and other estimated expenses in connection with the [REDACTED] paid and payable by us taking into account any additional discretionary incentive fee and assuming that the [REDACTED] is not exercised and an [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per H Share) will be approximately US\$[REDACTED] (HK\$[REDACTED]). We currently intend to apply such net [REDACTED] we will receive from this [REDACTED] for the following purposes:

- (a) approximately 45.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used primarily for the clinical development and commercialization of the following products:
 - (i) approximately 10.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the ongoing and planned clinical trials, preparation for registration filings, launch and, subject to regulatory approval, commercialization (including sales and marketing) of telitacicept (RC18);
 - (ii) approximately 15.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the ongoing and planned clinical trials and preparation for potential registration filings of disitamab vedotin (RC48);
 - (iii) approximately 5.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the ongoing and planned clinical trials of RC28 for the treatment of wet AMD, DME and DR in China; and

SUMMARY

- (iv) approximately 15.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the development of RC88 and RC98, as well as our early-stage drug discovery and development.
- (b) approximately 25.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the construction of our new manufacturing facility to expand our commercial manufacturing capacity, of which a majority will be used for the construction of the buildings and for the procurement of new machineries, instruments and equipment.
- (c) approximately 15.0%, or US\$[REDACTED] (HK\$[REDACTED]) will be used to repay the borrowings from RC Pharma.
- (d) approximately 15.0%, or US\$[REDACTED] (HK\$[REDACTED]) will be used for our general corporate and working capital purposes.

For more details, please refer to the section headed “Future Plan and Use of [REDACTED]” in this document.

[REDACTED] EXPENSE

[REDACTED] expenses to be borne by us are estimated to be approximately HK\$[REDACTED] (including [REDACTED] commission, assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per Share), assuming no Shares are issued pursuant to the [REDACTED]. In 2018, 2019 and the three-month period ended March 31, 2020, the [REDACTED] expenses charged to profit or loss were [REDACTED], RMB[REDACTED] (approximately HK\$[REDACTED]) and RMB[REDACTED] (approximately HK\$[REDACTED]), respectively, and the issue costs capitalized to deferred issue costs were [REDACTED], RMB[REDACTED] (approximately HK\$[REDACTED]) and RMB[REDACTED] (approximately HK\$[REDACTED]), respectively. After March 31, 2020, we estimate that additional [REDACTED] expenses of approximately HK\$[REDACTED] will be incurred by our Company, approximately HK\$[REDACTED] of which is expected to be charged to our consolidated statements of profit or loss, approximately HK\$[REDACTED] of which is expected to be capitalized, and approximately HK\$[REDACTED] of which is expected to be recognized directly as a deduction from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

DEFINITIONS

In this document, the following expressions shall have the meanings set out below unless the context otherwise requires.

“affiliate(s)” any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person

[REDACTED]

“Articles” or “Articles of Association” our articles of association, as conditionally adopted on May 27, 2020 and will come into effect upon [REDACTED] (as amended, supplemented or otherwise modified from time to time), a summary of which is set out in Appendix VI to this document

“associate(s)” has the meaning ascribed thereto under the Listing Rules

“Board” or “Board of Directors” our board of Directors

“Board of Supervisors” our board of Supervisors

“bridging study” a supplemental trial or study performed in the new region to provide pharmacodynamic or clinical data on efficacy, safety, dosage, and dose regimen in the new region that will allow extrapolation of the foreign clinical data to the new region

“Business Day” a day that is not a Saturday, Sunday or public holiday in Hong Kong

“CAGR” compound annual growth rate

“CCASS” the Central Clearing and Settlement System established and operated by HKSCC

“CCASS Clearing Participant” a person admitted to participate in CCASS as a direct clearing participant or a general clearing participant

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“CCASS Custodian Participant”	a person admitted to participate in CCASS as a custodian participant
“CCASS Investor Participant”	a person admitted to participate in CCASS as an investor participant, which may be an individual, joint individuals or a corporation
“CCASS Operational Procedures”	the Operational Procedures of HKSCC in relation to CCASS, containing the practices, procedures and administrative requirements relating to operations and functions of CCASS, as from time to time in force
“CCASS Participant”	a CCASS Clearing Participant, a CCASS Custodian Participant or a CCASS Investor Participant
“cDNA”	complementary DNA
“CelluPro”	Yantai CelluPro Biotechnology Co., Ltd. (煙台賽普生物技術有限公司), a limited liability company incorporated in the PRC on June 27, 2018 and owned by MabPlex and RC Pharma as to 51% and 49%, respectively
“China” or “the PRC”	the People’s Republic of China excluding, for the purposes of this document, Hong Kong, the Macau Special Administrative Region of the People’s Republic of China and Taiwan
“close associate(s)”	has the meaning ascribed thereto under the Listing Rules
“Companies Ordinance”	the Companies Ordinance, Chapter 622 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
“Companies (Winding Up and Miscellaneous Provisions) Ordinance”	the Companies (Winding Up and Miscellaneous Provisions) Ordinance, Chapter 32 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
“Company” or “our Company”	RemeGen Co., Ltd. (榮昌生物製藥(煙台)股份有限公司), a joint stock limited company incorporated in the PRC, the predecessor of which, RemeGen, Ltd. (榮昌生物製藥(煙台)有限公司) was incorporated in the PRC on July 4, 2008 and if the context requires, include its predecessor

DEFINITIONS

“Concert Parties” or “Concert Parties Group”	refer to Mr. Wang, Dr. Fang, Mr. Lin Jian (林健), Dr. Wang Liqiang (王荔強), Mr. Wang Xudong (王旭東), Mr. Deng Yong (鄧勇), Mr. Xiong Xiaobin (熊曉濱), Mr. Wen Qingkai (溫慶凱), Ms. Yang Minhua (楊敏華), Mr. Wei Jianliang (魏建良), Yantai Rongda Venture Capital Center (Limited Partnership) (煙台榮達創業投資中心(有限合夥)), RongChang Holding Group LTD. and I-NOVA Limited, and “Concert Party” means any one of them
“connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“Controlling Shareholders”	has the meaning ascribed to it under the Listing Rules and in this context, refers to the Concert Parties, for further details of which, please refer to the section headed “Relationship with our Controlling Shareholders” in this document
“core connected person(s)”	has the meaning ascribed thereto under the Listing Rules
“Core Products”	has the meaning ascribed to it in Chapter 18A of the Listing Rules and in this context, refers to our Core Products including telitacept (RC18), disitamab vedotin (RC48) and RC28
“CSRC”	China Securities Regulatory Commission (中國證券監督管理委員會)
“Director(s)”	the director(s) of our Company or any one of them
“Domestic Share(s)”	ordinary share(s) in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in Renminbi and are unlisted Shares which are currently not listed or traded in any stock exchange
“Dr. Fang”	Dr. Fang Jianmin (房健民), our executive Director, chief executive officer and chief scientific officer of our Company and one of our Controlling Shareholders upon [REDACTED]
“EIT”	enterprise income tax
“EIT Law”	the PRC Enterprise Income Tax Law (《中華人民共和國企業所得稅法》)

DEFINITIONS

“EMA”	the European Medicines Agency, the EU agency responsible for evaluating and granting centralized approval for market authorization valid in all EU, European Economic Area states, and European Free Trade Association states
“EU”	the European Union
“Extreme Conditions”	extreme conditions caused by a super typhoon as announced by the government of Hong Kong
“FDA”	U.S. Food and Drug Administration, the U.S. federal agency responsible for regulating food and drugs
“Foreign Shares”	ordinary shares in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in currencies other than Renminbi by foreign investors
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market research and consulting company
“Frost & Sullivan Report”	the industry report commissioned by us and independently prepared by Frost & Sullivan, summary of which is set forth in the section headed “Industry Overview” in this document
“General Rules of CCASS”	General Rules of CCASS published by the Stock Exchange and as amended from time to time

[REDACTED]

“Group”, “our Group”, “our”, “we”, or “us”	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
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DEFINITIONS

“H Share(s)” overseas listed foreign invested ordinary share(s) in the ordinary share capital of our Company, with a nominal value of RMB1.00 each, which are to be subscribed for and traded in Hong Kong dollars and for which an application has been made for the granting of [REDACTED] and permission to deal in on the Stock Exchange

[REDACTED]

“HKSCC” the Hong Kong Securities Clearing Company Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited

“HKSCC Nominees” HKSCC Nominees Limited, a wholly owned subsidiary of the HKSCC

“Hong Kong” the Hong Kong Special Administrative Region of the PRC

“Hong Kong dollars” or “HK\$” Hong Kong dollars and cents respectively, the lawful currency of Hong Kong

[REDACTED]

“Hong Kong Stock Exchange” or “Stock Exchange” The Stock Exchange of Hong Kong Limited, a wholly-owned subsidiary of Hong Kong Exchanges and Clearing Limited

DEFINITIONS

[REDACTED]

“IFRS”	International Financial Reporting Standards
“IIT Law”	the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》)
“Independent Third Party” or “Independent Third Parties”	a person or entity who is not a connected person of the Company under the Listing Rules

[REDACTED]

DEFINITIONS

“JLL” Jones Lang LaSalle Corporate Appraisal and Advisory Limited, the independent property valuer commissioned by us to conduct property valuation on the properties of our Company

[REDACTED]

“Joint Sponsors” the joint sponsors as named in “Directors, Supervisors and Parties Involved in the [REDACTED]”

“Latest Practicable Date” June 22, 2020, being the latest practicable date for the purpose of ascertaining certain information contained in this document prior to its publication

[REDACTED]

“Listing Committee” the listing committee of the Stock Exchange

[REDACTED]

“Listing Rules” the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (as amended, supplemented or otherwise modified from time to time)

“Main Board” the stock market (excluding the option market) operated by the Hong Kong Stock Exchange which is independent from and operated in parallel with the Growth Enterprise Market of the Stock Exchange

“MabPlex” Yantai MabPlex International Biomedical Co., Ltd. (煙台邁百瑞國際生物醫藥有限公司), a limited liability company incorporated in the PRC on June 25, 2013 and owned as to 41.96% by RC Pharma

DEFINITIONS

“Mandatory Provisions”	the “Mandatory Provisions for Articles of Association of Companies to be Listed Overseas” (到境外上市公司章程必備條款), as amended, supplemented or otherwise modified from time to time, for inclusion in the articles of association of companies incorporated in the PRC to be listed overseas (including Hong Kong), which were promulgated by the former Securities Commission of the State Council (國務院證券委員會) and the former State Commission for Restructuring the Economic Systems (國家經濟體制改革委員會) on August 27, 1994
“MOF”	Ministry of Finance of the PRC (中華人民共和國財政部)
“MOFCOM”	Ministry of Commerce of the PRC (中華人民共和國商務部)
“Mr. Wang”	Mr. Wang Weidong (王威東), our executive Director and Chairman of the Board and one of our Controlling Shareholders upon [REDACTED]
“NIPA”	the National Intellectual Property Administration of the PRC (中華人民共和國國家知識產權局)
“NDRC”	the National Development and Reform Commission of the PRC (中華人民共和國國家發展和改革委員會)
“NMPA”	the National Medical Products Administration of the PRC (國家藥品監督管理局), successor to the China Food and Drug Administration or CFDA (國家食品藥品監督管理總局)
“NPC”	the National People’s Congress of the PRC (中華人民共和國全國人民代表大會)

[REDACTED]

DEFINITIONS

[REDACTED]

“Onshore ESOP Platform(s)” Yantai Rongqian Enterprise Management Center (Limited Partnership) (煙台榮謙企業管理中心(有限合夥)), Yantai Rongshi Enterprise Management Center (Limited Partnership) (煙台榮實企業管理中心(有限合夥)), Yantai Rongyi Enterprise Management Center (Limited Partnership) (煙台榮益企業管理中心(有限合夥)) and Yantai Rongjian Enterprise Management Center (Limited Partnership) (煙台榮建企業管理中心(有限合夥))

[REDACTED]

“PBOC” the People’s Bank of China (中國人民銀行), the central bank of the PRC

“PRC Government” the central government of the PRC and all governmental subdivisions (including provincial, municipal and other regional or local government entities) and instrumentalities thereof or, where the context requires, any of them

“PRC Legal Advisor” King & Wood Mallesons

“Pre-[REDACTED] Investment(s)” the pre-[REDACTED] investment(s) in our Company undertaken by the Pre-[REDACTED] Investor(s), details of which are set out in the section headed “History, Development and Corporate Structure” in this document

DEFINITIONS

“Pre-[REDACTED] Investor(s)”	PAG Growth Prosperity Holding I (HK) Limited, PAG Growth Holding IV (HK) Limited, Wholly Sunbeam Limited, LBC Sunshine Healthcare Fund L.P., LAV Remegen Limited, Suzhou Likang Equity Investment Center (Limited Partnership) (蘇州禮康股權投資中心(有限合夥)), Suzhou Lirui Equity Investment Center (Limited Partnership) (蘇州禮瑞股權投資中心(有限合夥)), Vivo Capital Fund IX, L.P., Janchor Partners Pan-Asian Master Fund, TIBET Lapam Yijing Venture Capital Center LLP (西藏龍磐怡景創業投資中心(有限合夥)), Shandong Jifu Jingu New Kinetic Energy Equity Investment Fund Partnership (Limited Partnership) (山東吉富金谷新動能股權投資基金合夥企業(有限合夥)), OrbiMed Partners Master Fund Limited, OrbiMed Genesis Master Fund, L.P., Yan Tai Hong Da Investment Limited (煙台鴻大投資有限公司) and Hudson Bay Master Fund LTD.
“Promoters”	the promoters of our Company, being Shareholders of our Company as of May 11, 2020
“Property Valuation Report”	the text of a letter, the summary of values and valuation certificates from Jones Lang LaSalle Corporate Appraisal and Advisory Limited, as set out in Appendix III to this document
“Qualified Institutional Buyers” or “QIBs”	qualified institutional buyers within the meaning of Rule 144A under the U.S. Securities Act
“RC Pharma”	Yantai Rongchang Pharmaceutical Co., Ltd. (煙台榮昌製藥股份有限公司), a joint stock company incorporated in the PRC on March 18, 1993, the sole shareholder of our predecessor of our Company, RemeGen, Ltd. (榮昌生物製藥(煙台)有限公司), prior to the Reorganization
“Regulation S”	Regulation S under the U.S. Securities Act
“Reorganization”	the reorganization of our Group in preparation for the [REDACTED], details of which are set out in the paragraph headed “History, Development and Corporate Structure — Reorganization” in this document
“RMB” or “Renminbi”	Renminbi, the lawful currency of the PRC
“Rule 144A”	Rule 144A under the U.S. Securities Act

DEFINITIONS

“SAFE”	the State Administration of Foreign Exchange of the PRC (中華人民共和國外匯管理局)
“SAT”	the State Administration of Taxation of the PRC (中華人民共和國國家稅務總局)
“Securities and Futures Commission” or “SFC”	the Securities and Futures Commission of Hong Kong
“Securities Law”	the Securities Law of the PRC (中華人民共和國證券法), as amended, supplemented or otherwise modified from time to time
“SFO”	the Securities and Futures Ordinance, Chapter 571 of the Laws of Hong Kong (as amended, supplemented or otherwise modified from time to time)
“Share(s)”	ordinary share(s) in the capital of our Company with a nominal value of RMB1.00 each, comprising Domestic Shares, Unlisted Foreign Shares and H Shares
“Shareholder(s)”	holder(s) of the Share(s)
“Special Regulations”	the Special Regulations of the State Council on the Overseas Offering and Listing of Shares by Joint Stock Limited Companies (國務院關於股份有限公司境外募集股份及上市的特別規定), promulgated by the State Council on August 4, 1994, as amended from time to time
“sophisticated investor(s)”	has the meaning ascribed to it under Guidance Letter HKEX-GL-92-18 issued by the Stock Exchange
“Stabilizing Manager”	[●]
“State Council”	the State Council of the PRC (中華人民共和國國務院)
“subsidiary”	has the meaning ascribed thereto under the Listing Rules
“substantial shareholder(s)”	has the meaning ascribed thereto under the Listing Rules
“Supervisor(s)”	member(s) of our Board of Supervisors

DEFINITIONS

“Takeovers Code” the Code on Takeovers and Mergers and Share Buy-backs, as published by the SFC (as amended, supplemented or otherwise modified from time to time)

“Track Record Period” the two years ended December 31, 2018 and 2019 and the three months ended March 31, 2020

[REDACTED]

“United States” or “U.S.” the United States of America, its territories, its possessions and all areas subject to its jurisdiction

“Unlisted Foreign Shares” ordinary shares issued by our company with a nominal value of RMB1.00 each and are held by foreign investors and are not listed on any stock exchange

“Unlisted Shares” ordinary shares issued by our company with a nominal value of RMB1.00 each, comprising our Domestic Shares and Unlisted Foreign Shares

“U.S. dollars”, “US\$” or “USD” United States dollars, the lawful currency of the United States

“U.S. Securities Act” the U.S. Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder

[REDACTED]

DEFINITIONS

In this document, the terms “associate,” “close associate,” “connected person,” “core connected person,” “connected transaction,” “subsidiaries” and “substantial shareholder” shall have the meanings given to such terms in the Hong Kong Listing Rules, unless the context otherwise requires.

Certain amounts and percentage figures included in this document have been subject to rounding. Accordingly, figures shown as totals in certain tables may not be an arithmetic aggregation of the figures preceding them. Any discrepancies in any table or chart between the total shown and the sum of the amounts listed are due to rounding.

For ease of reference, the names of the PRC established companies or entities, laws or regulations have been included in this document in both the Chinese and English languages; in the event of any inconsistency, the Chinese versions shall prevail.

GLOSSARY OF TECHNICAL TERMS

This glossary contains explanations of certain technical terms used in this document in connection with our Company and our business. Such terminology and meanings may not correspond to standard industry meanings or usages of those terms.

“ACR20”	a measurement of disease activity improvement for rheumatoid arthritis, defined as at least 20% improvement in both the tender joint count and the swollen joint count and at least 20% improvement in 3 of the 5 other core set measures including physician’s assessment of disease activity, patient’s assessment of disease activity, patient’s assessment of pain, and patient’s assessment of physical function, and levels of an acute-phase reactant
“ADC”	antibody drug conjugate, a class of biopharmaceutical drugs that combine monoclonal antibodies specific to surface antigens present on particular tumor cells with highly potent antitumor small molecule agents linked via a chemical linker
“AE”	adverse event, which may be mild, moderate, or severe, any untoward medical occurrences in a patient administered a drug or other pharmaceutical product during clinical trials and which do not necessarily have a causal relationship with the treatment
“APRIL”	a proliferation inducing ligand, a B cell-stimulatory cytokine
“ALT”	alanine aminotransferase, a liver enzyme that is released in the blood when liver cells are damaged; the blood test for ALT is used to diagnose liver disorders
“AMD”	age-related macular degeneration, a medical condition characterized by the abnormal growth of blood vessels in the retina
“AR”	adverse reaction, any unexpected or dangerous reaction to a drug
“AST”	aspartate transaminase, an enzyme found in cells throughout the body but mostly in the heart and liver; the blood test for AST is used to detect or monitor liver damage

GLOSSARY OF TECHNICAL TERMS

“antagonist”	a type of drug or ligand that blocks or decreases a biological response by binding to and blocking a receptor without activating it
“AUC”	area under the curve
“autoimmune diseases”	diseases which arise from an abnormal immune response of the body against substances and tissues normally present in the body, such as SLE, RA and MS
“BC”	breast cancer
“B-cell”	a type of white blood cell that differs from other types of lymphocytes by expressing B-cell receptors on its surface, and responsible for producing antibodies
“BCVA”	best-corrected visual activity, a measurement for vision impairment
“BLA”	biologics license application
“BLyS”	B-cell lymphocyte stimulator, a B cell-stimulatory cytokine
“BOR”	best overall response
“BTC”	biliary tract carcinoma
“CD4 ⁺ T Lymphocyte”	a type of lymphocyte that helps coordinate the immune response by stimulating other immune cells to fight infection
“CDMO”	contract development and manufacturing organization, which is a pharmaceutical company that develops and manufactures drugs for other pharmaceutical companies on a contractual basis
“cGMP”	current good manufacturing practice
“chemotherapy” or “chemo”	a category of cancer treatment that uses one or more anti-cancer small molecule chemical agents as part of its standardized regimen
“C _{max} ”	maximum measured serum concentration

GLOSSARY OF TECHNICAL TERMS

“CMC”	chemistry, manufacturing, and controls processes in the development, licensure, manufacturing, and ongoing marketing of pharmaceutical products
“cohort”	a group of patients as part of a clinical study who share a common characteristic or experience within a defined period and who are monitored over time
“combination therapy”	a treatment modality that combines two or more therapeutic agents
“cORR”	confirmed objective response rate
“CR”	complete response, the disappearance of all signs of cancer in response to treatment
“CRC”	clinical research coordinator, which provides services including but not limited to coordinating clinical research, providing training to clinical research coordinators, managing clinical trial processes and providing supporting services for investigators
“CRO”	contract research organization, a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis
“cytotoxic”	toxic to living cells
“DCR”	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses (CR), partial responses (PR) and stable disease (SD)
“DLT”	dose-limiting toxicity, side effects of a drug or other treatment that are serious enough to prevent an increase in dose of that treatment in clinical trial
“DME”	diabetic macular edema, a complication of diabetes caused by fluid accumulation in the macula, or central portion of the eye, that leads the macula to swell
“DOR”	duration of response

GLOSSARY OF TECHNICAL TERMS

“DR”	diabetic retinopathy, a complication of diabetes caused by damage to the blood vessels of the light sensitive tissue at the retina
“EPO”	European Patent Office
“ESSDAI score”	EULAR Sjögren’s syndrome (SS) disease activity index, a systemic disease activity index that was designed to measure disease activity in patients with primary SS
“FAS”	full analysis set, the set of subjects derived from the set of all randomized subjects by minimal and justified elimination of subjects
“Fc”	fragment crystallisable region, which is the tail region of an antibody that interacts with cell surface receptors called Fc receptors and some proteins of the complement system
“FGF”	fibroblast growth factor, a family of cell signaling proteins that are involved in a wide variety of cellular processes, including mitogenesis, differentiation, migration, and cell survival
“FISH”	fluorescence in situ hybridization, a test that detects the genetic material in human cells, including specific genes or portions of genes. In the case of HER2 FISH test, fluorescent labels are used to attach to the HER2 proteins and return a score of either positive (+) or negative (-)
“first-line” or “1L”	with respect to any disease, the first line therapy, which is the treatment regimen or regimens that are generally accepted by the medical establishment for initial treatment. It is also called primary treatment or therapy
“GC”	gastric cancer
“GEJ”	gastroesophageal junction

GLOSSARY OF TECHNICAL TERMS

“Good Manufacturing Practice” or “GMP”	a system for ensuring that products are consistently produced and controlled according to quality standards, which is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. It is also the practice required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of pharmaceutical products
“GPCR”	G-protein coupled receptors, a type of receptors involved in most cellular responses to hormones and neurotransmitters and essential for intracellular communication, which are important targets in drug discovery
“HER2”	human epidermal growth factor receptor 2
“HER2-expressing”	HER2 status of tumor cells identified with a test score of IHC 1+ or above
“HER2 high-expressing”, “HER2+” or “HER2-positive”	HER2 status of tumor cells identified with a test score of either IHC 3+ or IHC 2+/FISH+ (IHC 2+ plus FISH+)
“HER2 low-expressing”	HER2 status of tumor cells identified with a test score of either IHC 2+/FISH-(IHC 2+ plus FISH-) or IHC 1+
“HER2-mutant” or “HER2-mutated”	HER2 status (usually in respect of lung cancer) identified with one or more mutations, or alterations, in the nucleotide sequence of HER2, which may or may not result in HER2 amplification or over-expression
“HER2-negative” or “HER2 non-expressing”	HER2 status of tumor cells identified with a test score of IHC 0
“HER2 over-expressing”	HER2 status of tumor cells identified with a test score of IHC 3+ or IHC 2+
“HiBody”	a novel bifunctional antibody that combines two antigen-recognizing elements into a single construct, able to bind to two different antigens at the same time
“HUVEC”	human umbilical vein endothelial cells, cells derived from the endothelium of veins from the umbilical cord

GLOSSARY OF TECHNICAL TERMS

“IFN- γ ”	interferon gamma, which is a cytokine that is critical for innate and adaptive immunity against viral, some bacterial infections and protozoal infections (infections caused by parasites)
“IHC”	immunohistochemistry, a test that uses a chemical dye to stain and measure specific proteins. IHC staining for HER2 status is the most widely used initial approach for evaluating HER2 as a predictor of response to anti-HER2 therapy. The HER2 IHC test gives a score of 0 to 3+ that measures the amount of HER2 proteins on the surface of cells in a tissue sample
“IL-2”	interleukin-2, a type of cytokine signaling molecule in the immune system to provoke an immune response in the body of a human and other animal (i.e., the ability to induce humoral and/or cell-mediated immune responses)
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
“in vivo”	Latin for “within the living”, studies <i>in vivo</i> are those in which the effects of various biological or chemical substances are tested on whole, living organisms including animals, humans and plants, as opposed to a partial or dead organism, or those done in vitro
“in vitro”	Latin for “within the glass”, studies using components of an organism that have been isolated from their usual biological surroundings, such as microorganisms, cells or biological molecules
“IgAN”	IgA nephropathy or IgA Nephritis, an autoimmune kidney disease that occurs when an antibody called immunoglobulin A (IgA) builds up in the kidneys, resulting in local inflammation that, over time, can hamper the kidneys’ ability to filter waste from the blood
“IgG”	human immunoglobulin G, the most common antibody type found in blood circulation that plays an important role in antibody-based immunity against invading pathogens

GLOSSARY OF TECHNICAL TERMS

“lymphocytes”	a subtype of white blood cells, such as T cells, B cells and NK cells
“mesothelin” or “MSLN”	a tumor-associated antigen with limited expression in normal tissues
“metastatic”	in reference to any disease, including cancer, disease producing organisms or of malignant or cancerous cells transferred to other parts of the body by way of the blood or lymphatic vessels or membranous surfaces
“monoclonal antibody” or “mAb”	an antibody generated by identical immune cells that are all clones of the same parent cell
“MG”	myasthenia gravis, a long-term neuromuscular disease that leads to varying degrees of skeletal muscle weakness
“MMAE”	monomethyl auristatin E, a potent tubulin binder with a half maximal inhibitory concentration (IC50) in the subnanomolar range
“MS”	multiple sclerosis, a demyelinating disease in which the insulating covers of nerve cells in the brain and spinal cord are damaged
“MTD”	maximum tolerated dose, the highest dose of a drug or treatment that does not cause unacceptable side effects
“NDA”	new drug application
“NMOSD”	neuromyelitis optica spectrum disorder, a central nervous system disorder that occurs when the body’s immune system mistakenly attacks against its own cells in the central nervous system, mainly in the optic nerves and spinal cord, but sometimes in the brain as well
“NSCLC”	non-small cell lung cancer
“orphan drug designation”	a special status granted by the FDA to drugs, including biologics, intended to treat a rare disease or condition upon request of a sponsor
“ORR”	objective response rate, which is equal to the sum of CR and PR

GLOSSARY OF TECHNICAL TERMS

“PD”	progressive disease, refers to a at least 20% increase in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
“PD-1”	programmed cell death protein 1, an immune checkpoint receptor expressed on T cells, B cells and macrophages
“PD-L1”	PD-1 ligand 1, which is a protein on the surface of a normal cell or a cancer cell that binds to its receptor, PD-1, on the surface of the T cell that causes the T cell to turn off its ability to kill the cancer cell
“PFS”	progression-free survival, the length of time during and after the treatment of a disease, such as cancer, that a patient lives with the disease but it does not get worse
“pharmacodynamics” or “PD”	the relationship between the concentration of the drug in animal or human body and the biological and physiological effects of the drug
“pharmacokinetics” or “PK”	a measurement of how fast and how completely the drug is absorbed into animal or human body, and the distribution, metabolism, and excretion of drugs in animal or human body
“Phase I clinical trials”	study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its effectiveness
“Phase II clinical trials”	study in which a drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases, and to determine dosage tolerance and optimal dosage
“Phase III clinical trials”	study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product

GLOSSARY OF TECHNICAL TERMS

“pivotal trial” or “registrational trial”	the clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
“placebo”	any dummy medical treatment administered to the control group in a controlled clinical trial in order that the specific and non-specific effects of the experimental treatment can be distinguished
“PPS”	per protocol set, the subset of subjects who complied with the protocol sufficiently to ensure that these data would be likely to exhibit the effects of treatment according to the underlying scientific model
“PR”	partial response, refers to an at least 30% but below 100% decrease in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
“pre-clinical studies”	studies or programs testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials
“QW”	once a week
“Q2W”	every two weeks
“Q3W”	every three weeks
“OS”	overall survival
“RA”	rheumatoid arthritis, an autoimmune disorder that occurs when the body’s immune system mistakenly attacks its healthy tissues, affect the joints and, in some cases, damage a wide range of human body systems, including the skin, eyes, lungs, heart and blood vessels

GLOSSARY OF TECHNICAL TERMS

“RECIST”	Response Evaluation Criteria in Solid Tumors, a set of published rules that define when tumors in cancer patients improve (“respond”), stay the same (“stabilize”), or worsen (“progress”) during treatment. The criteria were published in February 2000 by an international collaboration including the European Organisation for Research and Treatment of Cancer (EORTC), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group. Now the majority of clinical trials evaluating cancer treatments for objective response in solid tumors use RECIST. These criteria were developed and published in February 2000, and subsequently updated in 2009
“second-line” or “2L”	with respect to any disease, the therapy or therapies that are tried when the first-line treatments do not work adequately
“SAE”	serious AE, any medical occurrence in human drug trials that at any dose: results in death; is life-threatening; requires inpatient hospitalization or causes prolongation of existing hospitalization; results in persistent or significant disability/incapacity; may have caused a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage
“SAR”	serious adverse reaction, series adverse event related to the treatment drugs
“SD”	stable disease. In oncology, it refers to cancer that is neither decreasing at least 30% nor increasing at least 20% in the size of a tumor or in the extent of cancer in the body in response to treatment, according to RECIST
“SLE”	systemic lupus erythematosus, a systemic autoimmune disease in which the body’s immune system attacks normal, healthy tissue and can result in symptoms such as inflammation and swelling
“SLE Responder Index” or “SRI”	a composite disease activity assessment that incorporates a modification of SELENA-SLEDAI, BILAG, and a visual analog scale of physician-rated disease activity to determine disease improvement of SLE

GLOSSARY OF TECHNICAL TERMS

solid tumors	an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them
“SRI-4”	SLE responder index-4, a composite measurement for disease activity and response in SLE which is achieved if a greater than four point reduction in SRI occurred
“SS”	Sjögren’s syndrome, a female-dominated, autoimmune disorder of unknown etiology and diverse phenotypical expression, identified by two most common symptoms, dry eyes and dry mouth
standard of care	treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals
“TAC1”	transmembrane activator and CAML interactor, a TNF receptor superfamily member which is expressed at high levels on activated B cells and marginal zone B cells, and binds two ligands, BLyS and APRIL
“T cell”	a lymphocyte of a type produced or processed by the thymus gland and actively participating in the immune response, which plays a central role in cell-mediated immunity. T cells can be distinguished from other lymphocytes, such as B cells and NK cells, by the presence of a T cell receptor on the cell surface
“TRAE”	a treatment related AE, which is adverse events present after medical treatment
“UC”	urothelial carcinoma or urothelial cancer
“VEGF”	vascular endothelial growth factor, a signal protein produced by cells that stimulates the formation of blood vessels
“wet AMD”	one of two types of age-related macular degeneration, which can lead to sudden and severe vision loss and is the most advanced form of AMD

FORWARD-LOOKING STATEMENTS

This document contains certain forward-looking statements relating to our plans, objectives, beliefs, expectations, predictions and intentions, which are not historical facts and may not represent our overall performance for the periods of time to which such statements relate. Such statements reflect the current views of our management with respect to future events, operations, liquidity and capital resources, some of which may not materialize or may change. These statements are subject to certain risks, uncertainties and assumptions, including the other risk factors as described in this document. You are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The risks, uncertainties and other factors facing the Company which could affect the accuracy of forward-looking statements include, but are not limited to, the following:

- our business strategies and plans to achieve these strategies;
- our ability to complete the development and obtain the relevant requisite regulatory approvals of our drug candidates;
- our ability to commercialize our approved drugs in a timely manner;
- our future debt levels and capital needs;
- changes to the political and regulatory environment in the industry and markets in which we operate;
- our expectations with respect to our ability to acquire and maintain regulatory licenses or permits;
- changes in competitive conditions and our ability to compete under these conditions;
- future developments, trends and conditions in the industry and markets in which we operate;
- general economic, political and business conditions in the markets in which we operate;
- effects of the global financial markets and economic crisis;
- our financial conditions and performance;
- our dividend policy; and
- change or volatility in interest rates, foreign exchange rates, equity prices, volumes, operations, margins, risk management and overall market trends.

FORWARD-LOOKING STATEMENTS

Additional factors that could cause actual performance or achievement to differ materially including but not limited to those discussed in “Risk Factors” and elsewhere in this document. In some cases, we use the words “aim,” “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “going forward,” “intend,” “ought to,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “will,” “would” and similar expressions to identify forward-looking statements. In particular, we use these forward-looking statements in the “Business” and “Financial Information” sections of this document in relation to future events, our future financial, business or other performance and development, the future development of our industry and the future development of the general economy of our key markets.

We caution you not to place undue reliance on these forward-looking statements which are based on current plans and estimates, and speak only as of the date they were made. We undertake no obligation to update or revise any forward-looking statements in light of new information, future events or otherwise. Forward-looking statements involve inherent risks and uncertainties and are subject to assumptions, some of which are beyond our control. We caution you that a number of important factors could cause actual outcomes to differ, or to differ materially, from those expressed in any forward-looking statements.

Our Directors confirm that the forward-looking statements are made after reasonable care and due consideration. Nonetheless, due to the risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this document might not occur in the way we expect, or at all. Statements of or references to our intentions or those of any of our Directors are made as of the date of this document. Any such intentions may change in light of future developments.

Accordingly, you should not place undue reliance on any forward-looking statements in this document. All forward-looking statements contained in this document are qualified by reference to this cautionary statement.

RISK FACTORS

An investment in our H Shares involves significant risks. You should carefully consider all of the information in this document, including the risks and uncertainties described below, before making an investment in our H Shares. The following is a description of what we consider to be our material risks. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In any such case, the market price of our H Shares could decline, and you may lose all or part of your investment.

These factors are contingencies that may or may not occur, and we are not in a position to express a view on the likelihood of any such contingency occurring. The information given is as of the Latest Practicable Date unless otherwise stated, will not be updated after the date hereof, and is subject to the cautionary statements in the section headed “Forward-looking Statements” in this document.

We believe there are certain risks and uncertainties involved in our operations, some of which are beyond our control. We have categorized these risks and uncertainties into: (i) risks relating to our financial position and need for additional capital; (ii) risks relating to our business, comprising (a) risks relating to the development of our drug candidates, (b) risks relating to extensive government regulation, (c) risks relating to manufacturing of our products, (d) risks relating to commercialization of our products, (e) risks relating to our intellectual property rights; and (f) risks relating to our reliance on third parties; (iii) risks relating to our operations; (iv) risks relating to our doing business in China; and (v) risks relating to the [REDACTED].

Additional risks and uncertainties that are presently not known to us or not expressed or implied below or that we currently deem immaterial could also harm our business, financial condition, results of operations and prospects. You should consider our business and prospects in light of the challenges we face, including the ones discussed in this section.

RISKS RELATING TO OUR FINANCIAL POSITION AND NEED FOR ADDITIONAL CAPITAL

We have incurred significant net losses since inception, and expect to continue to incur net losses for the foreseeable future and we may not be able to generate sufficient revenue to achieve or maintain profitability. Potential investors may lose substantially all their investments in us given the high risks involved in our business.

Investment in biopharmaceutical drug companies is highly speculative. We have incurred substantial capital expenditures to date, and expect to continue to incur significant expenses related to clinical trials and pre-clinical studies. For the years ended December 31, 2018, December 31, 2019 and the three months ended March 31, 2020, we had net losses of RMB269.9 million, RMB430.3 million and RMB99.6 million, respectively. However, we cannot assure you that our drug candidates will obtain regulatory approvals and/or become commercially viable. Our ability to generate significant revenue from our drug candidates will depend primarily on the success of the regulatory approval, manufacturing, and

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commercialization of the drug candidates, which is subject to significant uncertainty. Even if we obtain regulatory approval to market our drug candidates, our future revenue will depend upon other factors such as the market size for the proposed indications of our drug candidates, and our ability to achieve sufficient market acceptance.

The amount of our future net losses will depend, in part, on our future expenses resulted from costs and expenses incurred by our research and development programs and in relation to our operations, the cost of commercializing any approved products, our ability to generate revenues, and the timing and amount of milestone and other payments we make or receive with or through arrangements with third parties. We expect to continue to incur significant expenses and losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue to advance the clinical trials and pre-clinical studies of our product pipeline;
- initiate pre-clinical, clinical or other studies for new drug candidates;
- seek regulatory approvals for our drug candidates to complete clinical development and commence commercialization;
- manufacture our drug candidates for clinical trials and for commercial sale;
- develop and expand our commercialization team to commercialize any drug candidates in our pipeline for which we may obtain regulatory approval;
- acquire or in-license other drug candidates, intellectual property assets and technologies;
- incur costs to develop or manufacture drug candidates under any collaboration or in-license agreements;
- maintain, protect, expand and enforce our intellectual property portfolio;
- attract and retain skilled personnel, and grant equity-settled awards to our employees under our share incentive schemes; and
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts.

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In addition, considering the numerous risks and uncertainties associated with regulatory approval, we are unable to accurately predict the timing or amount of additional expenses, or when, or if, we will be able to achieve or maintain profitability. Our expenses could increase beyond expectations if we are required by China’s National Medical Products Administration (“NMPA”), United States Food and Drug Administration (“FDA”), the European Medicines Agency (“EMA”) or other similar authorities to perform studies in addition to those that we currently anticipate. Even if our drug candidates are approved for commercial sale, we expect to continue incurring significant costs associated with the manufacturing and the commercial launch of the drug candidates.

Potential investors may lose substantially all their investments in us given the high risks involved in our business. Even if we are able to generate revenue from the sale of our approved drug candidates, we may not become profitable and may need to obtain additional funding to continue operations. Moreover, even if we manage to achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. Our failure to become and remain profitable may also impact investors’ perception of the potential value of our company and could impair our ability to raise additional capital, expand our business or continue our operations. Failure to become and remain profitable may also adversely affect the market price of our H Shares. A decline in the market price of our H Shares could cause potential investors to lose all or part of their investment in our business.

We had net liabilities and net cash outflows in operating activities during the Track Record Period.

We had net liabilities of RMB498.2 million and RMB232.0 million as of December 31, 2018 and December 31, 2019. We had net assets of RMB406.2 million as of March 31, 2020, respectively. We had net cash used in operating activities of RMB128.0 million, RMB282.7 million and RMB117.9 million for the years ended December 31, 2018 and 2019, and the three months ended March 31, 2020, respectively. While we believe we have sufficient working capital to fund our current operations, we expect that we may have net liabilities and experience net cash outflows from operating activities for the foreseeable future. If we are unable maintain adequate working capital or obtain sufficient equity or debt financings to meet our capital needs, we may be unable to continue our operations according to our plans and be forced to scale back our operations, which may have a material adverse effect on our business, financial condition, results of operations and prospects.

We have a limited operating history, particularly as a standalone company, and have limited experience in manufacturing and sales and marketing of drugs, which may make it difficult to evaluate our current business and predict our future performance.

We are a development-stage biopharmaceutical company with a relatively short operating history as a standalone company. We were founded in 2008 and only began to operate on a standalone basis from RC Pharma in 2019 after the completion of Reorganization. See “History, Development and Corporate Structure.” Our operations to date have focused on the pre-clinical studies and clinical trials of drug candidates in the therapeutic areas of autoimmune diseases, oncology and ophthalmology. However, as of the Latest Practicable Date, we have not yet successfully advanced any drug candidates from research and development to commercial sale. We have not generated any revenue from product sales. We also have limited experience

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in commercial-scale manufacturing and sales and marketing of drugs. In addition, we engaged our connected persons to provide various services to support our operations during the Track Record Period, and certain transactions with our connected persons will continue after the [REDACTED]. For further details, please refer to the section headed “Connected Transactions” in this document. For these reasons, particularly in light of the rapidly evolving biopharmaceutical industry, it may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

Historically, we have been funding our operations primarily through equity financing and debt financing, of which a substantial portion was borrowings from RC Pharma. We will need to obtain additional financing to fund our operations, and financing may not be available on terms acceptable to us, or at all. If we are unable to obtain sufficient financing, we may be unable to complete the development and commercialization of our drug candidates.

Our drug candidates require substantial investments for the completion of clinical development, regulatory review, drug manufacturing, marketing and launch before they can generate product sales revenue. Our operations have consumed substantial amounts of cash since our inception. We will need to expend substantial resources on the research and development and commercialization of our product pipelines. Our future funding requirements will depend on many factors, including but not limited to:

- the progress, timing, scope and costs of our clinical trials, including the ability to timely identify and enrol patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the progress, timing, scope and costs related to discovery and early development of additional drug candidates;
- the preparation required for anticipated commercialization of our drug candidates, and if regulatory approvals are obtained, to fund the product launch;
- the manufacturing requirements and capabilities related to clinical development and future commercialization for any approved drug candidates;
- selling and marketing costs associated with any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the amount and timing of any profit sharing, milestone and royalty payments we receive from our current or future collaborators;
- cash requirements of any future development of other pipeline drug candidates; and
- our headcount growth and associated costs.

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We had net cash used in operating activities of RMB128.0 million, RMB282.7 million and RMB117.9 million for the years ended December 31, 2018 and 2019, and the three months ended March 31, 2020, respectively. To date, we have funded our operations primarily through the proceeds from private equity and debt financings. A significant portion of our cash used in operations was funded by borrowings from RC Pharma. In 2018, 2019 and the three-month periods ended March 31, 2020, we borrowed loans from RC Pharma in form of cash and bank acceptance notes in a total amount of RMB380.9 million, RMB584.1 million and RMB134.8 million, respectively. As of April 30, 2020, the outstanding principal and interests of our borrowings due to RC Pharma amounted to RMB494.4 million. We plan to repay the borrowings from RC Pharma by using a portion of net [REDACTED] from the [REDACTED]. For more details, please refer to the section headed “Future Plan and Use of [REDACTED]” in this document. We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates, and launching and commercializing any approved drug candidates for which we receive regulatory approvals. However, if the commercialization of our drug candidates is delayed or terminated, or if the expenses associated with drug development and commercialization increase substantially, we may need to obtain additional financing to fund our operations. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. Our ability to raise funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate pre-clinical studies, clinical trials or other research and development activities or commercialization for one or more of our drug candidates, and in turn will adversely affect our business prospects.

The performance and value of our investments in equity investments are subject to uncertainties and fluctuation.

We hold a long-term equity investment in Yantai Heyuan Addis Biomedical Technology, Ltd. (煙台市和元艾迪斯生物醫藥科技有限公司) (“Heyuan Addis”). Such equity investment is classified as equity investments designated at fair value through other comprehensive income, and their fair value is measured based on expected cash flows discounted at current rates applicable for items with similar terms and risk characteristics. As of December 31, 2018 and 2019 and March 31, 2020, the balance of our equity investments designated at fair value through other comprehensive income was RMB10.0 million, RMB11.4 million and RMB11.4 million, respectively. The price of these securities may fluctuate with changes in market conditions as well as the performance and business prospects of Heyuan Addis, among others, all of which are beyond our control. Any decrease in the prices of these securities will result in fair value losses on financial assets at fair value through other comprehensive income, and may adversely affect our financial condition. See “Financial Information—Discussion of Certain Selected Items From the Consolidated Statements of Financial Position—Equity Investments Designated at Fair Value Through Other Comprehensive Income” for further details of our equity investment in Heyuan Addis.

Fluctuations in exchange rates of the Renminbi could result in foreign currency exchange losses.

The change in the value of RMB against the Hong Kong dollar and other currencies may fluctuate and is affected by, among other things, changes in China’s political and economic conditions and China’s foreign exchange policies. Substantially all of our costs are denominated in RMB and most of our financial assets are also denominated in RMB. However,

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our [REDACTED] from the [REDACTED] will be denominated in Hong Kong dollars. Any significant change in the exchange rates of the Hong Kong dollar against RMB may materially and adversely affect the value of and any dividends payable on, our H Shares in Hong Kong dollars.

We had Bill Transfer Arrangements during the Track Record Period and such transactions were not in compliance with relevant PRC laws.

During the Track Record Period, we had Bill Transfer Arrangements with RC Pharma that violated the issuance of bank acceptance bills and the requirements of underlying transactions under the Transfer which constitute systemic non-compliance under Guidance Letter HKEX-GL63-13 issued in July 2013 and last updated in March 2019 by the Stock Exchange. See “Business – Legal Proceedings and Compliance – Compliance – Bill Transfer Arrangements” for further details. We have ceased conducting the Bill Transfer Arrangements since March 31, 2019. We cannot assure you that the relevant regulatory authorities will not impose penalties on us retroactively for the previous Bill Transfer Arrangements. Any such penalties could adversely affect our business, financial condition and results of operations.

We were previously involved in the Bank Loan Transfer Arrangement that were not in compliance with the General Rules of Loans of the People’s Republic of China (中華人民共和國貸款通則) which may subject us to penalties and other liabilities.

We were previously involved in the Bank Loan Transfer Arrangements that were not in compliance with the General Rules of Loans of the People’s Republic of China (中華人民共和國貸款通則) which constitute systemic non-compliance under Guidance Letter HKEX-GL63-13 issued in July 2013 and last updated in March 2019 by the Stock Exchange which may subject us to penalties and other liabilities. Our Company has entered into some Loan Contracts which required the Company to use the loan proceeds to make payment to the Connected Suppliers under the Supplier Contracts. However, the Connected Suppliers transferred the loan proceeds back to the Company after receiving the proceeds from the Lending Banks and our Company applied such proceeds for different purposes including settlements with MabPlex, settlement of related party loans and payables owed to RC Pharma and other general working capital uses. As advised by our PRC Legal Advisor, the Bank Loan Transfer Arrangements as defined in the section headed “Business – Legal Proceedings and Compliance – Compliance – Deviation from intended use of loan proceeds” in this document were not in strict compliance with Article 19(iii) of the General Rules of Loans (貸款通則). It is not explicitly provided in the General Rules that our Company would be subject to administrative penalties imposed by the relevant PRC competent government authorities for the violation of Article 19(iii). We had ceased such Bank Loan Transfer Arrangements since March 1, 2020 and fully repaid the Loans under the Bank Loan Transfer Arrangements by March 13, 2020. Based on the above and the confirmations of the Lending Banks, our Company and the relevant PRC Government Authorities, our PRC Legal Advisor has advised that the Bank Loan Transfer Arrangements do not amount to any material non-compliances or criminal activities, and that our Company will not be subject to any administrative penalties by the PRC Governmental Authorities for the Bank Loan Transfer Arrangements. As such, the Bank Loan Transfer Arrangements are not expected to have any material adverse legal impact on our Company. However, we cannot preclude the possibilities that our Company will subject to administrative penalty or other liabilities for the previous non-compliance. Should the non-compliant bank loan transfer by our Company incur any administrative penalty or claim, our financial position may be adversely affected. For details of the relevant non-compliance incidents, please refer to the paragraph headed “Business—Legal Proceedings and Compliance—Compliance” in this document.

RISK FACTORS

RISKS RELATING TO OUR BUSINESS

Risks Relating to the Development of Our Drug Candidates

Our business and financial prospects depend substantially on the success of our clinical-stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain their regulatory approvals or achieve their commercialization, or if we experience significant delays in doing any of the foregoing, our business will be materially harmed.

Our ability to generate revenue and realize profitability is dependent on our ability to successfully complete the development of our drug candidates, obtain necessary regulatory approvals, and manufacture and commercialize our drug candidates. We have invested a significant portion of our efforts and financial resources in the development of our existing drug candidates, and we expect to continue to incur substantial and increasing expenditures for the development and commercialization of our drug candidates.

The success of our drug candidates will depend on several factors, including but not limited to:

- successful enrolment of patients in, and completion of, clinical trials, as well as completion of pre-clinical studies;
- favourable safety and efficacy data from our clinical trials and other studies;
- sufficient resources to acquire or discover additional drug candidates and successful identification of potential drug candidates based on our research or business development methodology or search criteria and process;
- obtaining sufficient supplies of any drug products that are used in combination with our drug candidates, competitor drugs or comparison drugs that may be necessary for use in clinical trials for evaluation of our drug candidates;
- receipt of regulatory approvals;
- establishing sufficient commercial manufacturing capabilities, either by building facilities ourselves or making arrangements with third-party manufacturers;
- the performance by contract research organizations (“CROs”) or other third parties we may retain to conduct clinical trials, of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;

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- obtaining, maintaining and enforcing patent, trademark, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- ensuring we do not infringe, misappropriate or otherwise violate the patents, trademarks, trade secrets or other intellectual property rights of third parties, and successfully defending against any claims by third parties that we have infringed, misappropriated or otherwise violated any intellectual property of any such third party;
- successfully launching commercial sales of our drug candidates, if and when approved;
- obtaining and maintaining favourable reimbursement from third-party payers for drugs, if and when approved;
- competition with other drug candidates and drugs; and
- continued acceptable safety profile of our drug candidates following regulatory approval.

Some of our drug candidates represent a novel approach to therapeutic needs compared with more commonly used medical methods, which carries inherent development risks and could result in delays in clinical development, regulatory approval or commercialization. Any modification to the protocols related to the demonstration of safety or efficacy of our drug candidates may delay the clinical program, regulatory approval or commercialization, and we may be required to supplement, modify, or withdraw and refile our applications for regulatory approval. In addition, potential patients and their doctors may be inclined to use conventional standard-of-care treatments rather than trying out a novel approach. Further, given the novelty of our drug candidates, patients and medical personnel may need a substantial amount of education and training. This may have a material impact on our ability to generate revenue from our drug candidates, which in turn may adversely affect our business, financial condition and results of operations.

As of the Latest Practicable Date, all of our existing drug candidates are in various phases of clinical development, and we have submitted the NDA for telitacicept (RC18) for the treatment of SLE to the NMPA in October 2019, which is currently under the priority review by the CDE of NMPA. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays in our ability to obtain approval for and/or to successfully commercialize our drug candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

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If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

The successful and timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enrol a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrolment in our clinical trials for a variety of reasons, including but not limited to:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial’s primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians’ and patients’ perceptions of the potential advantages and side effects of the drug candidate being studied compared to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will not complete a clinical trial; and
- the availability of approved therapies that are similar in mechanism to our drug candidates.

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enrol in our trials may instead opt to enrol in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Even if we are able to enrol a sufficient number of patients in our clinical trials, delays in patient enrolment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our drug candidates.

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Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical trials are expensive, difficult to design and implement, and can take years to complete with uncertainty as to outcome. Failure can occur at any time during the clinical trial process.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approvals for the development and commercialization of our drug candidates, including but not limited to situations whereby:

- regulators may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the patient enrolment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- our CROs may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate;
- our drug candidates may lack meaningful clinical responses or the participants may be exposed to unacceptable health and safety risks;
- regulators may require that we or our investigators suspend or terminate clinical research for various reasons such as non-compliance with regulatory requirements;
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our drug candidates may cause adverse events, have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

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If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates or not obtain regulatory approval at all;
- obtain approval for proposed indications that are not as broad as intended;
- have the drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how the drug is distributed or used; or
- be unable to obtain reimbursement for use of the drug.

Delays in clinical trials or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant delays in clinical trials could also shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do and impair our ability to commercialize our drug candidates and may have an adverse effect on our business and results of operations.

Results of earlier studies and trials may not be predictive of future trial results

The results of pre-clinical studies and early clinical trials may not be predictive of the success of later phase clinical trials, and successful initial or interim results of a clinical trial do not necessarily predict successful final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. As drug candidates are developed through pre-clinical and clinical trials towards approval and commercialization, it is customary that various aspects of the development programs, such as manufacturing and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the inherent risks that they may not necessarily achieve the intended objectives.

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In some instances, there can be significant variability in safety and/or efficacy results among different trials of the same drug candidate due to numerous factors, including, but not limited to, changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries and languages involved in such trials. Any of these changes could make the results of planned clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, which could delay completion of clinical trials, delay approval of our drug candidates and/or jeopardize our ability to commence commercialization of our drug candidates.

If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or may ultimately be unable to complete, the development and commercialization of our drug candidates.

Immuno-therapies are still considered as emerging and relatively novel therapeutics for treating autoimmune diseases, cancer and eye diseases. Their mechanisms of action are yet to be thoroughly understood, and adverse events or side effects have been observed in clinical studies and reported by medical practitioners in connection with their usage in patients with autoimmune diseases, cancer and eye diseases.

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. If the results of clinical trials of our drug candidates are not positive or only modestly positive for proposed indications or if they raise safety concerns, we may:

- be delayed in obtaining regulatory approval for our drug candidates, or not obtain regulatory approval at all;
- be required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate;
- be required to add labelling statements, such as a “boxed” warning or a contra-indication;
- be required to create a medication guide outlining the risks of the side effects for distribution to patients;
- be required to develop risk evaluation and mitigation strategies and plans to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;

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- not obtain regulatory approval for all the proposed indications as intended;
- be subject to restrictions on how the drug is distributed or used;
- be sued or held liable for injury caused to individuals exposed to or taking our drug candidates; and
- be unable to obtain reimbursement for use of the drug.

If our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results in future clinical trials, we would have expended a significant amount of capital to progress the relevant drug candidates to that stage, and would not realize any revenue on such drug candidate if it then ultimately failed to receive regulatory approval due to poor clinical trial results. Such an uncompensated expenditure could materially adversely affect our business, financial condition, results of operations and prospects.

We may seek approval from the NMPA, FDA, EMA or other comparable regulatory authorities to use data from registrational trials via accelerated development pathways for our drug candidates. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that we contemplate, which would increase the expense of obtaining, and delay the receipt of, necessary marketing approvals, if we receive them at all. In addition, even if we are able to use an accelerated approval pathway, it may not lead to expedited approval of our drug candidates, or approval at all, and we will likely be required to conduct post-approval clinical outcomes trials which, if failed, may cause us to discontinue marketing of our approved drug candidates for the relevant indications.

The NMPA, FDA, EMA and comparable regulatory authorities in other jurisdictions may allow the use of data from a registrational trial and grant accelerated approval to a drug candidate to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies, upon a determination that the drug candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. For example, the FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. Prior to seeking such accelerated approval, we will continue to seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval.

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There can be no assurance that in the future the regulatory authorities will agree with our surrogate endpoints or intermediate clinical endpoints, or that we will decide to pursue or submit any additional NDAs for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from the regulatory authorities, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, for any submission of an application for accelerated approval or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for our drug candidates, or withdrawal of a drug candidate, would result in a longer time period until commercialization of such drug candidate, could increase the cost of development of such drug candidate, and could harm our competitive position in the marketplace.

In addition, even if we are able to use an accelerated approval pathway, it may not lead to expedited approval of our drug candidates, or approval at all. Furthermore, if we obtain accelerated approval of a drug candidate based on a surrogate endpoint, we will likely be required to conduct a post-approval clinical outcomes trial to confirm the clinical benefit of the drug candidate and, if the post-approval trial is not successful, we may not be able to continue marketing the drug for the relevant indication.

We may be unable to identify, discover or develop new drug candidates, or to identify additional therapeutic opportunities for our drug candidates, to expand or maintain our product pipeline.

We cannot guarantee that we will be successful in identifying potential drug candidates. For example, although we have developed technology platforms such as an antibody and fusion protein platform, an antibody-drug conjugate (ADC) platform, and a bifunctional antibody (HiBody) platform which we believe enables us to design, evaluate and select optimal candidates and continue to enrich our pipeline, we cannot guarantee that we will be successful in identifying potential drug candidates. Drug candidates that we identify may be shown to have harmful side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approval. Some drug candidates are technically challenging to develop and manufacture, such as ADC drug candidates that we are developing. We may also pursue collaboration with third parties in the discovery and development of potential drug candidates, but we cannot assure you that such collaboration will be able to deliver the intended results.

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Research programs to pursue the development of our drug candidates for additional indications and to identify new drug candidates and drug targets require substantial technical, financial and human resources. Our research programs may initially show promising results in identifying potential indications and/or drug candidates, yet fail to yield results for clinical development for a number of reasons, including but not limited to the following factors:

- the research methodology used may not be successful in identifying potential indications and/or new drug candidates;
- potential drug candidates may, after further study, be shown to have adverse effects or other characteristics that indicate they are unlikely to achieve desired efficacy; or
- may take greater resources to identify additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates, thereby limiting our ability to diversify and expand our drug portfolio.

Accordingly, there can be no assurance that we will be able to identify new drug candidates or additional therapeutic opportunities for our drug candidates or to develop suitable potential drug candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential drug candidates or other potential programs that ultimately prove to be unsuccessful.

Risks Relating to Extensive Government Regulations

All material aspects of the research, development, manufacturing and commercialization of our drug candidates are heavily regulated.

All jurisdictions in which we intend to develop and commercialize our drug candidates regulate these activities in great depth and detail. We intend to focus our activities in China while pursuing global opportunities, particularly in the U.S. and the EU. These places all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of the development, approval, manufacturing, marketing, sales and distribution of products. However, there are differences in the regulatory regimes that make for a more complex and costly regulatory compliance burden for a company like us that plans to operate in these regions.

The process of obtaining regulatory approvals and maintaining compliance with appropriate laws and regulations requires the expenditure of substantial time and financial resources. Any recently enacted and future legislation may increase the difficulty and cost of us to obtain regulatory approval of, and commercialize, our drug candidates, and affect the prices we may obtain. Changes in government regulations or in practices relating to the pharmaceutical industry, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures, which would lower the entry barrier for potential competitors, or an increase in regulatory requirements, which may increase the difficulty for us to satisfy such requirements, may have a material adverse impact on our business, financial condition, results of operations, and prospects.

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Failure to comply with the applicable requirements at any time during the drug development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include but are not limited to a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any occurrence of the foregoing could therefore materially adversely affect our business, financial condition, results of operations and prospects.

The regulatory approval processes of the NMPA, FDA, EMA and other comparable regulatory authorities are lengthy, time-consuming and inherently unpredictable. If we are unable to obtain without undue delay any regulatory approval for our drug candidates in our targeted markets, our business may be substantially harmed.

The time required to obtain approval by the NMPA, FDA, EMA, and other comparable regulatory authorities is unpredictable but typically takes 10-15 years following the commencement of pre-clinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities. Our drug candidates could fail to receive regulatory approval for many reasons, including but not limited to:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that our drug candidate is safe, pure and potent for its proposed indications;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from pre-clinical studies or clinical trials;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

The NMPA, FDA, EMA or a comparable regulatory authority may require more information, including additional analyses, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs.

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Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, FDA, EMA and other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

Adverse events caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Drug-related adverse events and serious adverse events have been reported in our clinical trials. See “Business—Our Drug Candidates.” Undesirable adverse events caused by our drug candidates, or caused by our drug candidates when used in combination with other drugs, could potentially cause significant negative consequences, including but not limited to:

- regulatory authorities could interrupt, delay or halt pending clinical trials;
- we may suspend, delay or alter development or marketing of our drug candidates;
- regulatory authorities may order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications if results of our trials reveal a high and unacceptable severity or prevalence of certain adverse events;
- regulatory authorities may delay or deny approval of our drug candidates;
- regulatory authorities may withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label of an approved drug candidate or impose other limitations on an approved drug candidate;
- we may be required to develop a risk evaluation mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the risk evaluation mitigation strategy, or to develop a similar strategy as required by a comparable regulatory authority;
- we may be required to conduct post-market studies;
- we could be subject to litigation proceedings and held liable for harm caused to patients exposed to or taking our drug candidates may suffer from adverse events related to the treatment and patients;

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- the patient enrolment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated; and
- the costs of clinical trials of our drug candidates may be substantially higher than anticipated.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, and could significantly harm our business, results of operations and prospects.

We believe that our drug candidates’ Category 1 designation in China should confer certain regulatory advantages on us. These advantages may not result in commercial benefits to us as we have expected, and these advantages may change in the future in a manner adverse to us.

In China, prior to seeking approval from the NMPA, a pharmaceutical company needs to determine the drug’s registration category, which will determine the requirements for its clinical trial and marketing application. For therapeutic biological products, these categories include Category 1, for biological products that have not been marketed anywhere in the world, Category 2, for monoclonal antibodies, and the other 13 categories. Among our pipeline of more than ten drug candidates, five are in clinical development in China, all of which are designated as Category 1 drug candidates.

The NMPA has adopted several mechanisms for expedited review and approval for drug candidates that apply to Category 1 drug candidates. While we believe that the Category 1 designation of our internally developed clinical stage drug candidates should provide us with a significant regulatory, and therefore commercial, advantage over non-Chinese companies seeking to market products in China, we cannot be sure that this will be the case. The pharmaceutical regulatory environment is evolving quickly, and changes in laws, regulations, enforcement and internal policies could result in the “favoured” status of Category 1 products changing, or being eliminated altogether or our products classification in Category 1 changing. We cannot be certain that the advantages we believe will be conferred by our Category 1 classifications will be realized or result in any material development or commercial advantage.

We are subject to stringent privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

We routinely receive, collect, generate, store, process, transmit and maintain medical data treatment records and other personal details of subjects enrolled in our clinical trials, along with other personal or sensitive information. As such, we are subject to the relevant local, state, national and international data protection and privacy laws, directives regulations and standards that apply to the collection, use, retention, protection, disclosure, transfer and other

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processing of personal data in the various jurisdictions in which we operate and conduct our clinical trials, as well as contractual obligations. These data protection and privacy law regimes continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement and sanctions and increased costs of compliance. Failure to comply with any of these laws could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by customers and other affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

Such data protection and privacy laws and regulations generally require clinical trial sponsors and operators and their personnel to protect the privacy of their enrolled subjects and prohibit unauthorised disclosure of personal information. If such institutions or personnel divulge the subjects’ private or medical records without their consent, they will be held liable for damage caused thereby. We have taken measures to maintain the confidentiality of the medical records and personal data of subjects enrolled in our clinical trials we collected, including encrypting such information in our information technology system so that it cannot be viewed without proper authorisation, and setting internal rules requiring our employees to maintain the confidentiality of our subjects’ medical records. However, these measures may not be always effective. For example, our information technology systems could be breached through hacking activities, and personal information could be leaked due to theft or misuse of personal information arising from misconduct or negligence. In addition, our clinical trials frequently also involve professionals from third party institutions working on-site with our staff and enrolled subjects. We cannot ensure that such persons will always comply with our data privacy measures. For details, please see “Risk Factors – Risks Relating to Our Operations – Our internal information technology and other infrastructure, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches”. Furthermore, any change in such laws and regulations could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. Any failure to protect the confidentiality of patients’ medical records and personal data, or any restriction on or liability as a result of, our use of medical data, could have a material adverse effect on our business, financial condition and results of operations.

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, China’s Cyber Security Law, which became effective in June 2017, created China’s first national-level data protection for “network operators,” which may include all organizations in China that provide services over the internet or another information network. Numerous regulations, guidelines and other measures are expected to be adopted under the umbrella of the Cyber Security Law. Drafts of some of these measures have now been published, including the draft rules on cross-border transfers published by the Cyberspace Administration of China in 2017, which may, upon enactment, require security review before transferring human health-related data out of China. In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China.

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The Interim Measures for the Administration of Human Genetic Resources and implementation guidelines issued by the Ministry of Science and Technology and Ministry of Health, for example, require approval from the Human Genetic Resources Administration of China before entering into a definitive contract where human genetic resources (“HGR”), are involved in any international collaborative project and additional approval for any export or cross-border transfer of the HGR samples or associated data. The regulations of the People’s Republic of China on the Administration of Human Genetic Resources which became effective on July 1, 2019 and implemented on July 1, 2019 further stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in China, no approval is required in international clinical trial cooperation using China’s HGR at clinical institutions without export of HGR materials. However, the two parties shall file the type, quantity and usage of the HGR to be used with the administrative department of science and technology under the State Council before clinical trials. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, potentially resulting in confiscation of HGR samples and associated data and administrative fines. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

In addition, there are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as “protected health information”) and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services (“HHS”), and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

Additionally, the Gramm-Leach-Bliley Act of 1999 (along with its implementing regulations) (the “GLBA”) restricts certain collection, processing, storage, use and disclosure by covered companies of certain personal information, requires notice to individuals of privacy practices and provides individuals with certain rights to prevent the use and disclosure of

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certain non-public or otherwise legally protected information. The GLBA also imposes requirements regarding the safeguarding and proper destruction of personal information through the issuance of data security standards or guidelines. In addition, many U.S. states have laws that protect the privacy and security of sensitive and personal information. Certain U.S. state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, the California Consumer Privacy Act of 2018 (the “CCPA”), which went into effect on January 1, 2020, imposes stringent data privacy and security requirements and obligations with respect to the personal information of California residents and households. Among other things, it requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information that may increase the likelihood of, and risks associated with, data breach litigation. The CCPA was amended in September 2018 and November 2019, and it is possible that further amendments will be enacted. It remains unclear how various provisions of the CCPA will be interpreted and enforced, and multiple states have enacted or are expected to enact similar laws. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we may be subject.

In Europe, laws, regulations and standards in many jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information. For example, in the European Economic Area (the “EEA”) and the United Kingdom, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the “GDPR”). The GDPR came into effect in May 2018, superseding the European Union Data Protection Directive, and imposing more stringent data privacy and security requirements on companies in relation to the processing of personal data of EU data subjects. The GDPR, together with national legislation, regulations and guidelines of the EU member states and the United Kingdom governing the processing of personal data, impose strict obligations and restrictions on the ability to collect, use, retain, protect, disclose, transfer and otherwise process personal data. In particular, the GDPR includes obligations and restrictions concerning the consent and rights of individuals to whom the personal data relates, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications and the security and confidentiality of personal data. The GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater. Such fines are in addition to any civil litigation claims by customers and data subjects. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which contributes to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices is often updated or otherwise revised. Further, while the United Kingdom enacted the Data Protection Act 2018 in May 2018 that supplements the GDPR and has publicly announced that it will continue to regulate the protection of personal data in the same way post-Brexit, Brexit has created uncertainty with regard to the future of regulation of data protection in the United Kingdom. Some countries also are considering or have passed legislation requiring local storage and processing of data, or similar requirements, which could increase the cost and complexity of delivering our products and services.

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Complying with all applicable laws, regulations, standards and obligations relating to data privacy, security, and transfers may cause us to incur substantial operational costs or require us to modify our data processing practices and processes. Non-compliance could result in proceedings against us by data protection authorities, governmental entities or others, including class action privacy litigation in certain jurisdictions, which would subject us to significant awards, fines, penalties, judgments and negative publicity, and may otherwise materially and adversely affect our business, financial condition and results of operations. We may not be able to respond quickly or effectively to regulatory, legislative and other developments, and these changes may in turn impair our ability to offer our existing or planned drug candidates or increase our cost of doing business. In addition, if our practices are not consistent or viewed as not consistent with legal and regulatory requirements, including changes in laws, regulations and standards or new interpretations or applications of existing laws, regulations and standards, we may become subject to audits, inquiries, whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and reputational damage. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our drug candidates may face competition sooner than anticipated from biosimilar products.

Even if we are successful in achieving regulatory approval to commercialize a drug candidate faster than our competitors, our drug candidates may face competition from biosimilar products. In the United States, our drug candidates are regulated by the FDA as biologic products and we intend to seek approval for these drug candidates pursuant to the biologics license application (“BLA”), pathway. The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), created an abbreviated pathway for the approval of biosimilar and interchangeable biologic products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar drug cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our drug candidates.

There is a risk that any exclusivity we may be afforded if any of our drug candidates are approved as a biologic product under a BLA could be shortened due to congressional action or otherwise, or that the FDA will not consider our drug candidates to be reference products for competing products, potentially creating the opportunity for generic or biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for nonbiologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In addition, a competitor could

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decide to forego the biosimilar approval path and submit a full BLA after completing its own preclinical studies and clinical trials. In such cases, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In Europe, a competitor may reference data supporting approval of an innovative biological product, but will not be able to get it on the market until 10 years after the time of approval of the innovative product. This 10-year marketing exclusivity period may be extended to 11 years if, during the first eight of those 10 years, the marketing authorization holder obtains an approval for one or more new therapeutic indications that bring significant clinical benefits compared with existing therapies. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our drug candidates, if approved, such products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our drug candidates may have received approval. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Even after we obtain regulatory approval for the marketing and distribution of our drug candidates, our products will continue to remain subject to ongoing or additional regulatory obligations and continued regulatory review, which may result in significant additional expenses, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our future approved drugs.

If any of our drug candidates is approved in the future, it will be subject to ongoing or additional regulatory requirements for manufacturing, labelling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including requirements of regulatory authorities in China and other jurisdictions.

Any approvals that we receive for our drug candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, which could adversely affect the drug's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the drug candidates. The NMPA, FDA, EMA or a comparable regulatory authority may also require a risk evaluation mitigation strategy program as a condition of approval of our drug candidates or following approval. In addition, if the NMPA, FDA, EMA or a comparable regulatory authority approves our drug candidates, we will have to comply with requirements, including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and good clinical practice ("GCP"), for any clinical trials that we conduct post-approval.

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The NMPA, FDA, EMA and other regulatory authorities strictly regulate the marketing, labelling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The NMPA, FDA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

If we are able to commercialize our drug candidates, we may face uncertainties from national, provincial or other third party drug reimbursement practices and unfavorable drug pricing policies or regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. We intend to seek approval to market our drug candidates in China, the U.S., the EU and in other jurisdictions. In both China and the EU, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Our ability to commercialize any approved drug candidates successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations.

A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payers have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications.

In China, the Ministry of Human Resources and Social Security of China or provincial or local human resources and social security authorities, together with other government authorities, review the inclusion or removal of drugs from the China’s National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工商保險和生育保險藥品目錄》), or the National Reimbursement Drug List (the “NRDL”), or provincial or local medical insurance catalogues for the National Medical Insurance Program (the “PRDL”), regularly, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that any of our future approved drug candidates will be included in the NRDL or the PRDL. Products included in the NRDL or the PRDL are typically generic and essential drugs. Innovative drugs similar to our drug candidates have historically been more limited on their inclusion in the NRDL or the PRDL due to the affordability of the government’s Basis Medical Insurance.

In the U.S., no uniform policy of coverage and reimbursement for drugs exists among third-party payers. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payer is a time-consuming and costly process that could require us to provide to each payer supporting scientific, clinical and cost-effectiveness data for the use of our future approved drugs on a payer-by-payer basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given drug, the resulting reimbursement rates might not be adequate for us to achieve or sustain

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profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payers may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our future approved drug candidates. Patients are unlikely to use any of our future approved drug candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drugs. Because some of our drug candidates have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

Increasingly, third-party payers are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any approved drug candidates that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any approved drug candidates that we commercialize. Obtaining or maintaining reimbursement for our future approved drug candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidates that we successfully develop.

There may be significant delays in obtaining reimbursement for approved drug candidates, and coverage may be more limited than the purposes for which the drug candidates are approved by the NMPA, FDA, EMA or other comparable regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower cost drugs that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future weakening of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payers for any future approved drug candidates and any new drugs that we develop could have a material adverse effect on our business, our operating results, and our overall financial condition.

We may be directly or indirectly subject to applicable anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in China and other jurisdictions, which could, in the event of noncompliance, expose us to administrative sanctions, criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain the NMPA or the FDA approval for any of our drug candidates and begin commercializing those

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drugs in China or in the U.S., our operations may be subject to various PRC and U.S. federal and state fraud and abuse laws, including, without limitation, the PRC Anti-Unfair Competition Law (《反不正當競爭法》), PRC Criminal Law (《刑法》), the Federal Anti-Kickback Statute and the Federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs.

In addition, we are subject to similar healthcare laws in other jurisdictions, some of which may be broader in scope than others and may apply to healthcare services reimbursed by any source, which may include not only governmental payers, but also private insurers. There are ambiguities as to what is required to comply with any of these requirements, and if we fail to comply with any such requirement, we could be subject to penalties.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the Federal False Claims Act as well as under the false claims laws of several states.

Neither the PRC government nor the PRC courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. Governmental authorities could conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and if we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in governmental healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and have a significant impact on our businesses and results of operations.

Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results.

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs affecting certain products manufactured in China. In March 2018, U.S. President Donald J. Trump announced the imposition of tariffs on steel and aluminum entering the U.S. and in June 2018 announced further tariffs targeting goods imported from China. Recently both China and the U.S. have each imposed tariffs indicating the potential for further trade barriers. It is unknown whether and to what extent new tariffs (or other new laws or regulations) will be adopted, or the effect that any such actions would have on us or our

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industry. While we have not started commercialization of drug candidates, we plan to initiate our global clinical trials for telitaccept in SLE and for disitimab vedotin in UC and GC in the U.S. in the near future and may launch these products in the U.S. if it is approved by the FDA for marketing. Any unfavorable government policies on international trade, such as capital controls or tariffs, may affect the demand for our drug products, the competitive position of our drug products, the hiring of scientists and other research and development personnel, and import or export of raw materials in relation to drug development, or prevent us from selling our drug products in certain countries. If any new tariffs, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S. government takes retaliatory trade actions due to the recent U.S.-China trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

Risks Relating to Manufacturing of Our Products

We have limited experience in manufacturing therapeutic biologic products on a large commercial scale, which is a highly exacting and complex process, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.

We have limited experience in large-scale manufacturing of our products for commercial use. Moreover, the manufacturing of therapeutic biologics products is highly complex. Problems may arise during manufacturing for a variety of reasons, including but not limited to:

- equipment malfunction;
- failure to follow specific protocols and procedures;
- changes in product specification;
- low quality or insufficient supply of raw materials;
- delays in the construction of new facilities or the expansion of our existing manufacturing facilities as a result of changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements;
- changes in the types of products produced;
- advances in manufacturing techniques;
- physical limitations that could inhibit continuous supply; and
- man-made or natural disasters and other environmental factors.

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Products with quality issues may have to be discarded, resulting in product shortages or additional expenses. This could lead to, among other things, increased costs, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before the product is released to the market, recall and product liability costs may also be incurred. We face additional manufacturing risks in relation to the CMOs we engage from time to time. See “– Risks Relating to Our Business – Risks Relating to Our Reliance on Third Parties – We may rely on third parties to manufacture a portion of our drug candidates for clinical development and commercial sales. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices.”

Manufacturing methods and formulation are sometimes altered through the development of drug candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause the drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay the commercialization of drug candidates and require bridging studies or the repetition of one or more clinical trials, which may result in increases in clinical trial costs, delays in drug approvals and jeopardize our ability to commence product sales and generate revenue.

We may also encounter problems with achieving adequate or clinical-grade products that meet NMPA, FDA, EMA or other comparable regulatory agency standards or specifications, maintaining consistent and acceptable production costs, and experience shortages of qualified personnel, raw materials or key contractors, and experience unexpected damage to our facilities or the equipment in them. In these cases, we may be required to delay or suspend our manufacturing activities. We may be unable to secure temporary, alternative manufacturers for our drugs with the terms, quality and costs acceptable to us, or at all. Such an event could delay our clinical trials and/or the availability of our products for commercial sale. Moreover, we may spend significant time and costs to remedy these deficiencies before we can continue production at our manufacturing facilities.

In addition, the quality of our products, including drug candidates manufactured by us for research and development purposes and drugs manufactured by us for commercial use, depends significantly on the effectiveness of our quality control and quality assurance, which in turn depends on factors such as the production processes used in our manufacturing facilities, the quality and reliability of equipment used, the quality of our staff and related training programs and our ability to ensure that our employees adhere to our quality control and quality assurance protocol. However, we cannot assure you that our quality control and quality assurance procedures will be effective in consistently preventing and resolving deviations from our quality standards. We are, however, working on improving our documentation procedures for quality control and quality assurance activities. Any significant failure or deterioration of our quality control and quality assurance protocol could render our products unsuitable for use, jeopardize any GMP certifications we may have and/or harm our market reputation and relationship with business partners. Any such developments may have a material adverse effect on our business, financial condition and results of operations.

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Any delays in completing and receiving regulatory approvals for our manufacturing facilities, or any disruption of our current facilities or in the development of new facilities, could reduce or restrict our production capacity or our ability to develop or sell products, which could have a material and adverse effect on our business, financial condition and results of operations.

We currently manufacture our existing drug candidates for research and development purposes in Yantai, China. Our manufacturing facilities will be required to obtain and maintain regulatory approvals, including being subject to ongoing, periodic inspection by the NMPA, FDA, EMA or other comparable regulatory authorities to ensure compliance with GMP regulations. Further, we will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, other marketing application, and previous responses to any inspection observations if we were to build manufacturing facilities in the future. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We cannot guarantee that we will be able to adequately follow and document our adherence to such GMP regulations or other regulatory requirements. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to follow and document our adherence to such cGMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or their commercialization, if approved. Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of our drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

In addition, to obtain FDA approval for our products in the U.S., we would need to undergo strict pre-approval inspections of our manufacturing facilities. Historically, manufacturing facilities in China have had difficulty meeting FDA standards. When inspecting our manufacturing facilities, the FDA may cite cGMP deficiencies. Remediating deficiencies can be laborious, time consuming and costly. Moreover, the FDA will generally re-inspect the facility to determine whether the deficiency was remediated to its satisfaction, and may note further deficiencies during re-inspection.

Any interruption in manufacturing operations at our facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. A number of factors could cause interruptions, including equipment malfunctions or failures, technology malfunctions, work stoppages, damage to or destruction of either facility due to natural disasters or other unanticipated catastrophic events, water shortages or fire regional power shortages, product tampering or terrorist activities. Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially harm our business, financial condition and results of operation.

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If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any of our future approved drug candidates manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales if and when we are able to successfully commercialize one or more of our drug candidates. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates in a timely manner could materially adversely affect our business, financial condition, results of operations and prospects.

Currently, we maintain insurance coverage against damage to our property, facilities, equipment and inventories. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer.

If we are unable to meet the increasing demand for our existing drug candidates and future drug products by ensuring that we have adequate manufacturing capacity, or if we are unable to successfully manage our anticipated growth or to precisely anticipate market demand, our business could suffer.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel and compliance with strictly-enforced regulations. If our manufacturing facilities encounter unanticipated delays and expenses as a result of any of these difficulties, or if construction, regulatory evaluation and/or approval of our new facilities is delayed, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could also require us to raise additional funds from other sources.

To produce our drug candidates in the quantities that we believe will be required to meet anticipated market demand of our drug candidates, if approved, we will need to increase, or "scale up," the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed, the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our approved drug candidates in a sufficient quantity to meet future demand.

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In anticipation of commercialization of our drug candidates, we aim to significantly expand our manufacturing capacity, mainly through the construction of new manufacturing facilities. However, the timing and success of these plans are subject to significant uncertainty. Moreover, such plans are capital intensive and require significant upfront investment, and there can be no assurance that we will be able to timely obtain such financing, if at all.

Furthermore, given the size of our new facilities, we may not be able to fully utilize them immediately or within a reasonable period of time after we commence operation. During the construction and ramp up period, there may be significant changes in the macroeconomics of the pharmaceutical and biopharmaceutical industry, including, among other things, market demand, product and supply pricing trends and customer preferences. Any adverse trends in these respects could result in operational inefficiency and unused capacity in our facilities. We may also experience various unfavorable events in the course of developing our new manufacturing facilities, such as:

- unforeseen delays due to construction, land use rights or regulatory issues, which could result in loss of business opportunities;
- construction cost overruns, which may require diverting resources and management's attention from other projects; and
- difficulty in finding sufficient numbers of trained and qualified staff.

The success of our business expansion also depends on our ability to advance drug candidates through the development, regulatory approval and commercialization stages. Any delay, suspension or termination in such respects would harm our ability to generate satisfactory returns on our investment in manufacturing expansion, if at all, which in turn could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Commercialization of Our Products

Our drug candidates, once approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community that would be necessary for their commercial success.

Our drug candidates, once approved, may fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. In addition, physicians, patients and third-party payers may prefer other products to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- the clinical indications for which our drug candidates are approved;
- physicians, hospitals, medical treatment centres and patients considering our drug;
- efficacy and safety of our drug candidates;

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- the potential and perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labelling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labelling approved by regulatory authorities;
- the timing of market introduction of our drug candidates as well as competitive drugs;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payers and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payers and government authorities; and
- the effectiveness of our sales and marketing efforts.

If any approved drug candidates that we commercialize fail to achieve market acceptance among physicians, patients, hospitals, medical treatment centres or others in the medical community, we will not be able to generate significant revenue. Even if our future approved drug candidates achieve market acceptance, we may not be able to maintain such market acceptance over time if new products or technologies are introduced that are more favourably received than our drug candidates, are more cost-effective or render our drug candidates obsolete. Our failure to achieve or maintain market acceptance for our future approved drug candidates would materially adversely affect our business, financial condition, results of operations and prospects.

We have no track record and limited experience in commercialization of drugs. If we are unable to build or maintain sufficient sales and marketing capabilities, either by ourselves or through third parties, we may not be able to successfully create or increase market awareness of our products or sell our products, which will materially affect our ability to generate product sales revenue.

We have not yet demonstrated an ability to launch and commercialize any of our drug candidates. We only recently started the process of building a commercial team and a sales force for our drug candidates. As a result, our ability to successfully commercialize our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with experience launching and marketing drug candidates.

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We will have to compete with other pharmaceutical and biopharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to, or decide not to, further develop internal sales, marketing and commercial distribution capabilities for any or all of our drug candidates, we will likely pursue collaborative arrangements regarding the sales and marketing of our drug candidates. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties. We would have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts for our drug candidates.

There can be no assurance that we will be able to further develop and successfully maintain in-house sales and commercial distribution capabilities or establish or maintain relationships with third-party collaborators to successfully commercialize any product, and as a result, we may not be able to generate product sales revenue.

We face substantial competition and our competitors may discover, develop or commercialize competing drugs faster or more successfully than we do.

The development and commercialization of new drugs, especially biological products, is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies worldwide. There are a number of large pharmaceutical and biopharmaceutical companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of autoimmune diseases, cancer, eye diseases or other indications for which we are developing our drug candidates. Some of these competitors have better resources and expertise than us. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available.

Competition in therapeutic areas such as autoimmune diseases, oncology and ophthalmology to which our core products belong is extremely fierce given the abundance of existing competing drugs and drug candidates that continue to increase competition in the market. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial, technical and human resources and expertise in research and development, manufacturing, pre-clinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Competition may increase further as a result of advances in the commercial applicability of new or disruptive technologies.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we may develop or

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commercialize. Our competitors also may obtain approval from the NMPA, FDA, EMA or other comparable regulatory authorities for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our drug candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our drug candidates.

Mergers and acquisitions in the pharmaceutical and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Risks Relating to Our Intellectual Property Rights

If we are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially adversely affected.

Our success depends in large part on our ability to protect our proprietary technologies and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. We seek to protect the drug candidates and technology that we consider commercially important by filing patent applications in China, the U.S. and other jurisdictions, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. In particular, we have sought patents in China, the U.S. and various other jurisdictions for our core products (telitaccept, disitamab vedotin and RC28). For further information on our patent portfolio, see “Business—Intellectual Property.” If we or our licensors are unable to obtain and maintain patent and other intellectual property protection with respect to our drug candidates and technologies, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend, enforce or license all necessary or desirable patents at a reasonable cost or in a timely manner in all desirable jurisdictions. As a result, we may not be able to prevent competitors or other third parties from developing and commercializing competitive drugs in all such fields and jurisdictions. Furthermore, the patent position of pharmaceutical and biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

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The requirements for patentability differ in certain jurisdictions, particularly developing countries. For example, China has a heightened requirement for patentability and, specifically, requires a detailed description of medical uses of a claimed drug. Many jurisdictions have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many jurisdictions limit the enforceability of patents against government agencies or government contractors. In these jurisdictions, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be materially impaired and our business, financial condition, results of operations, and prospects may be adversely affected.

Patents may be invalidated and patent applications may not be granted for a number of reasons, including known or unknown prior art, deficiencies in the patent application or the lack of novelty of the underlying invention or technology. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases, not at all. Therefore, we cannot be certain that we or our licensors (if any) were the first to make the inventions claimed in our owned or licensed patents or pending patent applications or that we or our licensors (if any) were the first to file for patent protection of such inventions. Furthermore, China and, recently, the U.S. have adopted the “first-to-file” system under which whoever first files a patent application will be awarded the patent if all other patentability requirements are met. If a third party can establish that we or our licensors were not the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or ruled unenforceable, and third parties may be granted a patent relating to a technology which we invented.

We are primarily focused on protecting our intellectual property rights in our target markets, which are China, the U.S., the EU and other jurisdictions. Filing, prosecuting, maintaining, defending and enforcing patents and other intellectual property rights with respect to our drug candidates in all other jurisdictions throughout the world would be prohibitively expensive for us. Our intellectual property rights in certain jurisdictions may have a lessor or different scope and strength compared to those in our target markets. In addition, the laws of certain jurisdictions do not protect intellectual property rights to the same extent as the laws of our target markets. Consequently, in some cases, we may not be able to obtain issued patents or other intellectual property rights covering our drug candidates in jurisdictions outside our target markets and, as a result, we may not be able to prevent third parties from using our inventions in all jurisdictions outside our target markets, or from selling or importing drugs

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made using our inventions in and into our target markets or other jurisdictions. Competitors and other third parties may use our technologies in jurisdictions where we have not pursued and obtained patent and other intellectual property protection to develop their own drugs and further, may export otherwise infringing drugs to jurisdictions where we have patent or other intellectual property protection, but where enforcement rights are not as strong as those in markets such as the U.S. These drugs may compete with our drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in jurisdictions such as China. The legal system in these jurisdictions, particularly those in certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights in these jurisdictions. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and other intellectual property rights at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a commercial advantage from the intellectual property that we develop or license. In addition, under the PRC patent law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the NIPA, for confidentiality examination. Otherwise, if an application is later filed in China, the patent right will not be granted. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

The scope of our patent protection may be uncertain. Our current or any future patents may be challenged and invalidated even after issuance, which would materially adversely affect our ability to successfully commercialize any product or technology.

The patent position of pharmaceutical and biopharmaceutical companies is generally highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future owned and licensed patent applications may not issue as patents at all, and even if such patent applications do issue as patents, they may not issue in a form, or with a scope of claims, that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, its scope can be reinterpreted after issuance and changes in either the patent laws or interpretation

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of the patent laws in China, the U.S. and other jurisdictions may diminish the value of our patent rights or narrow the scope of our patent protection. Any patents that we own or in-license may be challenged, narrowed, circumvented or invalidated by third parties. We cannot predict whether the patent applications we are currently pursuing and may pursue in the future will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patent rights may be challenged in the courts or patent offices in China, the U.S. and other jurisdictions. We may be subject to a third-party submission of prior art to the United States Patent and Trademark Office (“USPTO”) challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent’s issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. We may become involved in opposition, derivation, revocation, re-examination, post-grant review, *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. In addition, a third party may claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. An adverse determination in any such submission, proceeding or litigation could put one or more of our owned or licensed patents at risk of being interpreted narrowly, invalidated, or ruled unenforceable and could allow third parties to commercialize products similar or identical to our technology or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges and proceedings may result in loss of patent rights or freedom to operate, loss of exclusivity, or patent claims being narrowed, invalidated, or held unenforceable, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or could limit the duration of the patent protection of our technology and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favourable to us. Consequently, we do not know whether any of our technology or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Despite measures we take to obtain patent protection with respect to our major drug candidates and technologies, any of our issued patents could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the U.S., for example, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity

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challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld material information from the relevant patent office, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in China, the U.S. or in other jurisdictions, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, interference proceedings, derivation, invalidation, revocation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer adequately cover and protect our drug candidates.

Additionally, patent rights we may own or license currently or in the future may be subject to a reservation of rights by one or more third parties. For example, under U.S. law, when new technologies are developed with U.S. government funding, the U.S. government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may also permit the U.S. government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology that was developed using U.S. government funding. The U.S. government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, or if it determines that action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such government-funded inventions may be subject to certain requirements to manufacture products embodying such inventions in the U.S. Any exercise by the government or other third parties of such rights could harm our competitive position, business, financial condition, results of operations, and prospects. Furthermore, the recipient of such U.S. government funding is required to comply with certain government regulations, including timely disclosing the inventions claimed in such patent rights to the U.S. government and timely electing title to such inventions. If we fail to meet these obligations, it may lead to a loss of rights or the unenforceability of relevant patents or patent applications. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Even if we are able to obtain patent protection for our drug candidates, the term of such protection, if any, is limited, and third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us after the expiration of our patent rights, if any, and our ability to successfully commercialize any product or technology would be materially adversely affected.

Although various adjustments and extensions may be available, the term of a patent, and the protection it affords, is limited. For example, in the U.S., the expiration of a patent is generally 20 years from the earliest date of filing of the first non-provisional patent application to which the patent claims priority. Even if we successfully obtain patent protection for an

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approved drug candidate, it may face competition from generic or biosimilar medications once the patent has expired. Manufacturers of generic or biosimilar drugs may challenge the scope, validity or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our drug candidates are expected to expire on various dates as described in “Business—Intellectual Property” of this document. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our owned and licensed patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our drug candidates for an adequate amount of time, and the absence of patent linkage, patent term extension and data and market exclusivity for NMPA-approved pharmaceutical products could increase the risk of early generic competition for our products in China.

In the U.S., the Federal Food Drug and Cosmetic Act (the “FDCA”), as amended by the law generally referred to as “Hatch-Waxman,” provides the opportunity for limited patent term extension. Hatch-Waxman permits a patent-term restoration that provides a patent term extension of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval; only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. The application for the extension must be submitted prior to the expiration of the patent for which extension is sought. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. Depending upon the timing, duration and specifics of any FDA marketing approval process for any drug candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under Hatch-Waxman. However, we may not be granted an extension because of, for example, failing to exercise due diligence

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during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extensions or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

Hatch-Waxman also has a process for patent linkage, pursuant to which the FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Moreover, Hatch-Waxman provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. Similarly, the U.S. Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases, where FDA designates the drug candidate as an orphan drug and the drug is approved for the designated orphan indication. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the FDA grants marketing approval for the innovative product.

In China, however, there is no currently effective law or regulation providing patent term extension, patent linkage, or data exclusivity (referred to as regulatory data protection). Therefore, a lower-cost generic drug can emerge onto the market much more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime, as well as for establishing a pilot program for patent term extension. To be implemented, this framework will require adoption of regulations. To date, no regulations have been issued. These factors result in weaker protection for us against generic competition in China than could be available to us in the U.S. For instance, the patents we have in China are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors or other third parties may obtain approval of competing products following our patent expiration. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may challenge the validity and enforceability of our patents or those of our licensing partners, infringe, misappropriate or otherwise violate our other intellectual property rights. To counter infringement, misappropriation or any other

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unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Litigation and other proceedings in connection with any of the foregoing claims can be expensive and time-consuming and, even if resolved in our favor, may cause us to incur significant expenses and could distract management and our scientific and technical personnel from their normal responsibilities. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any claims that we assert against perceived infringers and other violators could also provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs.

Moreover, we may not be able to detect infringement against our patents. Even if we detect infringement by a third party of any of our patents, we may choose not to pursue litigation against or settlement with such third party. If we later sue such third party for patent infringement, the third party may have certain legal defences available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defences may make it impossible for us to enforce our patents against such third party.

Although we believe that we have conducted our patent prosecution in accordance with the duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our collaboration partners, our or their patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates, leave our technology or drug candidates without patent protection, allow third parties to commercialize our technology or drug candidates and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our drug candidates without infringing third party patent rights. Even if a defendant does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

Moreover, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our drug candidates.

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Additionally, we may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, patent applications, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our drug candidates or technology. Litigation may be necessary to defend against these and other claims challenging inventorship of our owned or in-licensed patents, patent applications, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of or right to use intellectual property that is important to our drug candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain, and we may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our drug candidates or future drugs, or delay the commercialization of our drug candidates in certain jurisdictions, as a result of such litigation or other proceedings relating to patent or other intellectual property rights.

Our commercial success depends in part on our and our collaborators avoiding infringement, misappropriation, and other violations of the patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our drug candidates. For example, we are aware of a third-party issued patent in the U.S. that may be alleged to cover the use of our telitacicept in treating autoimmune disease which will expire in 2021, and a third-party issued patent in Europe that may be alleged to cover the use of our telitacicept in treating mild-to-moderate SLE, although we do not expect to commercially launch telitacicept in the U.S. before the expiration of the third-party patent in the U.S. and telitacicept targets to treat moderate-to-severe SLE. Moreover, we are aware of third-party issued patents in the U.S. and Europe that may be alleged to cover our disitamab vedotin, and pending third-party patent applications in the U.S., Europe and mainland China that may be alleged to cover our disitamab vedotin’s potential combination with immune checkpoint therapies. In addition, we are aware of a third-party issued patent in the U.S. that may be alleged to cover our RC88 which will expire in 2022, although we do not expect to commercially launch RC88 in the U.S. before the expiration of this third-party patent. Notwithstanding the foregoing, the timeline of commercial launch of aforementioned drug candidates in the U.S. is subject to significant uncertainty and we cannot rule out the possibility that we may launch those drug candidates in the U.S. earlier than we currently expect. For further details, please refer to the paragraph headed “Business – Intellectual Property”. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to issue that relate to aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the pharmaceutical and biopharmaceutical industries generally. As the pharmaceutical and biopharmaceutical industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

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Third parties may assert that we are using technology in violation of their patent or other proprietary rights. We may also be subject to allegations by third parties of unfair competition, defamation or violation of their other rights. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favour on questions of infringement, validity, enforceability or priority, and it could materially and adversely affect our ability to develop and commercialize any of our drug candidates and any other drug candidates covered by the asserted third-party patents. The burden of successfully challenging a third-party claim may be high and require us to present clear and convincing evidence as to the invalidity of any such claim, there is no assurance that a court of competent jurisdiction would invalidate any such third-party claim.

If third parties, including the third parties that control the patents described above, bring successful claims against us for infringement, misappropriation or other violations of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our drug candidates, including our telitaccept and disitamab vedotin. Defence of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim against us of infringement, misappropriation or other violation of intellectual property, or a settlement by us of any such claims, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, pay royalties and other payments or redesign our infringing drug candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our drug candidates. Any such license might not be available on reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent and other intellectual property infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

Even if litigation or other proceedings are resolved in our favour, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our H Shares. Such litigations or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and patent applications are due to be paid to the NIPA, the USPTO and other patent agencies in other jurisdictions in several stages over the lifetime of a patent. The NIPA, the USPTO and other governmental patent agencies also require compliance with a number of procedural, documentary, and other similar provisions during the patent application process. We rely on our outside counsel and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment, loss of priority or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors or other third parties might be able to enter the market, which would have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Changes in patent laws of China, the U.S. or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates and future drugs.

As is the case with other pharmaceutical and biopharmaceutical companies, our success is heavily dependent on obtaining, maintaining, enforcing and defending intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical and biopharmaceutical industry involves technological and legal complexity, and obtaining and enforcing pharmaceutical and biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or their interpretation in China, the U.S. or other jurisdictions may increase the uncertainties and costs surrounding the prosecution of our patents, diminish our ability to protect our inventions, obtain, maintain, defend, and enforce our intellectual property rights and, more generally, affect the value of our intellectual property or narrow the scope of our patent rights.

In China, intellectual property laws are constantly evolving, with efforts being made to improve intellectual property protection in China. For example, a Draft Amendment to the PRC Patent Law (《專利法(修正案草案)》) was released in January 2019 and proposed to introduce patent extensions to eligible innovative drug patents. If adopted, patents owned by third parties may be extended, which may in turn affect our ability to commercialize our products without facing infringement risks. The adoption of this draft amendment may enable the patent owner to submit applications for a patent term extension. The length of any such extension is

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uncertain. If we are required to delay commercialization for an extended period of time, technological advances may develop and new products may be launched, which may in turn render our products non-competitive. We cannot guarantee that any other changes to PRC intellectual property laws would not have a negative impact on our intellectual property protection.

Recently enacted U.S. laws have changed the procedures through which patents may be obtained and by which the validity of patents may be challenged. For example, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the U.S., the first to invent the claimed invention was entitled to the patent, while outside the U.S., the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the U.S. transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications in the U.S. and the enforcement or defence of our issued patents, each of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recent U.S. Supreme Court rulings have also changed the law surrounding patent eligibility and narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights all of which could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future, as well as on our competitive position, business, financial conditions, results of operations and prospects.

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If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers, and we may be subject to claims asserting ownership of what we regard as our own intellectual property.

In addition to our issued patents and pending patent applications, we rely on trade secrets and confidential information, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our drug candidates. We seek to protect our trade secrets and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to trade secrets or confidential information, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties that have access to them. However, we may not be able to prevent the unauthorized disclosure or use of our trade secrets and confidential information by the parties to these agreements. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Any of the parties with whom we enter into confidentiality agreements may breach or violate the terms of any such agreements and may disclose our proprietary information, and we may not be able to obtain adequate remedies for any such breach or violation. As a result, we could lose our trade secrets and third parties could use our trade secrets to compete with our drug candidates and technology. Additionally, we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

Furthermore, many of our employees, consultants, and advisors, including our senior management, may currently be, or were previously employed at other pharmaceutical or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and advisors, including each member of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or be required to obtain licenses to such intellectual property rights, which may not be available on commercially reasonable terms or at all. An inability to incorporate such

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intellectual property rights would harm our business and may prevent us from successfully commercializing our drug candidates. In addition, we may lose personnel as a result of such claims and any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates and technology, which would have a material adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our employees and management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Furthermore, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of which may result in claims by or against us related to the ownership of such intellectual property to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have pre-existing or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending any of the foregoing claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar drug candidates or technology, without payment to us, or could limit the duration of the patent protection covering our drug candidates and technology. Such challenges may also result in our inability to develop, manufacture or commercialize our drug candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our owned or licensed patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

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If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could be required to pay monetary damages or could lose license rights that are important to our business.

We may in the future enter into license agreements with third parties providing us with rights to various third-party intellectual property, including rights in patents, patent applications and copyrights. These license agreements may impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our business. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favourable terms, or cause us to lose our rights under such agreements to important intellectual property or technology or our rights to develop and commercialize our drug candidates. In addition, such an event may cause us to experience significant delays in the development and commercialization of our drug candidates or incur liability for damages. If any such license is terminated, our competitors or other third parties could have the freedom to seek regulatory approval of, and to market, products and technologies identical or competitive to ours and we may be required to cease our development and commercialization of certain of our drug candidates.

In addition, we may need to obtain additional licenses from licensors and others to advance our research or allow commercialization of drug candidates we may develop. In connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties, including our competitors, to receive licenses to a portion of the intellectual property that is subject to our existing licenses and to compete with our drug candidates and technology. It is possible that we may be unable to obtain any additional licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign our drug candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected drug candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Disputes may arise regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensors' obligation to obtain, maintain and defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, drug candidates and processes infringe, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the license agreement;

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- the sublicensing of patent and other intellectual property rights under our license agreements;
- our diligence, financial or other obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are, and any such future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our diligence, financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed or any other dispute described above related to our license agreements prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build brand recognition in our markets of interest and our business may be adversely affected.

We currently own issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the registration or maintenance of the same. We cannot assure you that any currently pending trademark applications or any trademark applications we may file in the future will be approved. During trademark registration proceedings, we may receive rejections and although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and in proceedings before comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceeding may be filed against our trademarks and our trademarks may not survive such proceedings. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or engaging in conduct that constitutes unfair competition, defamation or other violation of our rights, our business could be materially adversely affected.

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Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Intellectual property rights do not necessarily protect us from all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to any drug candidates we may develop or utilize similar technology that are not covered by the claims of the patents that we own or license now or in the future;
- we, our licensors or current or future collaboration partners might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future;
- we, our licensors or current or future collaboration partners might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our owned or licensed intellectual property rights;
- it is possible that our pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- issued patents that we hold rights to may not provide us with a competitive advantage, or may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

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- our competitors or other third parties might conduct research and development activities in jurisdictions where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent for certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could materially adversely affect our competitive position, business, financial conditions, results of operations and prospects.

Risks Relating to Our Reliance on Third Parties

We work with various third parties to develop our drug candidates, such as those who help us conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected timelines, we may not be able to obtain regulatory approval for, or commercialize, our drug candidates, and our business could be materially harmed.

We have worked with and plan to continue to work with third-party CROs to monitor and manage data for our ongoing pre-clinical and clinical programs. Some of those third-party CROs are our connected persons upon the [REDACTED]. For further details on the services provided by our connected persons, please refer to the section headed “Connected Transactions” in this document. We work with these parties to execute our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our collaboration with the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCP, which are regulations and guidelines enforced by the NMPA, FDA, EMA and other comparable regulatory authorities for all of our drugs in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, FDA, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and non-clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they or our clinical investigators obtain is compromised due to failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and delays, which can materially influence our ability to meet our desired clinical development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business.

In addition, we have engaged, and will continue to engage, other third party advisors, consultants or service providers to give advices for trial design and handle certain logistics matters in clinical trials from time to time. In the past, we did not enter into written contracts with a portion of such third parties in relation to their services, of which the amount of relevant service fees was immaterial. Although we did not have any material disputes with these third parties, we may not be able to claim legal remedies if these third parties fail to perform their obligations in an appropriate and timely manner.

Our future revenues are dependent on our ability to work effectively with collaborators to develop our drug candidates, including to obtain regulatory approval. Our arrangements with collaborators will be critical to successfully bringing products to market and commercializing them. We rely on collaborators in various respects, including to undertake research and development programs and conduct clinical trials, manage or assist with the regulatory filings and approval process and to assist with our commercialization efforts. We do not control our collaborators; therefore, we cannot ensure that these third parties will adequately and timely perform all of their obligations to us. If they fail to complete the remaining studies successfully, or at all, it could delay, adversely affect or prevent regulatory approval. We cannot guarantee the satisfactory performance of any of our collaborators and if any of our collaborators breach or terminate their agreements with us, we may not be able to successfully commercialize the licensed product which could materially and adversely affect our business, financial condition, cash flows and results of operations.

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In addition, we will rely on third parties to perform certain specification tests on our drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on our Company until deficiencies are remedied.

We have entered into collaborations with our partners and may form or seek additional collaborations or strategic alliances or enter into additional licensing arrangements in the future. We may not realize any or all benefits of such alliances or licensing arrangements, and disputes may arise between us and our collaboration partners.

We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders or disrupt our management and business.

Our strategic collaboration with partners involves numerous risks. We may not achieve the revenue and cost synergies expected from the transaction. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Also, the synergies from our collaboration with partners may be offset by other costs incurred in the collaboration, increases in other expenses, operating losses or problems in the business unrelated to our collaboration. As a result, there can be no assurance that these synergies will be achieved.

We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our drug candidates as having the requisite potential to demonstrate safety and efficacy or commercial viability. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. For any drug candidates that we may seek to in-license from third parties, we may face significant competition from other pharmaceutical or biopharmaceutical companies with greater resources or capabilities than us, and any agreement that we do enter into may not result in the anticipated benefits.

Disputes may arise between us and our collaboration partners. Such disputes may cause delay or termination of the research, development or commercialization of our drug candidates, or may result in costly litigation or arbitration that diverts management attention and resources.

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Global markets are an important component of our growth strategy. We have retained rights for the development and commercialization of all of our drug candidates globally. Outside China, we intend to focus on opportunities in the U.S. and the EU, in particular. If we fail to obtain licenses or enter into collaboration arrangements with third parties in other markets, or if third-party collaborator is not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management’s attention from the acquisition or development of drug candidates;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- third parties obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our drug candidates;
- difficulty of ensuring that third-party partners do not infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of others;
- unexpected changes in or imposition of trade restrictions, such as tariffs, sanctions or other trade controls, and similar regulatory requirements;
- economic weakness, including inflation;
- compliance with tax, employment, immigration and labour laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labour unrest;
- failure of our employees and contracted third parties to comply with United States Department of the Treasury’s Office of Foreign Assets Control rules and regulations and the United States Foreign Corrupt Practices Act of 1977, as amended (“FCPA”); and
- business interruptions resulting from geopolitical actions, including war and acts of terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

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These and other risks may materially adversely affect our ability to procure equipment and raw material and to attain or sustain any future revenue from international markets.

We may rely on third parties to manufacture a portion of our drug candidates for clinical development and commercial sales. Our business could be harmed if those third parties fail to deliver sufficient quantities of product or fail to do so at acceptable quality levels or prices.

We currently use third parties for a small portion of our manufacturing process and for the clinical supply of our drug candidates, which is not expected to be a major undertaking in addition to owning and operating our in-house manufacturing facilities. Some of those third parties are our connected persons upon the [REDACTED]. For further details on the services provided by our connected persons, please refer to the section headed “Connected Transactions” in this document.

Reliance on third-party manufacturers would expose us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the NMPA, FDA, EMA or other comparable regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our drug candidates;
- our third-party manufacturers might be unable to timely manufacture our drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- manufacturers are subject to ongoing periodic unannounced inspection and other government regulations by the NMPA, FDA, EMA or other comparable regulatory authorities to ensure strict compliance with cGMP. We do not have control over third-party manufacturers’ compliance with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our drug candidates;
- manufacturers may not properly obtain, protect, maintain, defend or enforce our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- manufacturers may infringe, misappropriate, or otherwise violate the patent, trade secret, or other intellectual property rights of third parties;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and

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- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact commercialization of our future approved drug candidates.

We depend on a stable and adequate supply of quality materials, including reagents and consumables and R&D and manufacturing equipment, from our suppliers, and price increases or interruptions of such supply could have an adverse impact on our business.

Our business operations require a substantial amount of raw materials, such as reagents and consumables, as well as equipment and other materials needed for research and development as well as manufacturing purposes. During the Track Record Period, we relied on third parties to supply certain materials. We expect to continue to rely on third parties to supply such materials and equipment for the research, development, manufacturing and commercialization of our drug candidates. See "Business—Raw Materials and Suppliers."

Currently, the materials and equipment are supplied by multiple source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business. Any disruption in production or the inability of our suppliers to produce adequate quantities to meet our needs could impair our operations and the research and development of our drug candidates.

Moreover, we require a stable supply of materials for our drug candidates in the course of our research and development activities, and such needs are expected to increase significantly once we enter commercial production of drugs upon receipt of marketing approval, but there is no assurance that current suppliers have the capacity to meet our demand. Any significant delay in receiving such materials in the quantity and quality that we need could delay the completion of our clinical studies, regulatory approval of our drug candidates or our ability to timely meet market demand for our commercialized products, as applicable. Our suppliers may not be able to cater to our growing demands or may reduce or cease their supply of materials to us at any time.

We are also exposed to the possibility of increased costs, which we may not be able to pass on to customers and as a result, lower our profitability. In the event of significant price increases for such materials, we cannot assure you that we will be able to raise the prices of our products and services sufficiently to cover the increased costs. As a result, any significant price increase for our needed materials may have an adverse effect on our profitability. Additionally, although we have implemented quality inspection on the materials before using them in the manufacturing process, we cannot assure you that we will be able to identify all of the quality issues.

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In addition, we cannot assure you that these third parties will be able to maintain and renew all licenses, permits and approvals necessary for their operations or comply with all applicable laws and regulations. Failure to do so by them may lead to interruption in their business operations, which in turn may result in shortage of the materials and equipment supplied to us, and cause delays in clinical trials and regulatory filings, or recall of our products. The non-compliance of these third parties may also subject us to potential product liability claims, cause us to fail to comply with the continuing regulatory requirements, and incur significant costs to rectify such incidents of non-compliance, which may have a material and adverse effect on our business, financial condition and results of operation.

RISKS RELATING TO OUR OPERATIONS

We operate in a competitive industry and may fail to compete effectively.

The industry in which we operate is highly competitive and rapidly changing. Large multinational pharmaceutical companies, established biopharmaceutical companies, specialty pharmaceutical companies, universities and other research institutions have commercialized or are commercializing or pursuing the development of drugs for the treatment of autoimmune diseases, cancer, eye diseases or other indications for which we are developing our drug candidates. For example, our telitacicept faces competition in China and the U.S. of belimumab, a single-target BLYS therapy, which is the only FDA-approved biologic drug for the treatment of SLE, and of many pipeline products under different stages of development. We may not be able to successfully compete with these products.

Many of our competitors have substantially more developed commercial infrastructure, greater financial, technical and human resources as well as more drug candidates in late-stage clinical development than we do. Even if successfully developed and subsequently approved by the NMPA, FDA, EMA or other similar authorities, our drug candidates will still face competition based on safety and efficacy, the timing and scope of the regulatory approvals, the availability and cost of supply, sales and marketing capabilities, price, patent position and other factors. Our competitors may succeed in developing competing drugs and obtaining regulatory approvals before us or gain better acceptance for the same target markets as ours, which will undermine our competitive position. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome price competition and to be commercially successful. Disruptive technologies and medical breakthroughs may further intensify the competition and render our drug candidates obsolete or non-competitive.

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Any failure to obtain or renew certain approvals, licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations.

Pursuant to relevant laws and regulations, we are required to obtain, maintain and renew various approvals, licenses, permits and certificates from relevant authorities to operate our business. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities to take remedial actions, suspend our operations or bear fines and penalties which could materially and adversely affect our business, financial condition and results of operations. Furthermore, if the interpretation or implementation of existing laws and regulations changes or new regulations come into effect, we may be required to obtain any additional approvals, permits, licenses or certificates and we cannot assure you that we will be able to do so. Our failure to obtain the additional approvals, permits, licenses or certificates may restrict the conduct of our business, increase our costs, and in turn, adversely affect results of operations and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, suppliers and other contractors and consultants, could be subject to natural or man-made disasters or business interruptions. In addition, we partially rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by government shutdowns or funding withdrawals. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and could increase our costs and expenses. We partially rely on third-party manufacturers to produce and process supplies of our drugs and drug candidates. Our ability to obtain supplies of our drugs and drug candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of our drug candidates. Although we maintain property damage insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

The loss of any key members of our senior management team or our inability to attract and retain highly skilled scientists, clinical and sales personnel could adversely affect our business.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, as well as other key clinical and scientific personnel, and other employees and consultants. The loss of services of any of these individuals or one or more of our senior management could delay or prevent the successful development of our drug candidates.

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Although we have not historically experienced unique difficulties attracting and retaining qualified employees, we could experience such problems in the future. Competition for qualified employees in the biopharmaceutical industry is intense and the pool of qualified candidates is limited. We may not be able to retain the services of, or attract and retain experienced senior management or key clinical and scientific personnel in the future. The departure of one or more of our senior management or key clinical and scientific personnel, regardless of whether or not they join a competitor or form a competing company, may subject us to risks relating to replacing them in a timely manner or at all, which may disrupt our drug development progress and have a material and adverse effect on our business and results of operations. In addition, we will need to hire additional employees as we expand our commercialization team. We may not be able to attract and retain qualified employees on acceptable terms.

We have been, and in the future may be, involved in lawsuits or other legal proceedings, which could adversely affect our business, financial conditions, results of operations and reputation.

We have been, and in the future may be, involved in lawsuits or other legal proceedings arising in the ordinary course of business from time to time. For instance, in January 2019, Shanghai Sang Ni Environmental Engineering Co., Ltd. (上海桑尼環境工程有限公司) (“Sang Ni”) brought a claim against Shanghai Si Fang Electronic Air Condition Purifying Engineering Co., Ltd. (上海四方電子空調淨化工程有限公司) (“Si Fang”) and us and asserted that Si Fang failed to pay the project construction fee of RMB1.2 million to Sang Ni. We are the owner of the concerned construction projects, and Si Fang acted as our contractor of the construction projects and further outsourced certain part of the construction work to Sang Ni. As advised by our PRC Legal Advisor, our potential liability to Sang Ni is limited to the unpaid amount of construction fees under our contract with Si Fang. As of the Latest Practicable Date, we have fully paid the construction fees to Si Fang according to our contract. The case is still pending in the court as of the Latest Practicable Date. Litigation and governmental proceedings can be expensive, lengthy and disruptive to normal business operations, and can require extensive management attention and resources, regardless of their merit. While we currently intend to defend the aforementioned matters vigorously, we cannot predict the results of complex legal proceedings and an unfavorable resolution of a lawsuit or proceeding could have adverse impact on our business, results of operations, financial conditions and reputation.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading.

We may be exposed to fraud, bribery or other misconduct committed by our employees, principal investigators, consultants and commercial partners that could subject us to financial losses and sanctions imposed by governmental authorities, which may adversely affect our reputation. During the Track Record Period and up to the Latest Practicable Date, we were not aware of any instances of fraud, bribery, or other misconduct involving employees and other third parties that had any material and adverse impact on our business and results of operations.

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However, we cannot assure you that there will not be any such instances in future. Although we consider our internal control policies and procedures to be adequate, we may be unable to prevent, detect or deter all such instances of misconduct. Any such misconduct committed against our interests, which may include past acts that have gone undetected or future acts, may have a material adverse effect on our business and results of operations.

We are subject to the risks of doing business globally.

Because we operate in China and other countries, our business is subject to risks associated with doing business globally. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- changes in a specific country’s or region’s political and cultural climate or economic condition;
- unexpected changes in laws and regulatory requirements in local jurisdictions;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management’s attention from the acquisition or development of drug candidates or cause us to forgo profitable licensing opportunities in these geographies;
- the occurrence of economic weakness, including inflation or political instability;
- the burden of complying with a variety of foreign laws including difficulties in effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in certain jurisdictions;
- enforcement of anti-corruption and anti-bribery laws;
- trade-protection measures, import or export licensing requirements and fines, penalties or suspension or revocation of export privileges;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment;
- the effects of applicable local tax regimes and potentially adverse tax consequences; and
- significant adverse changes in local currency exchange rates.

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In addition, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability and changes in diplomatic and trade relationships, which could cause our results to fluctuate and our revenue to decline. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially and adversely affect our business and results of operations

If we fail to comply with anti-bribery laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to the anti-bribery laws of various jurisdictions. As our business has expanded, the applicability of the applicable anti-bribery laws to our operations has increased. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, such as the FCPA, or if any of the physicians or other providers or entities we do business with are found to be not in compliance with applicable laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

Product and professional liability claims or lawsuits against us could result in expensive and time-consuming litigation, payment of substantial damages and increases in our insurance rates.

We face an inherent risk of product and professional liability as a result of the clinical testing and any future commercialization of our drug candidates inside and outside China. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under applicable consumer protection laws. If we cannot successfully defend ourselves against or obtain indemnification from our collaborators for product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our drug candidates; injury to our reputation; withdrawal of clinical trial participants and inability to continue clinical trials; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management’s time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labelling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any approved drug candidate; and a decline in the market price of our H Shares.

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It is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired. Should any of these events occur, it could have a material adverse effect on our business, financial condition and results of operations.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

We are subject to laws and regulations governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials. Our operation involves the use of hazardous materials, including chemicals, and may produce hazardous waste products. We cannot eliminate the risks of contamination or personal injury from these materials.

We maintain work injury insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials. This insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability claims that may be asserted against us in connection with our storage or disposal of hazardous materials. In the event of contamination or personal injury resulting from our use of hazardous materials or our or third parties' disposal of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

We may incur substantial costs in order to comply with current or future laws and regulations on use of hazardous materials. These current or future laws and regulations may impair our research, development or production activities. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our internal information technology and other infrastructure, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our information technology systems and those of our current or future CROs, consultants and other service providers are vulnerable to damage from cyber attacks, computer viruses, malicious codes, unauthorized access, employee theft or misuse, natural disasters, fire, power loss, terrorism, war, and telecommunication and electrical failures, among other things. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research and development programs. For example, our data may not be backed up in a timely manner and the loss of clinical trial data from ongoing or future clinical trials for any of our drug candidates could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential

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or proprietary information, we could incur liability and the further development of our drug candidates could be delayed. In addition, a security breach may result in the loss of, damage to, or public disclosure of personally identifiable information, and such an event could have serious negative consequences, including disputes, regulatory action, investigation, litigation, fines, penalties and damages, and time-consuming and expensive litigation, any of which could have a material adverse effect on our business, financial conditions, results of operations, or prospects.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our Company or vendors that provide information systems, networks or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could have a material adverse impact on us and our business, including loss of data and damage to equipment, among other things. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification, system malfunction or intentional or accidental release or loss of information maintained in the information systems and networks of our Company and our vendors, including but not limited to personal information of our employees and patients, and company, vendor and the other users of our vendors' confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data or systems. The risk of a security breach or disruption, particularly through cyber attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, nor may we be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. We cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or those of our third-party vendors and other contractors and

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consultants, or other cyber incidents that could have a material adverse effect upon our reputation, business, results of operations, financial condition or prospects. If we experienced any such material system failure or security breach and interruptions in our operations, it could result in a material disruption of our development programs and our business operations, a breach of sensitive personal information or a loss or corruption of critical data assets including trade secrets or other proprietary information. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing and other cyber attacks. If a material breach of our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we engage in more electronic transactions with payers and patients and collect and store an increasing volume of data, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems.

We may not have adequate insurance coverage to compensate for any losses associated with a system failure, any breach of our computer systems or other cybersecurity attack or any violation of any privacy laws or other obligations. Any breach or failure of our or our vendors' computer systems, information technology and other infrastructure could materially adversely affect our business, financial condition, results of operations and prospects.

If we engage in acquisitions or strategic partnerships, this may increase our capital requirements, cause dilution to our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

From time to time, we may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any completed, in-process or potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent or unforeseen liabilities;

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- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses, and acquire intangible assets that could result in significant future amortization expense.

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (《關於外國投資者併購境內企業的規定》), or the M&A Rules, and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time-consuming and complex. For example, the M&A Rules require that the MOFCOM be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honoured brand. Moreover, according to the Anti-Monopoly Law of PRC (《反壟斷法》) and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (《關於經營者集中申報標準的規定》), or the “Prior Notification Rules” issued by the State Council, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the MOFCOM when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (《實施外國投資者併購境內企業安全審查制度的規定》), or the “Security Review Rules,” issued by the MOFCOM specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns, and

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mergers and acquisitions through which foreign investors may acquire the de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time-consuming, and any required approval and filing processes, including obtaining approval or filings from the MOFCOM or its local counterparts, may delay or inhibit our ability to complete such transactions. It is unclear whether our business would be deemed to be in an industry that raises “national defense and security” or “national security” concerns. However, the MOFCOM or other government agencies may publish explanations in the future determining that our business is in an industry subject to security review, in which case our future acquisitions in China, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could materially adversely affect the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including but not limited to the treatment and discharge of pollutants into the environment and the use of toxic and hazardous chemicals in the process of our business operations. In addition, our construction projects can only be put into operation after the relevant administrative authorities in charge of environmental protection and health and safety have examined and approved the relevant facilities in certain jurisdictions. We cannot assure you that we will be able to obtain all the regulatory approvals for our construction projects in a timely manner, or at all. Delays or failures in obtaining all the requisite regulatory approvals for our construction projects may affect our abilities to develop, manufacture and commercialize our pipeline products as we plan. As requirements imposed by such laws and regulations may change and more stringent laws or regulations may be adopted, we may not be able to comply with, or accurately predict any potential substantial cost of complying with, these laws and regulations. If we fail to comply with environmental protection, and health and safety laws and regulations, we may be subject to rectification orders, substantial fines, potentially significant monetary damages, or production suspensions in our business operations. As a result, any failure by us to control the use or discharge of hazardous substances could have a material and adverse impact on our business, financial condition, results of operations and prospects.

In addition, we cannot fully eliminate the risk of accidental contamination, biological or chemical hazards or personal injury at our facilities during the process of discovery, testing, development and manufacturing of biopharmaceuticals. In the event of such accident, we could be held liable for damages and clean-up costs which, to the extent not covered by existing insurance or indemnification, could harm our business. Other adverse effects could result from

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such liability, including reputational damage. We may also be forced to close or suspend operations at certain of our affected facilities temporarily, or permanently. As a result, any accidental contamination, biological or chemical hazards or personal injury could have a material and adverse impact on our business, financial condition, results of operations and prospects.

We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Any of the foregoing could materially adversely affect our business, financial condition, results of operations and prospects.

We have historically received government grants and subsidies for our research and development activities. Expiration of, or changes to, these incentives or policies or our failure to satisfy any condition for these incentives would have an adverse effect on our results of operations.

We have historically benefited from government grants as incentives for our research and development activities. We recorded government grants of RMB11.7 million, RMB33.5 million and RMB5.9 million for the years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, respectively. These government grants were generally in support of our research and development activities of our drugs on auto-immune diseases, oncology and ophthalmology. See “Financial Information—Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income Items—Other Income and Gains” for further details. Our government grants may vary from period to period going forward and our results of operations may be affected as a result. Our eligibility to receive these financial incentives requires that we continue to qualify for them. The incentives are subject to the discretion of the central government or relevant local government authorities, which could determine at any time to eliminate or reduce these financial incentives, generally with prospective effect. Since our receipt of the financial incentives is subject to periodic time lags and inconsistent government practice, as long as we continue to receive these financial incentives, our net income in a particular period may be higher or lower relative to other periods depending on the potential changes in these financial incentives in addition to any business or operational factors that we may otherwise experience. The discontinuation of financial incentives currently available to us could have a material adverse effect on our business, financial condition and results of operations.

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We invest substantial resources in research and development in order to develop, enhance or adapt to new technologies and methodologies, which we may not be able to do successfully.

The global biologics market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. For the years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, our research and development costs were RMB216.4 million, RMB352.1 million and RMB75.2 million, respectively. We must continue to invest significant amounts of human and capital resources to develop or acquire technologies that will allow us to enhance the scope and quality of our clinical trials. We intend to continue to enhance our technical capabilities in drug discovery, development and manufacturing, which are capital-and-time-intensive. We cannot assure you that we will be able to develop, enhance or adapt to new technologies and methodologies, successfully identify new technological opportunities, develop and bring new or enhanced products to market, obtain sufficient or any patent or other intellectual property protection for such new or enhanced products, or obtain the necessary regulatory approvals in a timely and cost-effective manner, or, if such products are introduced, that those products will achieve market acceptance. Any failure to do so may make our techniques obsolete, which could harm our business and prospects.

We have significantly increased the size and capabilities of our organization since our inception, and we may experience difficulties in managing our growth.

As our development and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, manufacturing, sales, marketing, financial and other personnel. Our recent growth and any future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and regulatory authority review process for our drug candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our drug candidates will depend, in part, on our ability to effectively manage our recent growth and any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

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If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop and commercialize our drug candidates and, accordingly, may not achieve our research, development and commercialization goals. Our failure to do so could materially adversely affect our business, financial condition, results of operations and prospects.

Increased labor costs could slow our growth and affect our operations.

Since our operations are labour-intensive and our operations, to a certain extent, require the use of technical skills and know-how of our employees, our success depends in part on our ability to attract, retain and motivate a sufficient number of qualified employees. We have implemented a number of initiatives in an effort to attract, retain and motivate our qualified and competent staff. There is no assurance that these measures will be effective or that supply of skilled labour in local markets will be sufficient to fulfil our needs. Competition for competent and skilled labour is intensive in the industry. Our failure to hire and retain enough skilled employees could delay the construction schedule of the works undertaken by us or result in our expenses exceeding our initial budget, either of which could have a material adverse effect on our business, profitability and prospects.

Further, substantially our entire workforce is employed in the PRC. The average labour cost in the PRC has been steadily increasing over the past years as a result of government-mandated wage increases and other changes in the PRC labour laws. Further changes in the labour laws, rules and regulations may be promulgated by the PRC government in the future and our operations may be materially and adversely affected if such laws, rules or regulations impose additional burden on the employers. The labour cost will continue to increase in the future which is in line with the economic growth in the PRC. Competition for employees would require us to pay higher wages, which would result in higher labour costs.

We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control.

Natural disasters, acts of war or terrorism or other factors beyond our control may adversely affect the economy, infrastructure and livelihood of the people in the regions where we conduct our business. Our operations may be under the threat of natural disasters such as floods, earthquakes, sandstorms, snowstorms, fire or drought, the outbreak of a widespread health epidemic, such as swine flu, avian influenza, severe acute respiratory syndrome, or SARS, Ebola, Zika, COVID-19, or other events, such as power, water or fuel shortages, failures, malfunction and breakdown of information management systems, unexpected maintenance or technical problems, or are susceptible to potential wars or terrorist attacks.

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The occurrence of a disaster or a prolonged outbreak of an epidemic illness or other adverse public health developments in China or elsewhere in the world could materially disrupt our business and operations. For example, the recent outbreak of COVID-19 has sickened and killed many people in and outside of China, caused temporary suspension of productions and shortage of labor and raw materials in affected regions, and disrupted local and international travel and economy. The exacerbation, continuance or reoccurrence of COVID-19 has already caused and may continue to cause an adverse and prolonged impact on the economy and social conditions in China and other affected countries. The existing clinical trials and the commencement of new clinical trials could be substantially delayed or prevented by any delay or failure in patient recruitment or enrollment in our or our collaborators’ trials as a result of the outbreak of COVID-19. These factors could cause delay of clinical trials, regulatory submissions, and required approvals of our drug candidates, and could cause us to incur additional costs. If our employees or employees of our business partners are suspected of being infected with an epidemic disease, our operations may be disrupted because we or our business partners must quarantine some or all of the affected employees or disinfect the operating facilities. If we are not able to effectively develop and commercialize our drug candidates as a result of protracted clinical trials of enrolled patients, elevated public health safety measures, and/or failure to recruit and conduct patient follow-up, we may not be able to generate revenue from sales of our drug candidates as planned.

Serious natural disasters may result in loss of lives, injury, destruction of assets and disruption of our business and operations. Acts of war or terrorism may also injure our employees, cause loss of lives, disrupt our business network and destroy our markets. Any of these factors and other factors beyond our control could have an adverse effect on the overall business sentiment and environment, cause uncertainties in the regions where we conduct business, cause our business to suffer in ways that we cannot predict and materially and adversely impact our business, financial conditions and results of operations.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain insurance policies that are required under the PRC laws and regulations as well as based on our assessment of our operational needs and industry practice, including insurance for our new facilities. In line with industry practice in the PRC, we have elected not to maintain certain types of insurance, such as business interruption insurance or key man insurance. Our insurance coverage may be insufficient to cover any claims that we may have. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources and may negatively impact our drug development and overall operations.

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Any failure to comply with the PRC regulations regarding mandatory social insurance may subject us to fines and other legal or administrative sanctions.

According to the Social Insurance Law implemented on July 1, 2011 and other applicable PRC regulations, any employer operating in China must open social insurance registration accounts and contribute social insurance premium for its employees. Any failure to open social insurance registration account may trigger an order of correction where correction is not made within a specified period of time, the competent authority may further impose fines. Any failure to make timely and adequate contribution of social insurance premium for its employees may trigger an order of correction from competent authority requiring the employer to make up the full contribution of such overdue social insurance premium within a specified period of time, and the competent authority may further impose fines or penalties. During the Track Record Period, we didn't make timely and adequate contribution of social insurance premium involving an immaterial amount which will not bring any material adverse effect affecting our operations. As of the Latest Practicable Date, we have not received any order of correction or any fines or penalties from the competent authority as a result of any such failure. However, we cannot assure you that the competent authority will not require us to rectify any non-compliance by making contribution of overdue social insurance premium or to pay any overdue fine or penalty related thereto.

We are subject to risks associated with leasing space.

We lease our some of our offices in China. The lessors of the leased properties may not have valid title or have the legal rights to such leased properties or may not have complied with all the necessary procedures. In addition as our leases expire, we may fail to negotiate renewals, either on commercially acceptable terms or at all, which could require us to close such offices or manufacturing facilities. Our inability to enter into new leases or renew existing leases on terms acceptable to us could materially and adversely affect our business, results of operations or financial condition.

Pursuant to PRC law, both lessors and lessees are required to file the lease agreements for registration and obtain property leasing filing certificates for their leases. However, as of the Latest Practicable Date, because the lessors failed or are reluctant to provide necessary documents for us to register the leases, a few of the lessors of the premises under which our operated our branch offices had not obtained such registrations. The failure to register lease agreements as required under PRC law may subject to a fine for non-registration which may range from RMB1,000 to RMB10,000 for each non-registration agreement, which may negatively affect our ability to operate our business covered under those leases.

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Our property valuation is based on certain assumptions which, by their nature, are subjective and uncertain and may differ from actual results.

The property valuation report prepared by JLL, an independent property valuer, set out in the Property Valuation Report set out as Appendix III to this Document with respect to the appraised values of our properties is based on various assumptions, which are subjective and uncertain in nature. The assumptions that JLL used in the property valuation report include that the seller sells the property interest in the market without the benefit of a deferred term contract, leaseback, joint venture, management agreement or any similar arrangement, which could serve to affect the value of the property interest. Certain of the assumptions used by JLL in reaching the appraised value of our properties may be inaccurate or unreasonable. In addition, unforeseeable changes in general and local economic conditions or other factors beyond our control may affect the value of our properties. As a result, the appraised value of our properties may differ materially from the price we could receive in an actual sale of the properties in the market and should not be taken as their actual realizable value or an estimation of their realizable value. You should not place undue reliance on such values attributable to these properties as appraised by JLL.

Negative publicity and allegations involving us, our Shareholders, Directors, officers, employees and business partners may affect our reputation and may, as a result, negatively affect our business, financial condition and results of operations.

We, our Shareholders, Directors, officers, employees and business partners may be subject to negative media coverage and publicity from time to time. Such negative coverage in the media and publicity could threaten the perception of our reputation. In addition, to the extent our Shareholders, Directors, officers, employees and business partners were in compliance with any laws or regulations or became involved in lawsuits, disputes, or other legal proceedings or became subject to administrative measures, penalties or investigations by regulatory authorities, we may also suffer negative publicity or harm to our reputation. As a result, we may be required to spend significant time and incur substantial costs in response to allegations and negative publicity, and may not be able to diffuse them to the satisfaction of our investors and customers.

We are subject to registration or other requirements of government in China for cross-border sales or licensing of technology.

China imposes controls on the import and export of technology and software products. Under the Regulations on Administration of Import and Export of Technologies (《技術進出口管理條例》) promulgated by the State Council, which were amended in March 2019, the term “technology import and export” is defined to include, among other things, the transfer or licensing of patents and know-how, and the provision of services related to technology. Depending on the nature of the relevant technology, the import and export of technology require either approval by or registration with the relevant PRC governmental authorities. The Measures for the Administration of Registration of Technology Import and Export Contracts (《技術進出口合同登記管理辦法》), issued by the MOFCOM in February 2009, specify registration requirements related to the import and export of technology.

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We have entered into several agreements with a pre-clinical CRO for their technical support to assist us in the establishment of our ADC platforms and in connection with the development of individual drug candidates, which may be deemed to constitute the import of technology under the regulations. As a result, such transfers are required to be registered with applicable PRC governmental authorities. Although there are no explicit penalties set forth in these regulations for lack of such registration, failure to register an agreement where such registration is required may result in restrictions concerning foreign exchange, banking and taxation matters relating to such agreements. We have not registered our technology transfer agreements, and so far we have not encountered any problems with respect to foreign exchange, banking or taxation matters relating to our technology transfer agreements, nor have us received any notice from any governmental authority requiring us to complete the registration of the technology transfer agreements.

RISKS RELATING TO OUR DOING BUSINESS IN CHINA

The pharmaceutical industry in China is highly regulated and such regulations are subject to change, which may affect approval and commercialization of our drug candidates.

Our research operations and manufacturing facilities are in China, which we believe confers clinical, commercial and regulatory advantages. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. See “Regulatory Overview” for a discussion of regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our drug candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. PRC authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. We believe our strategy and approach are consistent with the PRC government’s policies, but we cannot ensure that our strategy and approach will continue to be consistent.

Changes in the political and economic policies of the Chinese government may materially adversely affect our business, financial condition, results of operations and prospects and may result in our inability to sustain our growth and expansion strategies.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China. China’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources.

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While the PRC economy has experienced significant growth over the past 40 years, growth has been uneven across different regions and among various economic sectors of China. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operation. More generally, if the business environment in China deteriorates from the perspective of domestic or international investment, our business in China may also be adversely affected.

There are uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations.

Substantially all of our operations are conducted in China through our PRC entities, and are governed by PRC laws, rules and regulations. Our PRC entities are subject to laws, rules and regulations applicable to foreign investment in China. The PRC legal system is a civil law system based on written statutes. Unlike the common law system, prior court decisions may be cited for reference but have limited precedential value.

In 1979, the PRC government began to promulgate a comprehensive system of laws, rules and regulations governing economic matters in general. The overall effect of legislation over the past four decades has significantly enhanced the protections afforded to various forms of foreign investment in China. However, China has not developed a fully integrated legal system, and recently enacted laws, rules and regulations may not sufficiently cover all aspects of economic activities in China or may be subject to significant degrees of interpretation by PRC regulatory agencies. In particular, because these laws, rules and regulations are relatively new and often give the relevant regulator significant discretion in how to enforce them, and because of the limited number of published decisions and the nonbinding nature of such decisions, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent and unpredictable. In addition, the PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

Additionally, the NMPA's recent reform of the drug-approval system may face implementation challenges. The timing and full impact of such reforms is uncertain and could prevent us from commercializing our drug candidates in a timely manner.

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome

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of administrative and court proceedings and the level of legal protection we enjoy than we would in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operations.

We may be restricted from transferring our scientific data abroad.

On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (《科學數據管理辦法》) (the “Scientific Data Measures”), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in China must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Further, any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given the term “state secret” is not clearly defined, we cannot assure you that we can always obtain relevant approvals for sending scientific data (such as the results of our pre-clinical studies or clinical trials conducted within China) abroad or to our foreign partners in China. If we are unable to obtain necessary approvals in a timely manner, or at all, our research and development of drug candidates may be hindered, which may materially and adversely affect our business, results of operations, financial conditions and prospects. If the relevant government authorities consider the transmission of our scientific data to be in violation of the requirements under the Scientific Data Measures, we may be subject to fines and other administrative penalties imposed by those government authorities.

The relationships between China and other countries may affect our business operations.

We may pursue partnerships with entities in foreign countries and regions, in particular in the U.S. and the EU, and establishing new collaboration partnerships is key to our future growth. In the event that China and/or the countries from which we import raw materials impose import tariffs, trade restrictions or other trade barriers affecting the importation of such components or raw materials, we may not be able to obtain a steady supply of necessary components or raw materials at competitive prices, and our business and operations may be materially and adversely affected. We may also sell a portion of our products to certain foreign countries in the future. Our business is therefore subject to constantly changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. It is notably that the U.S. government has recently made significant changes in its trade policy and has taken certain actions that may materially impact international trade, such as announcing import tariffs which have led to other countries, including China and members of EU, imposing tariffs against the U.S. in response. Also see “Risk Factors—Risks Relating to Extensive Government Regulations—Changes in U.S. and international trade policies, particularly with regard to China, may adversely impact our business and operating results.” These trade wars may escalate going forward and may result in certain types of goods, such as advanced R&D equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to export. Furthermore, there can be no

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assurance that our existing or potential service providers or collaboration partners will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between China and the relevant foreign countries or regions. Tensions and political concerns between China and the relevant foreign countries or regions may therefore adversely affect our business, financial condition, results of operations, cash flows and prospects.

We and our Shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company. Gains on the sales of H Shares and dividends on the H Shares may be subject to PRC income taxes.

Pursuant to the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7, an “indirect transfer” of “PRC taxable assets,” including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be re-characterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC EIT. As a result, gains derived from such indirect transfer may be subject to PRC EIT. When determining whether there is a “reasonable commercial purpose” of the transaction arrangement, factors to be taken into consideration include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consists of direct or indirect investment in China or if its income mainly derives from China; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. In respect of an indirect offshore transfer of assets of a PRC establishment, the resulting gain is to be reported on with the EIT filing of the PRC establishment or place of business being transferred, and would consequently be subject to PRC EIT at a rate of 25%. Where the underlying transfer relates to equity investments in a PRC resident enterprise, which is not related to a PRC establishment or place of business of a non-resident enterprise, a PRC EIT at the rate of 10% would apply, subject to available preferential tax treatment under applicable tax treaties or similar arrangements. Late payment of applicable tax will subject the transferor to default interest. Gains derived from the sale of shares by investors through a public stock exchange are not subject to the PRC EIT pursuant to Bulletin 7 where such shares were acquired in a transaction through a public stock exchange. As such, the sale of the Shares on a public stock exchange will not be subject to PRC EIT pursuant to Bulletin 7. However, the sale of our H Shares by a non-PRC resident enterprise outside a public stock exchange may be subject to PRC EIT under Bulletin 7.

There are uncertainties as to the application of Bulletin 7. Bulletin 7 may be determined by the tax authorities to be applicable to sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries

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may be requested to assist in the filing. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with Bulletin 7 or to establish that we and our non-resident enterprises should not be taxed under Bulletin 7, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial condition and results of operations.

The PRC tax authorities have the discretion under Bulletin 7 to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under the Announcement of the State Administration of Taxation—Announcement on Issues Concerning the Withholding of Enterprise Income Tax at Source on Non-Resident Enterprises, or Bulletin 37, or under Bulletin 7, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

Governmental control of currency conversion, and restrictions on the remittance of Renminbi into and out of China, may adversely affect the value of your investment.

The Renminbi is not currently a freely convertible currency, as the PRC Government imposes controls on the convertibility of Renminbi into foreign currencies and in certain cases, the remittance of currency out of China. A substantial majority of our future revenue is expected to be denominated in Renminbi and we will need to convert Renminbi into foreign currencies for the payment of dividends, if any, to holders of our H Shares. Shortages in the availability of foreign currency may restrict our ability to remit sufficient foreign currency to pay dividends or other payments, or otherwise satisfy our foreign currency denominated obligations.

Under China’s current foreign exchange control system, foreign exchange transactions under the current account conducted by us, including the payment of dividends, do not require advance approval from SAFE, but we are required to present relevant documentary evidence of such transactions and conduct such transactions at designated foreign exchange banks within China that have the licenses to carry out foreign exchange business. Approval from appropriate government authorities is required where Renminbi is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of loans denominated in foreign currencies. The PRC Government may also at its discretion restrict access in the future to foreign currencies for current account transactions. Since 2015, in response to China’s declining foreign currency reserves, the PRC Government has placed increasingly stringent restrictions on the convertibility of the Renminbi into foreign currencies. If the foreign exchange control system prevents us from obtaining sufficient foreign currencies to satisfy our foreign currency demands, we may not be able to pay dividends in foreign currencies to our Shareholders. Further, there is no assurance that new regulations will not be promulgated in the future that would have the effect of further restricting the remittance of Renminbi into or out of China.

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You may experience difficulties in effecting service of legal process, enforcing foreign judgments or bringing original actions in China against us or our management named in the documents based on Hong Kong or other foreign laws.

We are incorporated under the laws of the PRC, and substantially all of our assets are located in the PRC. In addition, a majority of our Directors, Supervisors and senior management personnel reside within the PRC, and substantially all of their assets are located within the PRC. As a result, it may not be possible for investors to effect service of process upon us or our Directors, Supervisors and senior management personnel in China. China has not entered into treaties or arrangements providing for the recognition and enforcement of judgments made by courts of most other jurisdictions.

In July 2006, the Supreme People’s Court of the PRC and the government of Hong Kong Special Administrative Region entered into the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region Pursuant to Choice of Court Agreements between Parties Concerned (《關於內地與香港特別行政區法院相互認可和執行當事人協議管轄的民商事案件判決的安排》) (the “Arrangement”). Under the Arrangement, where any designated PRC court or any designated Hong Kong court has made an enforceable final judgment requiring payment of money in a civil or commercial case under a choice of court agreement in writing, any party concerned may apply to the relevant PRC court or Hong Kong court for recognition and enforcement of the judgment. A choice of court agreement in writing is defined as any agreement in writing entered into between parties after the effective date of the Arrangement in which a Hong Kong court or a PRC court is expressly selected as the court having sole jurisdiction for the dispute. Therefore, it is not possible to enforce a judgment rendered by a Hong Kong court in the PRC if the parties in dispute have not agreed to enter into a choice of court agreement in writing. Although the Arrangement became effective in August 2008, the outcome and effectiveness of any action brought under the Arrangement remain uncertain. As a result, it may be difficult or impossible for investors to effect service of process against certain of our assets or Directors in China in order to seek recognition and enforcement of foreign judgments in China.

RISKS RELATING TO THE [REDACTED]

No public market currently exists for our H Shares, and an active trading market for our H Shares may not develop and the market price for our H Shares may decline or become volatile.

No public market currently exists for our H Shares. The initial [REDACTED] for our H Shares to the public will be the result of negotiations between our Company and the [REDACTED] (for themselves and on behalf of the [REDACTED]) and the [REDACTED] may differ significantly from the market price of the Shares following the [REDACTED]. We have applied for [REDACTED] of and permission to deal in our [REDACTED] on the Stock Exchange. A [REDACTED] on the Stock Exchange, however, does not guarantee that an active and liquid trading market for the Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the market price of the Shares will not decline following the [REDACTED].

RISK FACTORS

The price and trading volume of our H Shares may be volatile, which could lead to substantial losses to investors.

The price and trading volume of our H Shares may be subject to significant volatility in response to various factors beyond our control, including the general market conditions of the securities in Hong Kong and elsewhere in the world. In particular, the business and performance and the market price of the shares of other companies engaging in similar business may affect the price and trading volume of our H Shares. In addition to market and industry factors, the price and trading volume of our H Shares may be highly volatile for specific business reasons, such as the results of clinical trials of our drug candidates, the results of our applications for approval of our drug candidates, regulatory developments affecting the pharmaceutical industry, healthcare, health insurance and other related matters, fluctuations in our revenue, earnings, cash flows, investments and expenditures, relationships with our suppliers, movements or activities of key personnel or actions taken by competitors. Moreover, shares of other companies listed on the Stock Exchange with significant operations and assets in China have experienced price volatility in the past, and it is possible that our H Shares may be subject to changes in price not directly related to our performance.

There will be a gap of several days between pricing and trading of our H Shares, and the price of our H Shares when trading begins could be lower than the [REDACTED].

The [REDACTED] to the public of our H Shares sold in the public market is expected to be determined on the [REDACTED]. However, the Shares will not commence trading on the Hong Kong Stock Exchange until they are delivered, which is expected to be not more than five Business Days after the [REDACTED]. As a result, investors may not be able to sell or otherwise deal in the Shares during that period. Accordingly, holders of our H Shares are subject to the risk that the price of the Shares when trading begins could be lower than the indicative [REDACTED] range as a result of adverse market conditions or other adverse developments that may occur between the time of sale and the time trading begins.

Future sales or perceived sales of our H Shares in the public market by major Shareholders following the [REDACTED] could materially adversely affect the price of our H Shares.

Prior to the [REDACTED], there has not been a public market for our H Shares. Future sales or perceived sales by our existing Shareholders of our H Shares after the [REDACTED] could result in a significant decrease in the prevailing market price of our H Shares. Only a limited number of the Shares currently outstanding will be available for sale or issuance immediately after the [REDACTED] due to contractual and regulatory restrictions on disposal and new issuance. Nevertheless, after these restrictions lapse or if they are waived, future sales of significant amounts of our H Shares in the public market or the perception that these sales may occur could significantly decrease the prevailing market price of our H Shares and our ability to raise equity capital in the future.

In addition, our Unlisted Shares may be converted into H Shares subject to regulatory approvals and compliance with relevant regulatory requirements. Any conversion of our Unlisted Shares will increase the number of H Shares available on the market and may affect the trading price of our H Shares.

RISK FACTORS

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our H Shares. For example, in order to expand our business, we may consider to conduct the offering and listing of A shares at an appropriate time after the [REDACTED]. For details, please refer to the paragraph headed “History—The A Share Listing.” Issuance of additional Shares, or the possibility of such issuance, may cause dilution to our shareholders if we issue additional Shares at a price which is lower than the net tangible asset value per Share prior to the issuance of such additional Shares, and may cause the market price of our H Shares to decline. In addition, the incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavourable terms, including relinquishing or licensing to a third party on unfavourable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favourable terms.

Because we do not expect to pay dividends in the foreseeable future after the [REDACTED], you must rely on price appreciation of our H Shares for a return on your investment.

We currently intend to retain most, if not all, of our available funds and any future earnings after the [REDACTED] to fund the development and commercialization of our pipeline drug candidates. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in our H Shares as a source for any future dividend income.

Our Board has complete discretion as to whether to distribute dividends. Even if our Board decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions (if any) received by us from our subsidiaries, our financial condition, contractual restrictions and other factors deemed relevant by our Board. Accordingly, the return on your investment in our H Shares will likely depend entirely upon any future price appreciation of our H Shares. There is no guarantee that our H Shares will appreciate in value after the [REDACTED] or even maintain the price at which you purchased the Shares. You may not realize a return on your investment in our H Shares and you may even lose your entire investment in our H Shares.

RISK FACTORS

We have significant discretion as to how we will use the net [REDACTED] of the [REDACTED], and you may not necessarily agree with how we use them.

Our management may spend the net [REDACTED] from the [REDACTED] in ways with which you may not agree or which do not yield a favourable return to our shareholders. We plan to use the net [REDACTED] from the [REDACTED] for clinical development and commercialization of our products, for the commercial-scale manufacturing of our drug candidates and the construction of our manufacturing facility, to repay borrowings from RC Pharma, and for our general corporate and working capital purposes. For details, please see “Future Plans and Use of [REDACTED] – Use of [REDACTED]”.

However, our management will have discretion as to the actual application of our net [REDACTED]. You are entrusting your funds to our management, whose judgment you must depend on, for the specific uses we will make of the net [REDACTED] from this [REDACTED].

Facts, forecasts and statistics in this Document relating to the pharmaceutical industry may not be fully reliable.

Facts, forecasts and statistics in this Document relating to the pharmaceutical industry in and outside China are obtained from various sources that we believe are reliable, including official government publications as well as a report prepared by Frost & Sullivan that we commissioned. However, we cannot guarantee the quality or reliability of these sources. Neither we, the [REDACTED] nor our or their respective affiliates or advisors have verified the facts, forecasts and statistics nor ascertained the underlying economic assumptions relied upon in those facts, forecasts and statistics obtained from these sources. Due to possibly flawed or ineffective collection methods or discrepancies between published information and factual information and other problems, the industry statistics in this Document may be inaccurate and you should not place undue reliance on it. We make no representation as to the accuracy of such facts, forecasts and statistics obtained from various sources. Moreover, these facts, forecasts and statistics involve risk and uncertainties and are subject to change based on various factors and should not be unduly relied upon.

You should read the entire document carefully, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding us or the [REDACTED].

Subsequent to the date of this Document but prior to the completion of the [REDACTED], there may be press and media coverage regarding us and the [REDACTED], which may contain, among other things, certain financial information, projections, valuations and other forward-looking information about us and the [REDACTED]. We have not authorized the disclosure of any such information in the press or media and do not accept responsibility for the accuracy or completeness of such press articles or other media coverage. We make no representation as to the appropriateness, accuracy, completeness or reliability of any of the projections, valuations or other forward-looking information about us. To the extent such statements are inconsistent with, or conflict with, the information contained in this document, we disclaim responsibility for them. Accordingly, prospective investors are cautioned to make their investment decisions on the basis of the information contained in this document only and should not rely on any other information.

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTIONS FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

In preparation for the [REDACTED], our Company has sought [and has been granted] the following waivers from strict compliance with the relevant provisions of the Listing Rules and the following exemptions from compliance with the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

WAIVER IN RELATION TO MANAGEMENT PRESENCE IN HONG KONG

Pursuant to Rule 8.12 and Rule 19A.15 of the Listing Rules, we must have a sufficient management presence in Hong Kong. This normally means that at least two of our executive Directors must be ordinarily resident in Hong Kong.

Our management, business operations and assets are primarily located outside Hong Kong. The principal management headquarters of our Group are primarily based in the PRC. Our Company considers that our Group’s management is best able to attend to its functions by being based in the PRC. None of our executive Directors is or will be ordinarily resident in Hong Kong after the [REDACTED] of our Company. Our Directors consider that relocation of our executive Directors to Hong Kong will be burdensome and costly for our Company, and it may not be in the best interests of our Company and our Shareholders as a whole to appoint additional executive Directors who are ordinarily resident in Hong Kong. As such, we do not have, and for the foreseeable future will not have, sufficient management presence in Hong Kong for the purpose of satisfying the requirements under Rule 8.12 and Rule 19A. 15 of the Listing Rules.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, a waiver from strict compliance with the requirements under Rule 8.12 and Rule 19A.15 of the Listing Rules, provided that our Company implements the following arrangements:

- (1) We have appointed two authorized representatives pursuant to Rule 3.05 of the Listing Rules, who will act as our principal channel of communication with the Stock Exchange. The two authorized representatives appointed are Dr. Fang and Ms. Tam Pak Yu, Vivien. Ms. Tam Pak Yu, Vivien is situated and based in Hong Kong. Each of our authorized representatives will be available to meet with the Stock Exchange in Hong Kong within a reasonable time frame upon the request of the Stock Exchange and will be readily contactable by telephone, facsimile and email;
- (2) As and when the Stock Exchange wishes to contact our Directors on any matters, each of our authorized representatives has the means to contact all of our Directors (including the independent non-executive Directors) promptly at all times;

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTIONS FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

- (3) Although our executive Directors are not ordinary residents in Hong Kong, each of our Directors possesses or can apply for valid travel documents to visit Hong Kong and is able to meet with the Stock Exchange within a reasonable period of time, when required;
- (4) We have appointed Rainbow Capital (HK) Limited as our compliance advisor, pursuant to Rule 3A.19 of the Listing Rules, who will have access at all times to our authorized representatives, Directors and senior management, and will act as an additional channel of communication between the Stock Exchange and us; and
- (5) We have provided the Stock Exchange with the contact details of each Director (including their respective mobile phone number, office phone number and e-mail address).

Our Company will inform the Stock Exchange as soon as practicable in respect of any change in the authorized representatives, the Directors and/or the compliance advisor in accordance with the Listing Rules.

WAIVER IN RESPECT OF JOINT COMPANY SECRETARIES

Pursuant to Rule 8.17 of the Listing Rules, an issuer must appoint a company secretary who satisfies the requirements under Rule 3.28 of the Listing Rules. According to Rule 3.28 of the Listing Rules, we must appoint an individual as the company secretary of our Company who, by virtue of his or her academic or professional qualifications or relevant experience, is, in the opinion of the Stock Exchange, capable of discharging the functions of company secretary.

Note 1 to Rule 3.28 of the Listing Rules provides that the Stock Exchange considers that the following academic or professional qualifications to be acceptable:

- (a) a member of The Hong Kong Institute of Chartered Secretaries;
- (b) a solicitor or barrister (as defined in the Legal Practitioners Ordinance); or
- (c) a certified public accountant (as defined in the Professional Accountants Ordinance).

Note 2 to Rule 3.28 of the Listing Rules provides that in assessing "relevant experience", the Stock Exchange will consider the individual's:

- (a) length of employment with the Company and other listed companies and the roles he/she played;
- (b) familiarity with the Listing Rules and other relevant law and regulations including the Securities and Futures Ordinance, the Companies Ordinance, the Companies (Winding Up and Miscellaneous Provisions) Ordinance and the Takeovers Code;

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTIONS FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

- (c) relevant training taken and/or to be taken in addition to the minimum requirement of taking not less than fifteen hours of relevant professional training in each financial year under Rule 3.29 of the Listing Rules; and
- (d) professional qualifications in other jurisdictions.

We have appointed Mr. Li Jia and Ms. Tam Pak Yu, Vivien as the joint company secretaries of our Company on May 11, 2020. Ms. Tam Pak Yu, Vivien is an associate member of both The Hong Kong Institute of Chartered Secretaries and Chartered Governance Institute, and therefore meets the qualification requirements under Note 1 to Rule 3.28 of the Listing Rules and is in compliance with Rule 8.17 of the Listing Rules. Mr. Li Jia, however, does not possess the qualifications set out in Rule 3.28 of the Listing Rules. We believe that Mr. Li Jia, by virtue of his knowledge and experience in handling financial management and corporate development matters, is capable of discharging his functions as a joint company secretary. We therefore believe that it would be the best interests of our Company and of the corporate governance of our Group to appoint Mr. Li Jia as a joint company secretary. For more details of Mr. Li Jia and Ms. Tam Pak Yu, Vivien’s biographical information, please refer to the paragraph headed “Directors and Senior Management – Senior Management” in this document.

Accordingly, we have applied to the Stock Exchange for, and the Stock Exchange has [granted] us, a waiver from strict compliance with the requirements under Rules 3.28 and 8.17 of the Listing Rules. The waiver is valid for an initial period of three years from the [REDACTED] and is [granted] on the condition that we engage Ms. Tam Pak Yu, Vivien, who possesses all the requisite qualifications required under Rule 3.28 of the Listing Rules, to assist Mr. Li Jia in his discharge of duties as a joint company secretary and in gaining the “relevant experience” as is required of a company secretary under Note 2 to Rule 3.28 of the Listing Rules. Prior to the expiry of the three-year period, the qualifications and experience of Mr. Li Jia and the need for on-going assistance of Ms. Tam Pak Yu, Vivien will be further evaluated by us. We will liaise with the Stock Exchange to enable it to assess whether Mr. Li Jia, having benefited from the assistance of Ms. Tam Pak Yu, Vivien for the preceding three years, will have acquired the skills necessary to carry out the duties of a company secretary and the relevant experience within the meaning of Rule 3.28 Note 2 of the Listing Rules so that a further waiver will not be necessary.

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTIONS FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

WAIVER IN RELATION TO EXEMPTION FROM COMPLIANCE WITH PARAGRAPH 27 OF PART I AND PARAGRAPH 31 OF PART II OF THE THIRD SCHEDULE TO THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

Section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires all prospectuses to include matters specified in Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and set out the reports specified in Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance.

Paragraph 27 of Part I of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance requires a company to include in its prospectus a statement as to the gross trading income or sales turnover (as the case may be) of the company during each of the three financial years immediately preceding the issue of the prospectus, including an explanation of the method used for the computation of such income or turnover and a reasonable breakdown between the more important trading activities.

Paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance further requires the company to include in its prospectus a report by the auditors of the company with respect to (i) the profits and losses of the company and (ii) the assets and liabilities of the company for each of the three financial years immediately preceding the issue of the prospectus.

Section 342A(1) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance provides that the SFC may issue, subject to such conditions (if any) as the SFC thinks fit, a certificate of exemption from the compliance with the relevant requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance if, having regard to the circumstances, the SFC considers that the exemption will not prejudice the interests of the investing public and compliance with any or all of such requirements would be irrelevant or unduly burdensome, or would otherwise be unnecessary or inappropriate.

Rule 4.04(1) of the Listing Rules requires that the consolidated results of the Group in respect of each of the three financial years immediately preceding the issue of the document be included in the accountants’ report to this document.

Rule 18A.03(3) of the Listing Rules requires that a Biotech Company must have been in operation in its current line of business for at least two financial years prior to listing under substantially the same management. Rule 18A.06 of the Listing Rules requires that a Biotech Company must comply with Rule 4.04 of the Listing Rules modified so that references to “three financial years” or “three years” in Rule 4.04 shall instead reference to “two financial years” or “two years”, as the case may be.

We are a commercial-ready biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics for the treatment of autoimmune, oncology and ophthalmic diseases with unmet medical needs in China and globally.

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTIONS FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

In compliance with the abovementioned requirements under the Listing Rules, the accountants’ report of our Company set out in Appendix I to this document is prepared to cover the two financial years ended December 31, 2019, and the three months ended March 31, 2020.

As such, the Joint Sponsors have applied on behalf of our Company to the SFC for a certificate of exemption from strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance regarding the inclusion of the accountants’ report covering the full three financial years immediately preceding the issue of this document on the following grounds:

- (a) Our Company is primarily engaged in the research and development, application and commercialization of biotech products, and falls within the scope of biotech company as defined under Chapter 18A of the Listing Rules. Our Company will fulfil the additional conditions for [REDACTED] applicable to a Chapter 18A company;
- (b) as of the Latest Practicable Date, our Company has not commercialized any products and therefore did not generate any revenue from product sales. Please refer to the section headed “History, Development and Corporate Structure” in this document for the details of the major financing activities conducted by us since our incorporation, including our Pre-[REDACTED] Investments.
- (c) notwithstanding that the financial results set out in this document are only for the two financial years ended December 31, 2019, and the three months ended March 31, 2020 in accordance with Chapter 18A of the Listing Rules, other information required to be disclosed under the Listing Rules and requirements under the Companies (Winding Up and Miscellaneous Provisions) Ordinance has been adequately disclosed in this document pursuant to the relevant requirements; therefore, strict compliance with section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to the requirements of paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance would be unduly burdensome as this would require additional work to be performed by our Company and the reporting accountants;
- (d) the accountants’ report for the two financial years ended December 31, 2019 and the three months ended in March 31, 2020 has been prepared and is set out in Appendix I to this document in accordance with Rule 18A.06 of the Listing Rules; and

WAIVERS FROM STRICT COMPLIANCE WITH THE LISTING RULES AND EXEMPTIONS FROM COMPLIANCE WITH THE COMPANIES (WINDING UP AND MISCELLANEOUS PROVISIONS) ORDINANCE

- (e) the accountants’ report covering the two financial years ended December 31, 2019 and the three months ended March 31, 2020, together with other disclosure in this document, has already provided the potential investors with adequate and reasonable up-to-date information in the circumstances to form a view on the track record of our Company, and that all information which is necessary for the investing public to make an informed assessment of the business, assets and liabilities, financial position, management and prospects has been included in this document. Therefore, the exemption would not prejudice the interest of the investing public.

The SFC has [granted] a certificate of exemption under section 342A of the Companies (Winding Up and Miscellaneous Provisions) Ordinance exempting our Company from strict compliance with section 342(1)(b) in relation to paragraph 27 of Part I and paragraph 31 of Part II of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance on the condition that particulars of the exemption are set out in this document.

CONTINUING CONNECTED TRANSACTIONS

We have entered into certain transactions which will constitute continuing connected transactions for our Company under the Listing Rules after the [REDACTED]. We have applied to the Stock Exchange for, and the Stock Exchange [has granted] us, waivers from strict compliance with the announcement requirement under Chapter 14A of the Listing Rules in respect of the continuing connected transactions as disclosed in the paragraph headed “Connected Transactions – B. Continuing Connected Transactions subject to the Reporting, Annual Review, and Announcement Requirements but Exempt from the Independent Shareholders’ Approval Requirement”. Please refer to the section headed “Connected Transactions” in this document for further information.

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

INFORMATION ABOUT THIS DOCUMENT AND THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

DIRECTORS

Name	Address	Nationality
Executive Directors		
Mr. Wang Weidong (王威東)	Room 1902, Unit 1, Building No. 007 Tianyue Bay, Laishan District Yantai, Shandong Province PRC	Chinese
Dr. Fang Jianmin (房健民)	Room 601, No. 52 Lane 1088, Guoquan North Road Yangpu District, Shanghai PRC	Canadian
Dr. He Ruyi (何如意)	13708 Mount Prospect Drive Rockville Maryland 20850-3510 United States	American
Mr. Lin Jian (林健)	Building No. 53, Danyang Community Yantai Economic and Technological Development Area Yantai, Shandong Province PRC	Chinese
Non-executive Directors		
Dr. Wang Liqiang (王荔強)	4-1-2101 Wanda Mansion Zhifu District Yantai, Shandong Province PRC	Chinese
Dr. Su Xiaodi (蘇曉迪)	Room 1202, No. 2, Lane 375 Weidi Road, Baoshan District Shanghai PRC	Chinese

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

Independent non-executive Directors

Ms. Yu Shanshan (于珊珊)	Flat F, 41/F, Tower 3 The Avenue Phase 2 200 Queen’s Road East Hong Kong	Canadian
Mr. Hao Xianjing (郝先經)	1102, Unit 1, Block 7 Liyang Street, Central District Jinan, Shandong Province PRC	Chinese
Dr. Lorne Alan Babiuk	1030 Hume Ave Kelowna, B.C. Canada	Canadian

SUPERVISORS

Mr. Ren Guangke (任廣科)	36-1-10 Green Homeland Laishan District Yantai, Shandong Province PRC	Chinese
Mr. Li Yupeng (李宇鵬)	602, 18/F Phase I Shouzuoyu Yuan Community No. 7 Guanghe Street Daxing District Beijing PRC	Chinese
Mr. Li Zhuanglin (李壯林)	3-1-28 Bihai Lvzhou District, Kunlun Mountain Road Yantai Economic and Technological Development Area Shandong Province PRC	Chinese

For the biographies and other relevant information of the Directors and Supervisors, please refer to the section “Directors, Supervisors and Senior Management” in this document.

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

PARTIES INVOLVED IN THE [REDACTED]

Joint Sponsors

Morgan Stanley Asia Limited

46th Floor, International Commerce Centre
1 Austin Road West
Kowloon
Hong Kong

**Huatai Financial Holdings (Hong Kong)
Limited**

62nd Floor, the Center
99 Queen’s Road Central
Hong Kong

J.P. Morgan Securities (Far East) Limited

28/F Chater House
8 Connaught Road Central
Hong Kong

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

[REDACTED]

Legal Advisors to the Company

as to Hong Kong and U.S. laws:

O’Melveny & Myers

31/F, AIA Central
1 Connaught Road Central
Hong Kong

as to PRC law:

King & Wood Mallesons

18th Floor, East Tower,
World Financial Center
1 Dongsanhuan Zhonglu
Chaoyang District
Beijing 100020

DIRECTORS, SUPERVISORS AND PARTIES INVOLVED IN THE [REDACTED]

**Legal Advisors to the Joint Sponsors
and [REDACTED]**

as to Hong Kong and U.S. laws:

Davis Polk & Wardwell

18/F, The Hong Kong Club Building
3A Chater Road
Hong Kong

as to PRC law:

Tian Yuan Law Firm

10/F, Tower B, China Pacific Insurance Plaza
28 Fengsheng Lane
Xicheng District
Beijing 100032
China

Auditors and Reporting Accountants

Ernst & Young

Certified Public Accountants
22/F CITIC Tower
1 Tim Mei Avenue, Central
Hong Kong

Industry Consultant

**Frost & Sullivan (Beijing) Inc., Shanghai
Branch Co.**

Room 1018, Tower B
No. 500 Yunjin Road
Xuhui District
Shanghai
China

Independent Property Valuer

**Jones Lang LaSalle Corporate Appraisal and
Advisory Limited**

7th Floor, One Taikoo Place
979 King's Road
Hong Kong

Receiving Bank

[●]

CORPORATE INFORMATION

Registered Office, Headquarters and Principal Place of Business in the PRC	58 Middle Beijing Road Yantai Economic Technological Development Zone Shandong PRC
Principal Place of Business in Hong Kong	[40th Floor, Sunlight Tower No. 248 Queen's Road East Wanchai Hong Kong]
Company Website	<u>www.remegen.com</u> (Information contained on this website does not form part of this document)
Joint Company Secretaries	Mr. Li Jia (李嘉) Flat B, 37/F, Block 6A Imperial Cullinan 10 Hoi Fai Road Tai Kok Tsui, Kowloon Hong Kong Ms. Tam Pak Yu, Vivien (譚栢如) (ACIS ACS) 40th Floor, Sunlight Tower No. 248 Queen's Road East Wanchai Hong Kong
Authorized Representatives	Dr. Fang Jianmin (房健民) Room 601, No. 52 Lane 1088, Guoquan North Road Yangpu District, Shanghai PRC Ms. Tam Pak Yu, Vivien (譚栢如) (ACIS ACS) 40th Floor, Sunlight Tower No. 248 Queen's Road East Wanchai Hong Kong

CORPORATE INFORMATION

Audit Committee

Mr. Hao Xianjing (*Chairman*)
Ms. Yu Shanshan
Dr. Wang Liqiang

Remuneration and Appraisal Committee

Ms. Yu Shanshan (*Chairwoman*)
Mr. Hao Xianjing
Mr. Lin Jian

Nomination Committee

Mr. Wang Weidong (*Chairman*)
Mr. Hao Xianjing
Ms. Yu Shanshan

Strategy Committee

Dr. Fang Jianmin (*Chairman*)
Mr. Wang Weidong
Dr. He Ruyi
Dr. Su Xiaodi
Dr. Lorne Alan Babiuk
Dr. Wang Liqiang

Compliance Advisor

Rainbow Capital (HK) Limited
Room 5B, 12/F, Tung Ning Building
No. 2 Hillier Street
Sheung Wan
Hong Kong

[REDACTED]

CORPORATE INFORMATION

Principal Bankers

China Construction Bank
Yantai Development branch
77 Changjiang Road
Yantai Economic and Technological
Development Area
Yantai, Shandong Province
PRC

Yantai Bank
Development Zone branch
161 Changjiang Road
Yantai Economic and Technological
Development Area
Yantai, Shandong Province
PRC

Qingdao Bank
Yantai Development
Zone Technological branch
108 Hengda • Haixin Garden
Yantai Economic and Technological
Development Area
Yantai, Shandong Province
PRC

INDUSTRY OVERVIEW

The information and statistics set out in this section and other sections of this document were extracted from different official government publications, available sources from public market research and other sources from independent suppliers. In addition, we engaged Frost & Sullivan to prepare the Frost & Sullivan Report, an independent industry report in respect of the [REDACTED]. We believe that the sources of the information in this section and other sections of this document are appropriate sources for such information, and we have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. The information from official and non-official sources has not been independently verified by us, the Joint Sponsors, [REDACTED], [REDACTED], [REDACTED], any of the [REDACTED], any of their respective directors and advisors, or any other persons or parties involved in the [REDACTED] (other than Frost & Sullivan), and no representation is given as to its accuracy. Accordingly, the information from official and non-official sources contained herein may not be accurate and should not be unduly relied upon. Our Directors confirm that, after making reasonable enquiries, there is no adverse change in the market information since the date of the Frost & Sullivan Report that would qualify, contradict or have a material impact on the information in this section. Unless otherwise noted, the amounts related to market size in China in this section used an exchange rate of US\$1 = RMB6.5.

GLOBAL AND CHINA’S BIOLOGICS MARKETS

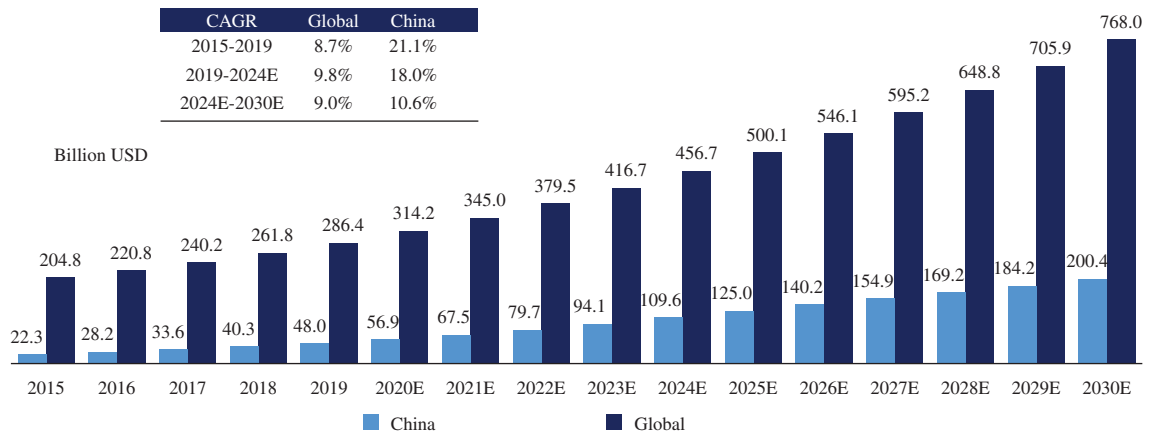
Biologics are pharmaceutical products manufactured using biological methods and sources, and are designed to replicate the activity of natural substances such as enzymes, antibodies or hormones. The major types of biologics include monoclonal antibodies (mAbs), fusion proteins, antibody-drug conjugates (ADCs), recombinant proteins, vaccines, gene therapies and cell therapies. Among the various types of biologics, fusion proteins, ADCs and bifunctional antibodies stand at the frontier of the research and development of biologics, especially in the therapeutic areas of autoimmune diseases, oncology and ophthalmology, and each promises tremendous clinical and market potential as a novel drug modality.

Market Size and Growth Drivers of Global and China’s Biologics Markets

The global biologics market has experienced rapid growth in the past few years and is expected to continue to grow significantly in the near future. Driven by increasing market demand, technology advancements and revenue growth from new generation products, the global biologics market is expected to grow from US\$286.4 billion in 2019 to US\$768.0 billion in 2030. As illustrated in the chart below, the growth of China’s biologics market has outpaced that of the global biologics market in recent years. In 2019, China’s biologics market was US\$48.0 billion in terms of total sales and is expected to reach US\$109.6 billion in 2024 and US\$200.4 billion in 2030.

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Global and China Biologics Market Size (2015-2030E)



Source: Frost & Sullivan

The growth of China’s biologics markets is primarily driven by the following factors:

- Increasing Investment in Biologics Research and Development.* Increases in investment in research and development of biologics have led to a rapid expansion of the pipeline of biologic products as a result of people’s improved understanding of biologics and the human immune system. Discovery and development of new biologics often take a long, difficult and expensive process. Investment in the research and development of biologics in China is expected to continue to rise in the future, leading to more new products entering the market.
- Increasing Affordability.* Chinese residents’ average disposable income has grown rapidly. This trend is expected to continue enhancing Chinese residents’ ability and willingness to pay for more expensive medical treatments, particularly those life-threatening diseases. In addition, recent reforms in government-sponsored medical insurance schemes have lowered the cost and improved the affordability of some biologics to Chinese residents.
- Favorable Government Policies.* The PRC government has established a set of regulations and policies to support the development of China’s biologics market. In October 2017, the General Office of the CPC Central Committee and the General Office of the State Council issued the *Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices*, which aims to improve the regulatory regime for the biologics industry, encourage the technological innovation for new drugs and enhance the competitiveness of the biologics industry. In October 2018, the National Medical Insurance Bureau (NMIB) announced that the List B catalogue of the National Reimbursement Drug List (NRDL) was expanded to include 17 anti-cancer drugs. In November 2019, NMIB further announced 70 new therapies to be added to the NRDL with an average price reduction of 60.7%. For details, please refer to the paragraphs headed “Regulatory Overview – Other Laws and Regulations in Relation to Medical Industry – Laws and Regulations in relation to Basic Medical Insurance – Medical Insurance Catalogue” in this document.

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- Demand for Effective Therapies Targeting Unmet Needs Including Oncology and Autoimmune Diseases.** To date, there is no cure for many oncology and autoimmune diseases. Targeted biologics that aim to improve physical functioning and prevent irreversible tissue or organ damage offer a promising trajectory for drug development. This class of biologics is expected to stimulate the growth of the biologics market sector that targets oncology and autoimmune diseases in China.

Comparison of Top Ten Drugs Globally and in China

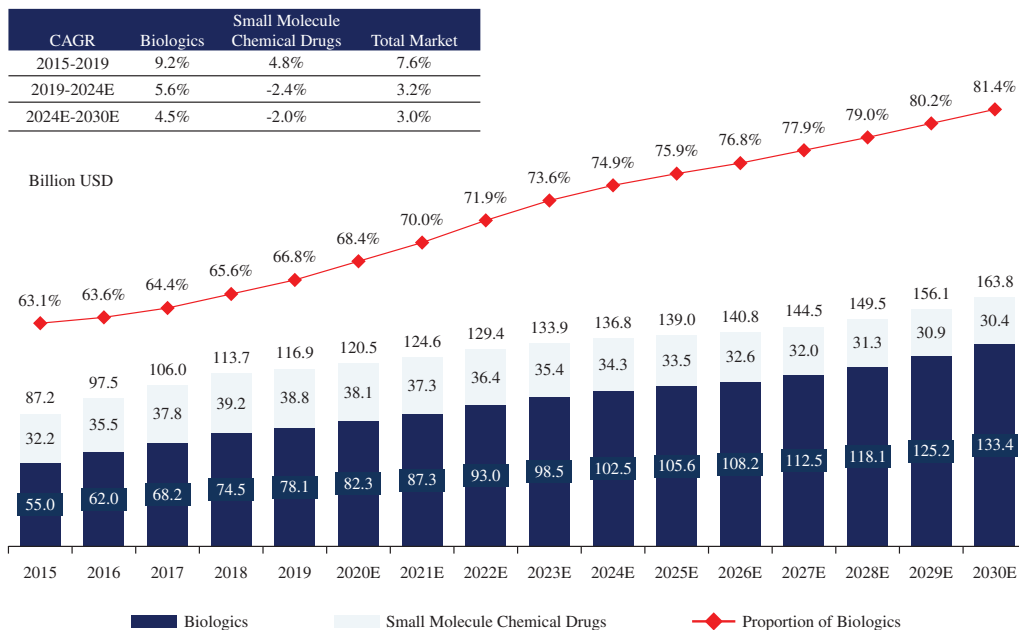
Despite the rapid growth of China’s biologics market in recent years, the penetration rate of biologics in the China market remains low. There is still great potential for biologics to capture more market share in China among all pharmaceutical products. In 2019, while seven out of the top ten best-selling drugs sold globally were biologics, only three of the top ten drugs sold in China were biologics, indicating huge potentials for biologics market growth in China.

AUTOIMMUNE DISEASE DRUG MARKET

Overview of Autoimmune Diseases

Autoimmune diseases are conditions in which the human body’s immune system mistakenly attacks the body, and can be associated with over-activity of the immune system. There are roughly 100 different types of autoimmune disorders, which can affect almost any part of the body. Both genetic and environmental factors may contribute to the development of autoimmune diseases, which can lead to organ failure and impose a severe economic and social burden upon patients. There is a large patient pool in need of biologics for treatment of autoimmune diseases worldwide. The global autoimmune diseases drug market is expected to reach US\$163.8 billion in 2030, growing from US\$116.9 billion in 2019. The market share of biologics in the global autoimmune disease market is expected to increase from 66.8% in 2019 to 81.4% by 2030.

Global Autoimmune Diseases Treatment Market Size (2015-2030E)



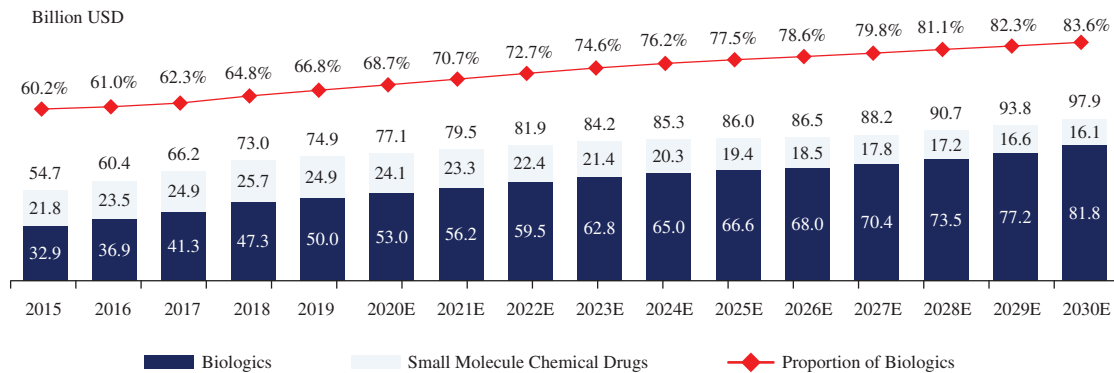
Source: Frost & Sullivan

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The autoimmune diseases drug market in the U.S. is expected to reach US\$97.9 billion in 2030, growing from US\$74.9 billion in 2019. The market share of biologics in the autoimmune disease market in the U.S. is expected to increase from 66.8% in 2019 to 83.6% by 2030.

U.S. Autoimmune Diseases Treatment Market Size (2015-2030E)

CAGR	Biologics	Small Molecule Chemical Drugs	Total Market
2015-2019	11.0%	3.4%	8.2%
2019-2024E	5.4%	-4.0%	2.6%
2024E-2030E	3.9%	-3.8%	2.3%

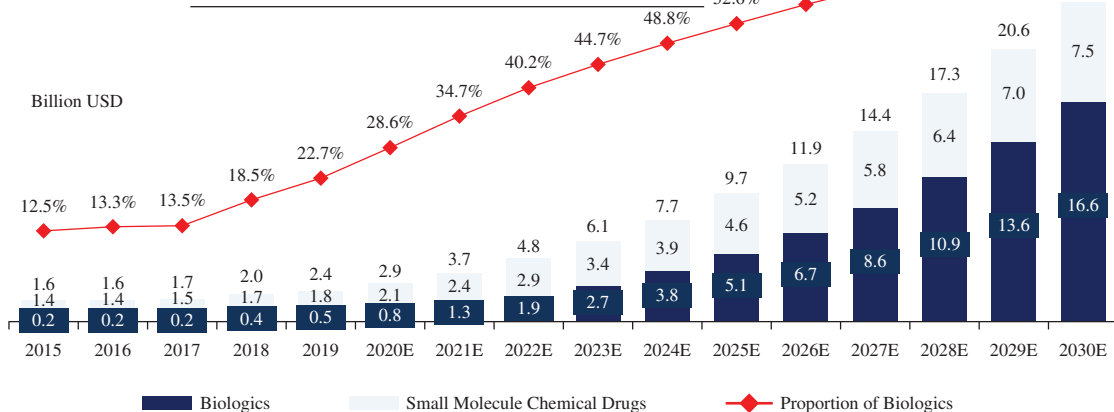


Source: Frost & Sullivan

Driven by the development of diagnostics for autoimmune disease, China's autoimmune diseases market is expected to continue to grow. The biologics market for autoimmune diseases in China is expected to reach US\$16.6 billion in 2030, growing from US\$0.5 billion in 2019. Biologics' share of China's autoimmune diseases market is expected to increase from 22.7% in 2019 to 68.8% in 2030.

China's Autoimmune Diseases Treatment Market Size (2015-2030E)

CAGR	Biologics	Small Molecule Chemical Drugs	Total Market
2015-2019	7.4%	28.4%	11.4%
2019-2024E	16.8%	47.8%	28.1%
2024E-2030E	11.4%	28.1%	20.9%



Source: Frost & Sullivan

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Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is a chronic, multi-system and incurable autoimmune disease that can potentially lead to serious organ damage, systemic complications and even death. Common symptoms of SLE include painful and swollen joints, unexplained fever, chest pain, hair loss, mouth ulcers, swollen lymph nodes, extreme fatigue, and red rashes that most commonly appear on the face, and these symptoms vary widely among patients and fluctuate unpredictably over time as the disease progresses. At the advanced stage of the disease, patients can develop renal damage and renal failure.

The management of SLE typically requires a comprehensive assessment of the disease activity, the damage from the disease, and the careful tailoring of the treatment according to the involved organs and the disease severity. In general, treatment aims to manage and control symptoms during the acute periods of active disease, and to minimize the risk of flares during periods of remission.

In mild, non-organ threatening disease, anti-malarials, low-dose steroids, and the transient use of non-steroidal anti-inflammatory drugs can be administered. In the case of worsening of disease, hydroxychloroquine is usually prescribed and the steroid doses can be increased. For patients with more severe disease, or when steroid doses cannot be reduced to acceptable levels, immunosuppressive agents such as azathioprine, mycophenolate mofetil, and methotrexate are usually recommended. For renal disease, cyclophosphamide and mycophenolate mofetil in combination with steroid treatment is often administered.

The drugs currently used to treat SLE can be associated with significant risks and adverse effects. Corticosteroid therapy remains problematic in the management of SLE as it contributes significantly to cardiovascular risk and can lead to the development of osteoporosis. Therefore, if treatment with a biological agent can allow a corticosteroid sparing regimen, this is considered of significant clinical value in SLE management. Currently, belimumab is the only mAb for the treatment of SLE marketed globally. However, belimumab is also known for its limitations, such as limited efficacy, slow onset of action, restrictive label, and a high price.

SLE Prevalence Globally, in the U.S. and in China

Growing prevalence of SLE diagnosis around the world drives future market growth. The number of global SLE patients increased from 7.4 million in 2015 (including approximately 271,000 in the U.S. and approximately 994,100 in China) to 7.7 million in 2019 (including approximately 279,600 in the U.S. and 1.03 million in China). The total number of global SLE patients is forecasted to reach 8.0 million by 2024 (including approximately 290,600 in the U.S. and 1.06 million in China), and to 8.6 million by 2030 (including approximately 303,400 in the U.S. and 1.09 million in China).

INDUSTRY OVERVIEW

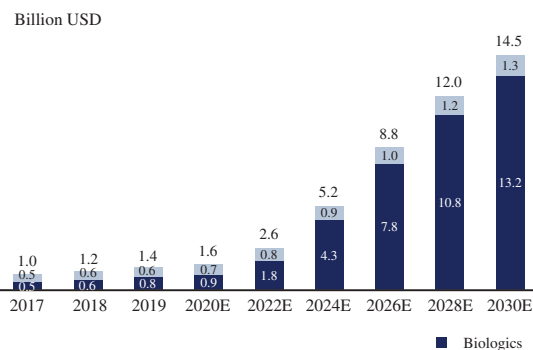
SLE Therapeutics Market Sizes Globally, in the U.S. and in China

Overall, there is a substantial unmet medical need for more effective and better-tolerated therapies for the treatment of SLE. The improving understanding of the immunopathology of SLE, based on a better knowledge of how immune responses work, has led to the development of biologics targeting key cells or molecules implicated in the diseases. Increasingly, biologics are developed to substitute current standards of care that lack efficacy and tolerability among patients. For example, GlaxoSmithKline’s Benlysta (belimumab), a B-lymphocyte stimulator (BLyS) specific inhibitor, has been approved for the treatment of adult patients with active, autoantibody-positive SLE who are receiving standard therapy.

Significant unmet needs and increase in available therapeutic options for patients with potent clinical benefits will boost future market growth. As illustrated in the following chart, the global biologics market for SLE treatment increased from about US\$0.4 billion to US\$0.8 billion, representing a CAGR of 22.1% from 2015 to 2019, and is expected to further increase at a CAGR of 29.3% to 2030, reaching US\$13.2 billion in terms of sales revenue. The biologics market for SLE treatment in the U.S. is expected to increase to US\$3.5 billion in 2024 from US\$0.7 billion in 2019, representing a CAGR of 38.7%, and is expected to further increase at a CAGR of 16.0% to 2030, reaching US\$8.5 billion in terms of sales revenue.

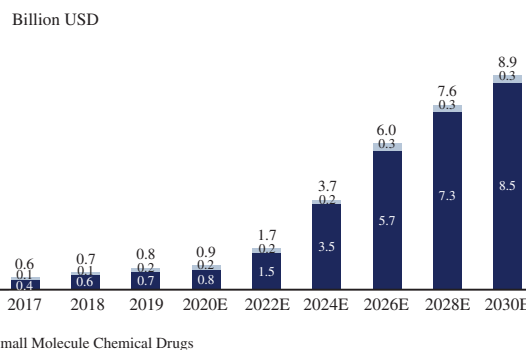
Global SLE Therapeutics Market Size (2017-2030E)

	Small Molecule		
CAGR	Biologics	Chemical Drugs	Total Market
2017-2019	27.3%	7.3%	17.3%
2019-2023E	40.6%	8.0%	30.1%
2023E-2030E	20.5%	6.7%	18.7%



U.S. SLE Therapeutics Market Size (2017-2030E)

	Small Molecule		
CAGR	Biologics	Chemical Drugs	Total Market
2017-2019	25.2%	6.3%	21.0%
2019-2023E	38.7%	7.8%	34.9%
2023E-2030E	16.0%	5.7%	15.5%



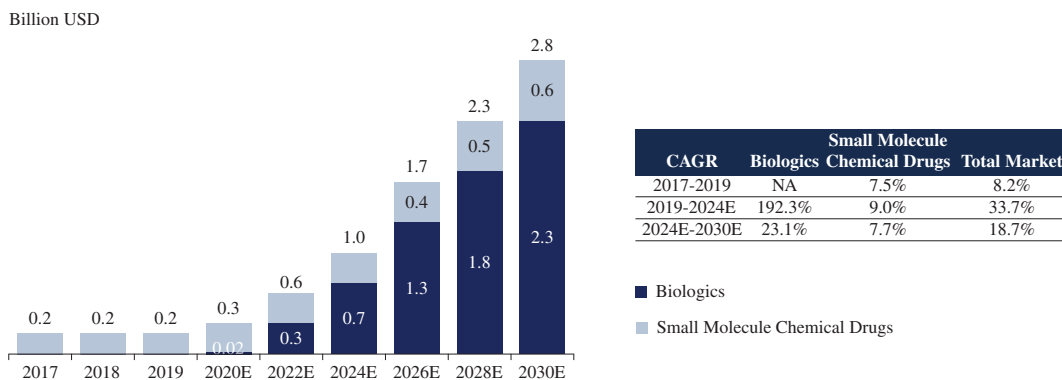
Note: The market size presented covers approved uses only and does not reflect any off-label use.

Source: Frost & Sullivan

The SLE therapeutics market in China reached US\$0.2 billion in 2019 based on the sales of chemical drugs. The biologics market for SLE treatment started to generate revenue in 2019 with the approval and introduction of GlaxoSmithKline’s Benlysta (belimumab) in China. The biologics market in China is expected to increase from US\$0.003 billion in 2019 to US\$2.3 billion by 2030, with a CAGR of 82.4%, as shown in the chart below.

INDUSTRY OVERVIEW

China’s SLE Therapeutics Market Size (2017-2030E)



Note: The market size presented covers approved uses only and does not reflect any off-label use.

Source: Frost & Sullivan

Competitive Landscape of Biologic Therapies for SLE in the U.S. and in China

There are currently two biologic drugs for the treatment of SLE under Phase III clinical trials in the U.S., namely anifrolumab and dapirolizumab pegol. Belimumab is the only biologic drug approved by the NMPA (in 2019) for the treatment of SLE in China. There are five innovative biologics for the treatment of SLE under various clinical trial stages in China. The following tables illustrate the competitive landscape of marketed and clinical-stage innovative biologics treating SLE in the U.S. and in China.

Marketed Innovative Biologics for SLE Treatment in the U.S. and in China

Target	Generic Name	Product	Company	FDA Approval Date	Annual Cost in the U.S. ⁽¹⁾	NMPA Approval Date	Annual Cost in China ⁽¹⁾	Annual Cost in China under PAP ⁽²⁾	Patent Expiration Date
					(USD)		(RMB)	(RMB)	
BlyS	belimumab	Benlysta	GlaxoSmithKline	2011	42,000	2019	148,200	79,040	2025

Pipeline Innovative Biologics for SLE Treatment in the U.S.

Target	Generic Name	Product	Company	Status	Date ⁽³⁾
IFNAR1	anifrolumab	MEDI-546	AstraZeneca	Phase III	May-2015
CD40L	dapirolizumab pegol	CDP-7657	UCB	Phase III	Mar-2020
BlyS, APRIL	atacept	–	Merck KGaA	Phase II	Oct-2013
BlyS, ICOSL	rozibafusp alfa	AMG-570	Amgen, AZ	Phase II	Aug-2019
BAFF-R	ianalumab	VAY736	Novartis	Phase II	Sep-2018
CD40	iscalimab	CFZ533	Novartis	Phase II	Sep-2018
CD19	obexelimab	XmAb-5871	Xencor	Phase II	Apr-2016
CD28	iulizumab	BMS-931699	BMS	Phase II	Oct-2014
IL-6	vobarilizumab	ALX-0061	Abbvie	Phase II	May-2015
IL-21	–	BOS-161721	Boston Pharmaceuticals	Phase II	Dec-2017
IL-10	–	BT063	Biotest AG	Phase II	Sept-2015
RNA	–	RSLV-132	Resolve Therapeutics	Phase II	Jan-2016
CLEC4C	–	BIIB059	Biogen	Phase II	Jul-2016
IL2R	aldesleukin	ILT-101	ILTOO Pharma	Phase II	Nov-2016
IL-2	efavaleukin alfa	AMG-592	Amgen	Phase I/II	Mar-2018
CD74	milatuzumab	IMMU-115	Immunomedics	Phase I/II	May-2013
ILT7	–	VIB7734	Viela Bio	Phase I	Jan-2019
Interferon type 1	–	JNJ-55920839	Janssen Research & Development	Phase I	Nov-2015
CD6	itolizumab	Bmab-600/EQ-001	Equillum, Biocon Limited	Phase I	Oct-2019
CXCR5	–	SAR113244	Sanofi	Phase I	Jan-2015

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Pipeline Innovative Biologics for SLE Treatment in China

Target	Generic Name	Product	Company	Status	Date ⁽³⁾
BlyS, APRIL	telitacicept	RC18	RemeGen (榮昌生物)	NDA Submission	Nov-2019
BAFF-R	ianalumab	VAY736	Novartis	Phase II	Nov-2019
CD40	iscalimab	CFZ533	Novartis	Phase II	Nov-2019
BlyS	–	UBP-1213	Junshi (君實生物)	Phase I	Nov-2016
CD22	–	SM-03	Sinomab (中國抗體)	Phase I	Jan-2015

Notes:

- (1) The annual cost refers to the average wholesale acquisition cost for SLE patients on a 365-day-basis based on the recommended dosage for each patient.
- (2) The annual cost under PAP refers to the annual cost under patient assistance programs which are operated by the pharmaceutical companies to lower the cost of medications.
- (3) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

For the competitive advantages of telitacicept, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Telitacicept (RC18) – Competitive Advantages of Telitacicept” in this document.

Neuromyelitis Optica Spectrum Disorders

Neuromyelitis optica spectrum disorder (NMOSD) is a rare, severe, relapsing, neuroinflammatory autoimmune disease that attacks the optic nerve, spinal cord and brain stem, and often leads to irreversible blindness, paralysis, loss of sensation, bladder and bowel dysfunction, nerve pain and respiratory failure. NMOSD occurs more commonly in women. There is currently no cure for NMOSD. Patients are treated with immunosuppressants, steroids and plasmapheresis in an effort to prevent NMOSD attacks. However, these treatments are known to cause adverse events (such as upper gastrointestinal bleeding, femoral head necrosis, progressive multifocal leukoencephalopathy, cardiotoxicity and acute leukemia) which may lead to treatment discontinuation.

NMOSD Prevalence Globally and in China

According to Frost & Sullivan, the number of NMOSD patients globally increased from approximately 162,000 in 2015 to approximately 169,300 in 2019 (including approximately 48,300 in China). The total number of global NMOSD patients is forecasted to reach approximately 177,900 by 2024 (including approximately 50,800 in China), and to approximately 187,600 by 2030 (including approximately 52,600 in China).

Market Size of NMOSD Therapeutics Markets Globally and in China

According to Frost & Sullivan, the market for global NMOSD therapeutics market is expected to reach US\$1.6 billion in 2030 from US\$0.5 billion in 2019. China’s NMOSD therapeutics market reached US\$46.6 million in 2019 and is expected to grow to US\$118.5 million in 2024, representing a CAGR of 20.5%. This market is expected to increase at a CAGR of 17.0% from 2024 to US\$303.7 million in 2030.

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Competitive Landscape of Biologics Treatment of NMOSD in the U.S. and in China

Soliris (eculizumab) and Uplizna (inebilizumab) are currently approved and marketed drugs for the treatment of NMOSD in the U.S. To date, none of the biologics has received the marketing approval for NMOSD in China. Our telitacept is the only innovative biologic drug candidate currently in Phase III clinical development for NMOSD in China. The following tables illustrate the competitive landscape of the Phase III clinical-stage or more advanced innovative biologics treating NMOSD in the U.S. and in China.

Marketed Innovative Biologics for NMOSD Treatment in the U.S.

Target	Generic Name	Product	Company	FDA Approval Date	Annual Cost ⁽¹⁾	Patent Expiration Date
					(USD)	
C5	eculizumab	Soliris	Alexion	2019	763,840	2026 ⁽²⁾
CD19	inebilizumab	Uplizna	Viela	2020	–	2030

Pipeline Innovative Biologics for NMOSD Treatment in the U.S.

Target	Generic Name	Product	Company	Status	Date ⁽³⁾
IL-6	satralizumab	RG-6168	Roche	BLA Submission	Oct-2019
C5	ravulizumab ⁽⁴⁾	Ultomiris	Alexion	Phase III	Dec-2019

Pipeline Innovative Biologics for NMOSD Treatment in China

Target	Generic Name	Product	Company	Status	Date ⁽³⁾
BlyS, APRIL	telitacept	RC18	RemeGen (榮昌生物)	Phase III	Oct-2017

Notes:

- (1) The annual cost refers to the average wholesale acquisition cost for NMOSD patients on a 365-day-basis based on the recommended dosage for each patient.
- (2) Composition of matter patent expires in 2021. Method of use patents for NMOSD expires in 2026.
- (3) Date denotes the date on which the relevant status was publicly disclosed.
- (4) Ravulizumab is the next-generation long-acting complement 5 inhibitor in comparison to eculizumab.

Source: Frost & Sullivan

For the advantages of telitacept, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Telitacept (RC18) – Competitive Advantages of Telitacept” in this document.

Rheumatoid Arthritis

Rheumatoid arthritis (RA) is a chronic inflammatory autoimmune disease which is clinically characterized by stiffness, joint pain and joint swelling, leading to joint damage, deformity, severe disability, and increased mortality. Patients may develop multiple systemic symptoms including fever, fatigue, anemia, and osteoporosis. The goal of treatment in patients with RA is to reduce inflammation, inhibit joint damage, prevent loss of function, decrease pain, and improve function and quality of life. Initial treatment options include conventional synthetic disease-modifying anti-rheumatic drugs (DMARDs), non-steroidal anti-inflammatory drugs, corticosteroids, analgesics, physiotherapy, and occupational therapy. The DMARDs most commonly used include methotrexate, sulfasalazine, leflunomide, and hydroxychloroquine.

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For patients with an inadequate response or intolerance to synthetic DMARDs, biologic drugs may be prescribed. These block certain key molecules that are involved in the pathogenesis of the illness. Targets include Tumor Necrosis Factor alpha (TNF- α), selective T-cell co-stimulation molecules, Cluster of Differentiation 20 (CD20), interleukin (IL), IL-1, IL-6 and IL-6 receptor (IL-6R). Although anti-TNF- α agents and other biological DMARDs have been established as effective treatment options for RA, there is still a need for new therapeutic agents. Clinical response to available therapies may be lost over time for various reasons such as disease burden, low drug serum levels, rapid clearance and immunogenicity. In addition, biological DMARDs have limitations with respect to safety, dosing regimen and price. As a result, there is the need for new therapeutic agents to address these limitations and to improve the care of patients suffering from RA.

RA Prevalence Globally and in China

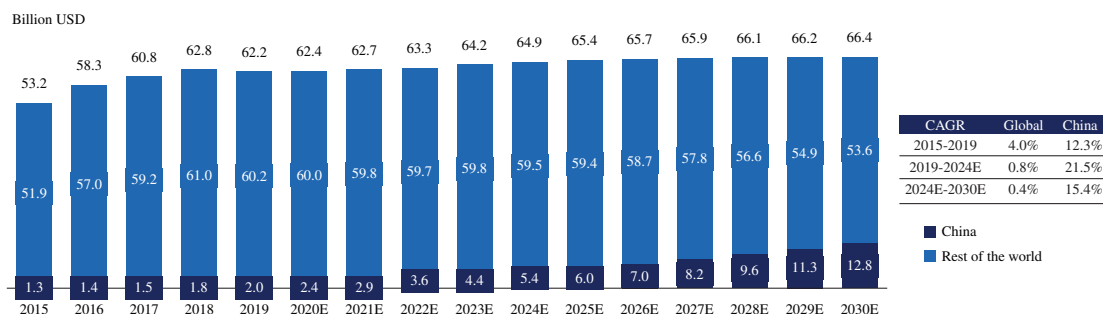
According to Frost & Sullivan, the global prevalence of RA patients increased from 37.7 million in 2015 to 39.3 million in 2019 (including approximately 5.9 million in China). The total number of global RA patients is forecasted to reach 41.7 million by 2024 (including 6.1 million in China), and to 45.0 million by 2030 (including 6.4 million in China).

Market Size of RA Therapeutics Markets Globally and in China

With the launch of a variety of emerging biologic pipeline drugs, the global RA therapeutics market will remain relatively stable in the future. The global RA therapeutics market is expected to grow from US\$62.2 billion in 2019 to US\$64.9 billion in 2024, representing a CAGR of 0.8%, and further increase to US\$66.4 billion in 2030, representing a CAGR of 0.4%.

China’s RA therapeutics market reached US\$2.0 billion in 2019. With significant improvements in RA diagnosis and increase in patients’ income level, the biologics market for RA treatment in China is expected to increase to US\$5.4 billion in 2024, representing a CAGR of 21.5%, and further increase to US\$12.8 billion in 2030, representing a CAGR of 15.4%.

Global and China’s RA Therapeutics Market Size (2015-2030E)



Note: The market size presented covers approved uses only and does not reflect any off-label use.

Source: Frost & Sullivan

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Competitive Landscape of Biologics Treatment of RA in the U.S. and in China

According to Frost & Sullivan, the lower price of biologics supports improving access and higher market penetration in RA. In China, currently, Actemra (IL-6 inhibitor) Orencia (CD80/CD86 inhibitor) are the only biologic drugs approved for the treatment of patients that have moderate or severe active RA and have exhibited poor responses to the TNF- α inhibitors. In addition, there are a few other innovative biologic drug candidates currently in Phase III clinical trials in China that can potentially meet the needs of TNF- α inhibitor refractory RA patients, such as RemeGen’s telitacicept. The following tables illustrate the competitive landscape of Phase III clinical-stage or more advanced innovative biologics treating RA in the U.S. and in China.

Marketed Innovative Biologics for RA Treatment in the U.S. and/or in China

Target	Generic Name	Product	Company	FDA Approval Date	Annual Cost in the U.S. ⁽¹⁾	NMPA Approval Date	Annual Cost in China ⁽¹⁾	Patent Expiration Date
					(USD)		(RMB)	
TNF- α	infliximab	Remicade	Janssen	1999	19,357	2007	31,607	2018
TNF- α	adalimumab	Humira	Abbvie	2002	281,372	2010	33,540	2016
TNF- α	etanercept	Enbrel	Pfizer	1998	70,460	2010	113,672	2028
TNF- α	golimumab	Simponi	Janssen	2009	60,360	2018	58,800	2024
TNF- α	certolizumab	Cimzia	UCB	2009	135,810	2019	147,420	2024
IL-6	tocilizumab	Actemra	Roche	2010	37,206	2013	64,740	2015
CD80, CD86	abatacept	Orencia	BMS	2005	52,515	2020	–	2019
IL-1	anakinra	Kineret	SOB	2001	56,368	–	–	2032
IL-6	sarilumab	Kevzara	Sanofi	2017	45,227	–	–	2027
CD20	rituximab	Rituxan	Roche	1997	39,600	–	–	2018

Pipeline Innovative Biologics for RA Treatment in the U.S.

Target	Generic Name	Product	Company	Status	Date ⁽²⁾
CSF-2	GSK-165	otilimab	GlaxoSmithKline	Phase III	Oct-2019
IL-6	CDP-6038	olokizumab	R-Pharm/UCB	Phase III	Apr-2017

Pipeline Innovative Biologics for RA Treatment in China

Target	Generic Name	Product	Company	Status	Date ⁽²⁾
CD22	–	SM03	SinoMab (中國抗體)	Phase III	Mar-2020
BlyS, APRIL	telitacicept	RC18	RemeGen (榮昌生物)	Phase III	Jan-2017

Notes:

- (1) The annual cost refers to the average wholesale acquisition cost for RA patients on a 365-day-basis based on the recommended dosage for each patient.
- (2) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

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For the competitive advantages of telitacicept, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Telitacicept (RC18) – Competitive Advantages of Telitacicept” in this document.

Sjögren’s Syndrome

Sjögren’s syndrome (SS) is a chronic systemic autoimmune disease characterized by autoimmune destruction of the exocrine glands. SS may be an isolated disease or may accompany other autoimmune diseases. Clinical presentation varies from mild symptoms such as classic sicca symptoms of dry eyes (xerophthalmia), dry mouth (xerostomia) and parotid gland enlargements to severe systemic symptoms involving multiple organ systems such as arthritis, arthralgia, myalgia, pulmonary disease, gastrointestinal disease, neuropathy and lymphoma. Because SS’s symptoms frequently overlap with or mimic those of other diseases and because symptoms of dryness can occur for reasons other than SS, it makes a diagnosis of SS difficult.

Currently, no specific drug has been approved for SS so far apart from the symptomatic relief of signs and symptoms with the use of cholinergic agonists, e.g. Salagen (pilocarpine) and Evoxac (cevimeline). Immuno-modulatory treatments, usually for extra-glandular disease, include cyclosporine (ocular inflammation), hydroxychloroquine (mild inflammatory symptoms of joints, muscles and skin), corticosteroids (rare but serious symptoms: vasculitic rash, interstitial lung disease, interstitial nephritis, glomerulonephritis), immunosuppressive agents e.g. methotrexate, azathioprine, cyclophosphamide (used to treat serious internal organ manifestations) and biologic agents e.g. rituximab. Corticosteroids and immunosuppressants lead to broad, non-selective immunosuppression often associated with significant adverse events.

SS Prevalence Globally and in China

According to Frost & Sullivan, the global prevalence of SS patients increased from 3.7 million in 2015 to 3.9 million in 2019 (including 628,600 in China). The total number of global SS patients is forecasted to reach 4.1 million by 2024 (including 640,200 in China), and to 4.3 million by 2030 (including 644,900 in China).

Market Size of SS Therapeutics Markets Globally and in China

According to Frost & Sullivan, the market for global SS therapeutics market is expected to reach US\$6.0 billion in 2030 from US\$2.1 billion in 2019. China’s SS therapeutics market reached US\$0.1 billion in 2019 and is expected to grow to US\$0.2 billion in 2024, representing a CAGR of 11.0%. This market is expected to increase at a CAGR of 22.0% from 2024 to US\$0.8 billion in 2030.

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Competitive Landscape of Biologics Treatment of SS in the U.S. and in China

Currently, no biologics have been approved globally for the treatment of SS. The pipeline of innovative biologic drugs in development for treating SS in China is relatively small with only one drug candidate in Phase II, namely RemeGen’s telitacicept. The following tables illustrate the competitive landscape of the Phase II clinical-stage or more advanced innovative biologics treating SS in the U.S. and in China.

Pipeline Innovative Biologics for SS Treatment in the U.S.

Target	Generic Name	Product	Company	Status	Date ⁽¹⁾
CD80, CD86	abatacept	BMS-188667	BMS	Phase III	Sep-2016
CD40	iscalimab	CFZ533	Novartis	Phase II	Apr-2019
RNA	RSLV-132	NA	Resolve Therapeutics	Phase II	Aug-2017
BAFF-R	ianalumab	VAY736	Novartis	Phase II	Nov-2016
ICOSL	prezalumab	AMG-557	Amgen	Phase II	Jan-2015

Pipeline Innovative Biologics for SS Treatment in China

Target	Generic Name	Product	Company	Status	Date ⁽¹⁾
BlyS, APRIL	telitacicept	RC18	RemeGen (榮昌生物)	Phase II	Jul-2019

Note:

(1) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

For the competitive advantages of telitacicept, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Telitacicept (RC18) – Competitive Advantages of Telitacicept” in this document.

Immunoglobulin A Nephropathy

Immunoglobulin A Nephropathy (IgAN) is an immune-complex-mediated glomerulonephritis characterized by hematuria, proteinuria, and variable rates of progressive renal failure. IgAN, while considered rare, is the most common cause of primary kidney disease worldwide. IgAN is associated with kidney inflammation, blood in the urine, or hematuria, and protein in the urine, or proteinuria. Patients ultimately progress to kidney failure, or end-stage kidney disease, and require dialysis or kidney transplantation in up to 50% of cases over the course of the disease. Currently, there is no specifically approved therapy for IgAN. The current standard of care is renin-angiotensin-aldosterone system blockade with immunosuppression, which is also commonly used for patients with significant proteinuria or rapidly progressive glomerulonephritis.

INDUSTRY OVERVIEW

IgAN Prevalence Globally and in China

According to Frost & Sullivan, the number of IgAN patients globally increased from 8.8 million in 2015 to 9.2 million in 2019 (including 2.18 million in China). The total number of IgAN patients globally is forecasted to reach 9.6 million by 2024 (including 2.28 million in China), and to 10.2 million by 2030 (including 2.37 million in China).

Market Size of IgAN Therapeutics Market Globally and in China

According to Frost & Sullivan, the market for global IgAN therapeutics market is expected to reach US\$2.5 billion in 2030 from US\$0.5 billion in 2019. China’s IgAN therapeutics market reached US\$34.1 million in 2019 and is expected to grow to US\$78.3 million in 2024, representing a CAGR of 18.1%. This market is expected to increase at a CAGR of 38.1% from 2024 to US\$543.7 million in 2030.

Competitive Landscape of Biologics Treatment of IgAN in the U.S. and in China

In the U.S., there are several biologic drugs for the treatment of IgAN under various clinical trial stages. In China, the pipeline of innovative biologic drugs in development for treating IgAN is small with only RemeGen’s telitacicept in Phase II clinical trial. The following tables set forth the competitive landscape of Phase II clinical-stage or more advanced innovative biologics treating IgAN in the U.S. and in China.

Pipeline Innovative Biologics for IgAN Treatment in the U.S.

Target	Generic Name	Product	Company	Status	Date ⁽¹⁾
MASP-2	narsoplimab	OMS721	Omeros	Phase III	Jul-2018
APRIL	–	VIS-649	Visterra	Phase II	Feb-2020
GAS6	–	AVB-S6-500	Aravive	Phase II	Aug-2019
BlyS, APRIL	atacept	–	Merck KGaA	Phase II	Jun-2016

Pipeline Innovative Biologics for IgAN Treatment in China

Target	Generic Name	Product	Company	Status	Date ⁽¹⁾
BlyS, APRIL	telitacicept	RC18	RemeGen (榮昌生物)	Phase II	Nov-2019

Note:

(1) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

For the competitive advantages of telitacicept, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Telitacicept (RC18) – Competitive Advantages of Telitacicept” in this document.

Myasthenia Gravis

Myasthenia gravis (MG) is a neuromuscular disorder caused by autoantibodies against the acetylcholine receptor, muscle specific kinase or other acetylcholine receptor-related proteins in the post-synaptic muscle membrane. The underlying pathogenesis has a high degree of similarity to NMOSD in that autoantibodies secreted by plasmablasts and/or plasma cells play a key role and are thought to be directly pathogenic. Patients with MG are currently treated with off-label immunosuppressants or steroids, or with one recently approved treatment, namely eculizumab.

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MG Prevalence Globally and in China

According to Frost & Sullivan, the number of MG patients globally increased from 1.0 million in 2015 (including approximately 194,000 in China) to 1.1 million in 2019 (including approximately 204,000 in China). The total number of MG patients globally is forecasted to reach 1.2 million by 2030 (including approximately 223,000 in China).

Market Size of MG Therapeutics Market Globally and in China

According to Frost & Sullivan, the market for global MG therapeutics market is expected to reach US\$7.2 billion in 2030 from US\$1.2 billion in 2019. China’s MG therapeutics market reached US\$43.1 million in 2019 and is expected to grow to US\$148.5 million in 2024, representing a CAGR of 28.1%. This market is expected to increase at a CAGR of 39.1% from 2024 to US\$1.1 billion in 2030.

Competitive Landscape of Biologics Treatment of MG in the U.S. and in China

Currently, Alexion’s Soliris (eculizumab) is the only product marketed for the treatment of MG in the U.S. In China, there is only one innovative biologic drug candidate currently in Phase II clinical trials, namely RemeGen’s telitacicept. The following tables illustrate the competitive landscape of the Phase II clinical-stage or more advanced innovative biologics treating MG in the U.S. and in China.

Marketed Innovative Biologics for MG Treatment in the U.S.

Target	Generic Name	Product	Company	FDA Approval Date	Annual Cost ⁽¹⁾ (USD)	Patent Expiration Date
C5	eculizumab	Soliris	Alexion	2017	763,840	2024

Pipeline Innovative Biologics for MG Treatment in the U.S.

Target	Generic Name	Product	Company	Status	Date ⁽²⁾
FcRn	nipocalimab	M-281	Momenta	Phase III	Mar-2019
FcRn	rozanolixizumab	UCB-7665	UCB	Phase III	Jun-2019
C5	zilucoplan	RA 101495	Ra Pharmaceuticals	Phase III	Oct-2019
C5	ravulizumab	ALXN-1210	Alexion	Phase III	Apr-2019
FcRn	efgartigimod	ARGX-113	argenx BVBA	Phase III	Dec-2018
Immunostimulator	–	CV-MG01	CuraVac	Phase III	May-2017
CD38	–	TAK 079	Takeda	Phase II	Nov-2019
CD40	iscalimab	CFZ533	Novartis	Phase II	Oct-2015

Pipeline Innovative Biologics for MG Treatment in China

Target	Generic Name	Product	Company	Status	Date ⁽²⁾
BlyS, APRIL	telitacicept	RC18	RemeGen (榮昌生物)	Phase II	Mar-2020

Notes:

- (1) The annual cost refers to the average wholesale acquisition cost for MG patients on a 365-day-basis based on the recommended dosage for each patient.
- (2) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

INDUSTRY OVERVIEW

For the competitive advantages of telitacicept, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Telitacicept (RC18) – Competitive Advantages of Telitacicept” in this document.

Multiple Sclerosis

Multiple Sclerosis (MS) is a devastating inflammatory neurologic disease in which white matter, known as myelin, is damaged-causing episodic or neurological symptoms. The destruction of myelin inhibits communications between the nerves in the brain. Symptoms of MS include extreme fatigue, numbness, weakness, difficulty with eyesight, spasticity, speech problems, and problems with coordination. MS has its greatest incidence in young adults and patients are usually diagnosed at less than 55 years of age at the onset of the illness. Currently, patients with MS are commonly treated with disease-modifying therapies and resistance training.

MS Prevalence Globally and in China

According to Frost & Sullivan, the number of MS patients globally increased from 2.4 million in 2015 to 2.7 million in 2019 (including approximately 47,400 in China). The total number of MS patients globally is forecasted to reach 3.2 million by 2024 (including approximately 53,200 in China), and to 3.7 million by 2030 (including approximately 60,400 in China).

Market Size of MS Therapeutics Market Globally and in China

According to Frost & Sullivan, the market for global MS therapeutics market is expected to reach US\$31.5 billion in 2030 from US\$23.5 billion in 2019. China’s MS therapeutics market reached US\$0.3 billion in 2019 and is expected to grow to US\$0.7 billion in 2024, representing a CAGR of 19.7%. This market is expected to increase at a CAGR of 21.6% from 2024 to US\$2.1 billion in 2030.

Competitive Landscape of Biologics Treatment of MS in the U.S. and in China

A number of companies have committed resources to develop novel MS drug therapies. There are currently three innovative biologics marketed for the treatment of MS in the U.S. and no innovative biologics is available in China. The only innovative biologic drug candidate currently in Phase II clinical trials in China is RemeGen’s telitacicept. The following tables illustrate the competitive landscape of Phase II clinical-stage and more advanced innovative biologics treating MS in the U.S. and in China.

INDUSTRY OVERVIEW

Marketed Innovative Biologics for MS Treatment in the U.S.

Target	Generic Name	Product	Company	FDA Approval Date	Annual Cost ⁽¹⁾	Patent Expiration Date
					<i>(USD)</i>	
Integrin α 4	natalizumab	Tysabri	Biogen	2004	89,973	2027
CD52	alemtuzumab	Lemtrada	Genzyme	2014	97,828	2017
CD20	ocrelizumab	Ocrevus	Genentech	2017	67,896	2023

Pipeline Innovative Biologics for MS Treatment in the U.S.

Target	Generic Name	Product	Company	Status	Date ⁽²⁾
CD20	ublituximab	R-603	TG Therapeutics Inc	Phase III	Nov-2017
CD20	ofatumumab	OMB-157	Novartis	Phase III	Apr-2020
RGMa	elezanumab	ABT-555	AbbVie	Phase II	Nov-2018
LINGO 1	opicinumab	BIIB-033	Biogen	Phase II	Jul-2017
HERV	temelimab	GNbAC1	GeNeuro	Phase II	May-2016

Pipeline Innovative Biologics for MS Treatment in China

Target	Generic Name	Product	Company	Status	Date ⁽²⁾
BLYS, APRIL	telitacicept	RC18	RemeGen (荣昌生物)	Phase II	Mar-2020

Notes:

- (1) The annual cost refers to the average wholesale acquisition cost for MS patients on a 365-day-basis based on the recommended dosage for each patient.
- (2) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

For the competitive advantages of telitacicept, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Telitacicept (RC18) – Competitive Advantages of Telitacicept” in this document.

ONCOLOGY DRUG MARKET

Overview of Global Oncology Market

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled fashion and which are usually classified as either hematological malignancies or solid tumors. It is the leading cause of death worldwide and is rapidly overtaking heart disease in many countries to become the number one cause of mortality. According to Frost & Sullivan, it is estimated that worldwide, approximately 9.8 million individuals died from cancer in 2019. Cancer treatment has been revolutionized in the last few years. The most common cancer treatments today typically include chemotherapies, immune-oncology therapies and targeted therapies, such as small molecule targeted therapies and antibody-based therapies.

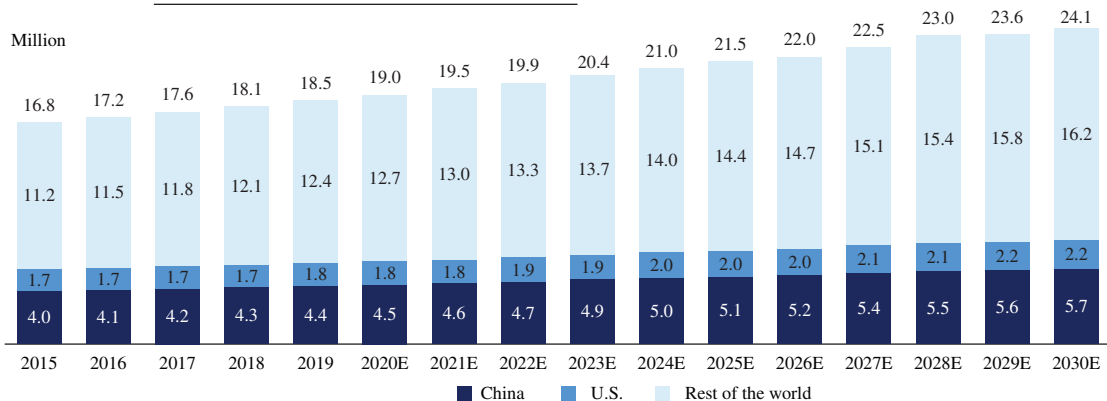
INDUSTRY OVERVIEW

Cancer Incidence Globally, in the U.S. and in China

Cancer incidence and mortality have been increasing globally. According to Frost & Sullivan, there were 18.5 million new cancer cases globally in 2019 (including 1.8 million new cancer cases in the U.S.). It is estimated that in 2030, there will be 24.1 million new cancer cases (including 2.2 million new cancer cases in the U.S.), representing a CAGR of 2.4% from 2019 to 2030. Despite advances in new treatments, cancer remains a major challenge for modern medicine with significant unmet medical needs in China. According to Frost & Sullivan, cancer is the second leading cause of death in China. The number of new cancer patients in China was 4.4 million in 2019 and is expected to reach 5.0 million in 2024.

Cancer Incidence Globally, in the U.S. and in China (2015-2030E)

CAGR	Global	China	U.S.
2015-2019	2.5%	2.7%	1.5%
2019-2024E	2.5%	2.5%	2.1%
2024E-2030E	2.4%	2.2%	1.9%



Source: Frost & Sullivan

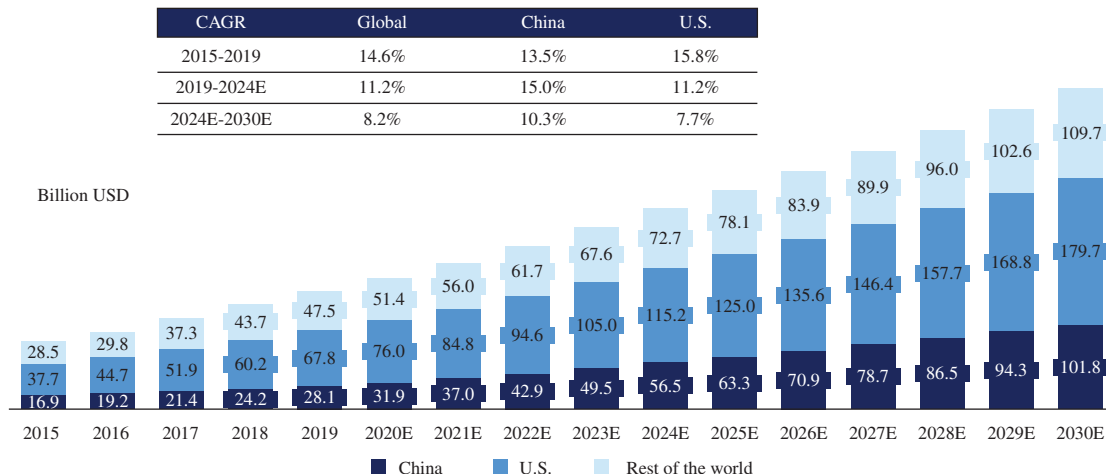
Market Size of Oncology Drug Market Globally, in the U.S. and in China

Despite the variations with different cancer patient populations, the global market size for oncology therapies is projected to continue its growth at a substantial rate both inside and outside China. According to Frost & Sullivan, the global oncology drug market is expected to grow from US\$143.5 billion in 2019 to US\$244.4 billion in 2024 and further to US\$391.3 billion in 2030. The oncology drug market in the U.S. is expected to grow from US\$67.8 billion in 2019 to US\$115.2 billion in 2024 and further to US\$179.7 billion in 2030. Noticeably, an increasing number of innovative therapeutics for oncology treatment have been approved by the FDA recently. In 2019, three ADC drugs were approved by the FDA, as compared with five ADC drugs that were approved by the FDA over the course of seven years between 2011 and 2018. Frost & Sullivan expects more innovative types of biologics, with better efficacy or less adverse effects than currently available therapies, to emerge in the oncology drug market in the near future.

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China’s oncology drug market has grown rapidly in recent years. Revenue of oncology drugs in China grew from US\$16.9 billion in 2015 to US\$28.1 billion in 2019, representing a CAGR of 13.5%. It is expected to further grow at a CAGR of 15.0% to US\$56.5 billion in 2024. It is estimated to further increase to US\$101.8 billion in 2030, outpacing the growth and representing an increasing percentage of China’s overall pharmaceutical market. It is expected that more innovative oncology drugs will be approved in China. For example, Roche’s Kadcycla was launched in 2020 as the first ADC drug approved in China.

Oncology Drug Market Size Globally, in the U.S. and in China (2015-2030E)



Source: Frost & Sullivan

Overview of HER2-Targeted Therapy Market

Human epidermal growth factor receptor 2 (HER2) is a validated molecular target for cancer therapy. Over-expression of HER2 has been shown to play a critical role in the progression of malignancies, especially breast cancer, and is also associated with a number of other cancer types, including gastric cancer (GC) and urothelial cancer (UC). The level of HER2 expression in tumors can be classified into HER2 high-expressing, HER2 low-expressing and HER2-negative with reference to immunohistochemistry (IHC) or fluorescence in situ hybridization (FISH) standards. Cancer treatments targeting HER2 low expression indications are expected to have great potential as the last-line treatment for later-stage cancers.

The future trends of HER2-targeted therapies primarily include the following:

- *Untapped Patient Population with Cancers Expressing HER2 at Low Level.* Approximately 50% of breast cancer patients have HER2 low-expression and are ineligible for currently approved HER2-targeted therapies. Approximately 22% of GC patients and 28% of UC patients are HER2 high-expressing. Novel anti-HER2 mAbs-based therapies (including anti-HER2 ADCs) with better affinity to HER2 target are being developed and have the potential to address the needs of patients with a low HER2 expression level.

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- *Last-line treatment for later-stage BC.* The treatment and management of breast cancer are largely dependent on early diagnosis and timely medical intervention. For late-stage breast cancer, there are very limited treatment options and the prognosis is often poor. However, a number of emerging HER2-targeted ADCs have shown a potential to bring better efficacy and protect patients’ frail bodies from adverse effects. For example, both of Kadcyla (ado-trastuzumab emtansine) and Enhertu (fam-trastuzumab deruxtecan-nxki) are approved ADCs for treating late-stage HER2-positive/high-expressing breast cancer and have demonstrated good efficacy.
- *Combination Therapies.* The observed difficulties in inactivating the significant amount of HER2 proteins on tumor cells with single drugs have driven the development of combinations with HER2-targeted drugs as a component. The combination therapy of trastuzumab, pertuzumab and chemotherapy has shown an improved overall survival benefit in women diagnosed with HER2 high-expressing metastatic breast cancer and has become the standard of care in the U.S. As HER2 over-expressing cancer biology and resistance mechanisms become increasingly studied, combination therapies of HER2-targeted drugs including mAbs with other oncology drugs like chemotherapeutic agents, PD-(L)1 inhibitors, endocrine therapy, and new anti-HER2 agents are being extensively investigated in clinical trials.

Overview of Antibody-Drug Conjugates Therapies

ADC represents a novel therapeutic approach in oncology and functions by selectively delivering potent chemotherapeutic cytotoxins directly to tumor cells, with the goal of maximizing therapeutic activity in tumor cells while minimizing toxicity to healthy cells. An ADC consists of three components: (i) a monoclonal antibody that selectively targets a distinct antigen preferentially expressed on tumor cells or other cells in the tumor microenvironment; (ii) a cytotoxic chemotherapy payload that kills the target cell; and (iii) a linker that joins the two.

While the traditional chemotherapies are unable to distinguish healthy cells from tumor cells, ADCs possess unique targeting capabilities and have shown promising clinical trial results, making them a promising treatment option for cancer patients.

As of May 2020, the FDA has approved nine ADC drugs. In the U.S., Kadcyla, an ADC drug containing trastuzumab and emtansine, is considered the standard second-line treatment for HER2 high-expressing metastatic breast cancer patients who received trastuzumab, pertuzumab and taxane in the first-line treatment. In China, there are currently only two ADC products, Kadcyla and Adcetris, approved by NMPA in 2020. As of the Latest Practicable Date, there were 26 ADC agents under clinical trials in China. In addition to HER2, other targets of ADC products include c-Met, EGFR, Trop 2 and CD 20. Major players in China’s ADC market include ourselves, Roche and Bio-Thera.

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Therapeutic Advantages of ADCs

ADCs are an important part of the cancer treatment paradigm with the following advantages:

- *Greater/Superior Efficacy.* ADCs combine antigen-specific antibodies with potent cytotoxic chemotherapy payloads. They can target tumor cells or other cells in the tumor microenvironment with greater precision and selectivity than traditional chemotherapies could, and as a result, they tend to demonstrate higher efficacy than mAbs alone. This combinational design allows ADCs to use potent cytotoxins at dose levels that otherwise would not be tolerable. As a result, ADCs represent a highly effective treatment approach while maintaining manageable side effects.
- *Better Safety.* Traditional chemotherapies are unable to distinguish between healthy cells and tumor cells. As a result, these therapies typically have a narrow therapeutic window (i.e., the dose range that can treat disease effectively without causing unacceptable toxic side effects). In contrast, the ADCs’ targeted delivery of the cytotoxic agent to tumor cells maximizes the antitumor effect. It also minimizes normal tissue exposure that results in an improved therapeutic index and less damage to the surrounding, healthy tissue.
- *Potential Synergistic Activity in Combination Therapies.* ADC represents a promising component for novel combo-therapies and helps to expand cancer treatment options. Combination therapies involving ADCs have shown enhanced anti-tumor efficacy as a result of the synergistic effects between the components. Combining ADC with other therapies such as chemotherapy has been proved to be effective to maximize ADC’s therapeutic outcome in cancer treatment. Approaches such as dosing regimen alteration or novel biomarkers selection enable regimens with better versatility, which can either optimize the treatment efficacy or expand patient pool based on different cancer indication. By incorporating the novel ADCs to traditional approaches, the combination therapies may provide clinical benefits to a much larger patient population in oncology treatment.
- *Large Addressable Patient Population.* mAb-based drugs are a major type of biologics therapies. However, most of them have not been able to generate a high response rate even in a large population of patients who have the targeted gene mutation, which is largely due to the limited tumor-killing effect of mAb-based drugs alone. In comparison, the potent payloads of ADCs may turn these patient populations into potentially addressable target patient populations. Moreover, ADCs have unique potentials in relapsed or refractory patients. Traditional therapies typically have limited effectiveness for patients who exhibit relapsed or refractory cancers. In contrast, some ADCs have proven efficacious in such patient populations while maintaining a manageable tolerability profile. Therefore, ADCs represent an important part of the cancer treatment paradigm, further expanding the treatment options available to patients suffering from relapsed or refractory cancers.

INDUSTRY OVERVIEW

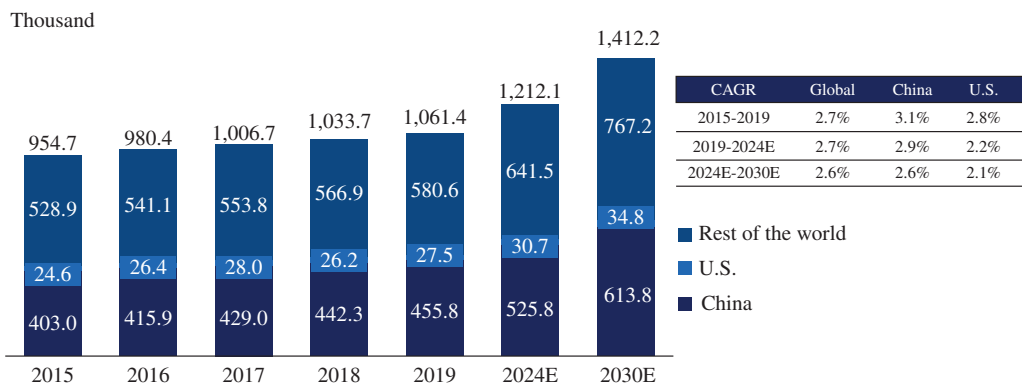
Gastric Cancer

Gastric cancer is a disease in which the cells forming the inner lining of the stomach become abnormal and start to divide uncontrollably, forming a cancerous tumor mass. Symptoms and outcomes of the disease vary depending on the location of the cancer. Gastric cancer is one of the leading causes of cancer deaths in the world. Annually, almost one million people will be diagnosed worldwide with gastric cancer and over 700,000 will die from the disease. More than 90% of gastric cancers are caused by adenocarcinomas, malignant cancers that originate in glandular tissues. Approximately 22% of gastric cancer patients are HER2 high-expressing.

Gastric Cancer Incidence Globally, in the U.S. and in China

Gastric cancer affects a large population worldwide. The number of new diagnosis for gastric cancer globally increased from 1.0 million in 2015 to 1.1 million in 2019 (including approximately 455,800 in China). The total number of new gastric cancer patients worldwide is forecasted to reach 1.2 million by 2024 (including approximately 525,800 in China), and to 1.4 million by 2030 (including approximately 613,800 in China). Approximately 24% of gastric cancer patients have HER2 low-expression and are ineligible for currently approved HER2-targeted therapies that treat gastric cancer with HER2 high-expression, which indicates large market potential for novel anti-HER2 drug candidates that treat cancers with HER2 low-expression.

Gastric Cancer Incidence Globally, in the U.S. and in China (2015-2030E)



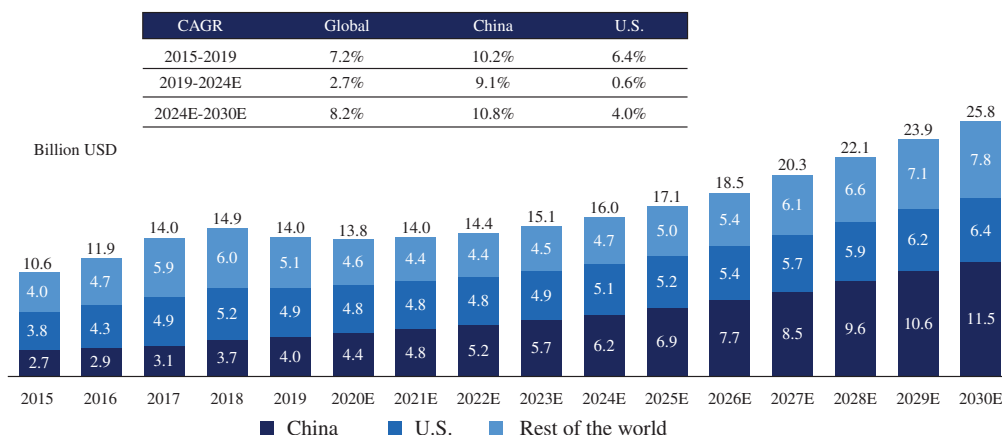
Source: Frost & Sullivan

Gastric Cancer Drug Market Size Globally, in the U.S. and in China

According to Frost & Sullivan, the market for global gastric cancer drug market is expected to reach US\$25.8 billion in 2030 (including US\$6.4 billion in the U.S.) from US\$14.0 billion in 2019 (including US\$4.9 billion in the U.S.). The gastric cancer drug market in China reached US\$4.0 billion in 2019 and is expected to grow to US\$6.2 billion in 2024, representing a CAGR of 9.1%. This market is expected to increase at a CAGR of 10.8% from 2024 to 2030.

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Gastric Cancer Drug Market Size Globally, in the U.S. and in China (2015-2030E)



Note: The market size presented covers approved uses only and does not reflect any off-label use.

Source: Frost & Sullivan

Treatment Paradigm for Gastric Cancer in the U.S. and in China

Surgery is the main method in treating gastric cancer from stage I to III, while chemotherapy and targeted therapy are adopted to treat advanced metastatic gastric cancer in the U.S and China. In particular, the addition of trastuzumab to chemotherapy significantly improved response, progression free survival and overall survival in advanced gastric cancer patients with HER2 positive disease, defined by IHC 3+ or FISH+. The average HER2-positivity rate for the U.S. is similar to that observed in China. To date, trastuzumab is the first and only targeted agent in gastric cancer approved by authorities in the U.S. and in China. It is indicated in combination with cisplatin and capecitabine or 5-fluorouracil in the first line treatment of HER2 high-expressing advanced gastric cancer; strong HER2 expression with IHC3+ or IHC2+ plus FISH+ is required by the Chinese guidelines.

When gastric cancer progresses to stage IV, the treatment strategies switch to targeted therapies in combination with chemotherapies to relieve symptoms and improve the quality of life. In the U.S., the treatment paradigm for stage IV gastric cancer includes a combination of trastuzumab and first-line chemotherapy agents (such as fluoropyrimidine and cisplatin) in the first line, a combination of ramucirumab and paclitaxel in the second line, and pembrolizumab in the third line. In China, the treatment paradigm for stage IV gastric cancer includes a combination of trastuzumab and first-line chemotherapy agents (such as fluoropyrimidine/capecitabine and cisplatin) in the first line, a combination of trastuzumab and second-line chemotherapy regimen (excluding anthracyclines) in the second line, and apatinib or PD-1 monoclonal antibody in the third line.

INDUSTRY OVERVIEW

Competitive Landscape of Biologics Treatment of Gastric Cancer in the U.S. and in China

According to Frost & Sullivan, many innovative biologic drugs that have proved to have superior efficacy and less side effects for treating gastric cancer were approved for market use in the U.S. but only two innovative biologic drug, Herceptin (trastuzumab), and Opdivo (nivolumab), are available in China. Others, such as Cyramza (ramucirumab) and Keytruda (pembrolizumab) have been approved in the U.S. but not in China. The following tables illustrate the competitive landscape of HER2-targeted innovative biologic gastric cancer treatment in the U.S. and in China.

Marketed Gastric Cancer Innovative Biologics Treatment in the U.S. and/or in China

Target	Generic Name	Product	Company	FDA Approval Date	Treatment Line in the U.S.	Annual Cost in the U.S. ⁽¹⁾	NMPA Approval Date	Treatment Line in China	Annual Cost in China ⁽¹⁾	Patent Expiration Date
						(USD)			(RMB)	
PD-1	nivolumab	Opdivo	BMS	–	–	–	2020	3L	478,492	2027
PD-1	pembrolizumab	Keytruda	MSD	2017	≥2L	183,060	–	–	–	2028
VEGFR2	ramucirumab	Cyramza	Lilly	2014	≥2L	162,630	–	–	–	2026
HER2	trastuzumab	Herceptin	Roche	2010	1L	68,712	2012	1L	82,500	2019

Pipelines for HER2-targeted Innovative Biologics Gastric Cancer Treatment in the U.S.

Target	Generic Name	Company	Indications	Status	Date ⁽²⁾
HER2	pertuzumab	Roche	HER2 high-expressing GC (IHC 3+)	Phase III	Jan-2013
HER2	margetuximab	MacroGenics/ ZaiLab	HER2+ over-expressing GC (IHC 2+/3+)	Phase II/III	Sep-2019
HER2	trastuzumab deruxtecan	Daiichi Sankyo, AstraZeneca	HER2+ over-expressing GC (IHC 2+/3+)	Phase II	Jul-2019

Pipelines for HER2-targeted Innovative Biologics Gastric Cancer Treatment in China

Target	Generic Name	Company	Indications	Status	Date ⁽²⁾
HER2	pertuzumab	Roche	HER2 over-expressing GC (IHC 2+/3+)	Phase III	Apr-2014
HER2	disitamab vedotin	RemeGen (榮昌生物)	HER2 over-expressing GC (IHC 2+/3+)	Pivotal Phase II	Jul-2018
HER2	–	Alphamab (康寧傑瑞)	HER2 over-expressing GC (IHC 2+/3+)	Phase II	May-2019
HER2	–	Hangzhou DAC Biotech (杭州多禧生物科技)	HER2 over-expressing GC	Phase I	Jun-2019
HER2	–	Zhejiang Medicine/ Ambrx (浙江醫藥)/ Ambrx	HER2 over-expressing GC (IHC 2+/3+)	Phase I	Apr-2019
HER2	–	Beijing Mabworks Biotech (北京天廣實)	HER2 high-expressing GC (IHC 3+)	Phase I	Mar-2019

Notes:

- (1) The annual cost refers to the average wholesale acquisition cost for GC patients on a 365-day-basis based on the recommended dosage for each patient.
- (2) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

For the competitive advantages of disitamab vedotin, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Disitamab vedotin (RC48) – Competitive Advantages of Disitamab Vedotin” in this document.

INDUSTRY OVERVIEW

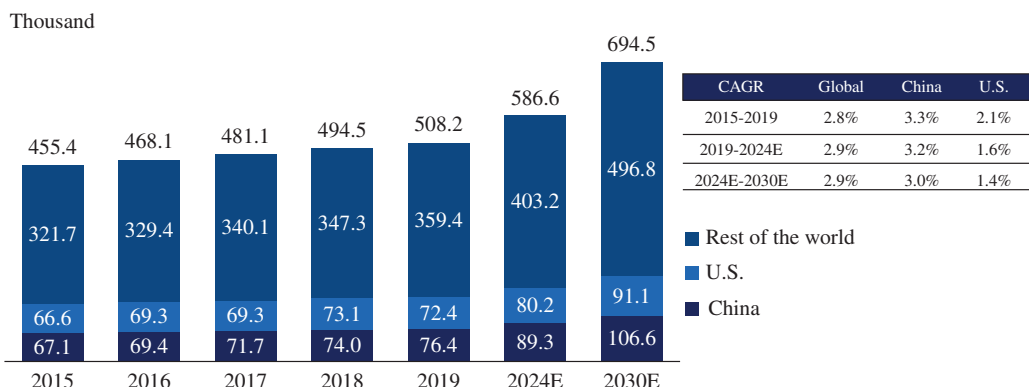
Urothelial Cancer

Urothelial cancer (UC) is a type of cancer that starts from the urothelial cells on the urinary tract. Symptoms include blood in the urine, pain with urination and lower back pain. FGFR aberrations were found in 31.7% of UC cases. Approximately 48% of UC patients have a HER2 expression level, and among them, approximately 20% of UC patients have a low HER2 expression level. Though UC can be treated at an early stage, the treatment method depends on the clinical stage of the cancer and the degree of metastasis.

UC Incidence Globally and in the U.S., in the U.S. and in China

UC, which is mostly comprised of bladder cancer, affects a large and underserved patient population worldwide. The global new cases of UC increased from approximately 455,400 in 2015 to approximately 508,200 in 2019, which is projected to reach approximately 586,600 in 2024 at a CAGR of 2.9% from 2019, and to approximately 694,500 in 2030 at a CAGR of 2.9% from 2024. In China, the new cases of UC grew from approximately 67,100 in 2015 to approximately 76,400 in 2019, and is expected to reach approximately 89,300 in 2024 at a CAGR of 3.2% from 2019, and to approximately 106,600 in 2030 at a CAGR of 3.0% from 2024.

UC Incidence Globally, in the U.S. and in China (2015-2030E)



Source: Frost & Sullivan

Market Size of UC Drug Market Globally, in the U.S. and in China

According to Frost & Sullivan, the market for global UC therapeutics market is expected to reach US\$11.9 billion in 2030 from US\$2.5 billion in 2019. China’s UC therapeutics market reached US\$150.9 million in 2019 and is expected to grow to US\$711.9 million in 2024, representing a CAGR of 36.4%. This market is expected to increase at a CAGR of 16.4% from 2024 to US\$1.8 billion in 2030.

Treatment Paradigm for UC

The disease tends to progress from its early stages to local recurrence, metastasis, and ultimately potentially death. The general goal of therapy is to detect and treat the disease in its early stages so as to prevent such progression.

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UC is the seventh leading cause of male cancer incidence in China. UC imposes unique challenges as it is more common in adults aged over 50 years and recurs frequently. Muscle-invasive UC is also more difficult to treat and is associated with lower five-year survival rate. Current treatment options for muscle-invasive UC outside China include first-line treatment such as cystectomy, radiotherapy, chemotherapy and checkpoint inhibitors such as atezolizumab and pembrolizumab, and second-line treatment such as chemotherapy with gemcitabine and cisplatin. In China, chemotherapy remains the first-line treatment for UC. Limited by its side effects, chemotherapy has not been approved for treatment beyond first-line in China. Moreover, chemotherapy for UC has a very short median progression-free survival (mPFS) of one to two months, which dramatically threatens patients' survival and represents a significant unmet medical need.

Competitive Landscape of Biologics Treatment of UC in the U.S. and in China

The FDA has approved six immunotherapy drugs known as checkpoint inhibitors: Padcev (enfortumab vedotin), Bavenico (avelumab), Imfinzi (durvalumab), Tecentriq (atezolizumab), Keytruda (pembrolizumab) and Opdivo (nivolumab) for the treatment of UC. Tislelizumab is the only biologics drug approved by the NMPA (in 2020) for the treatment of UC in China. The following tables illustrate the competitive landscape of HER2-targeted innovative biologics treating UC in the U.S. and in China.

Marketed UC Innovative Biologics Treatment in the U.S.

Target	Generic Name	Product	Company	FDA Approval Date	Annual Cost ⁽¹⁾	Treatment Line	NMPA Approval Date	Annual Cost in China ⁽¹⁾	Treatment Line	Patent Expiration Date
					(USD)			(RMB)		
NECTIN4	enfortumab vedotin	Padcev	Astellas Pharma/Seattle Genetics	2019	323,505	≥2L	-	-	-	2031
PD-L1	avelumab	Bavencio	Pfizer	2017	132,678	≥2L	-	-	-	2032
PD-L1	durvalumab	Imfinzi	AstraZeneca	2017	147,992	≥2L	-	-	-	2030
PD-1	nivolumab	Opdivo	BMS	2017	178,880	≥2L	-	-	-	2027
PD-1	pembrolizumab	Keytruda	MSD	2017	183,060	≥1L	-	-	-	2028
PD-L1	atezolizumab	Tecentriq	Roche	2016	172,944	≥1L	-	-	-	2030
PD-1	tislelizumab	Baize'an	BeiGene (百濟神州)	-	-	-	2020	384,768	≥2L	2033

Major HER2-Targeted Innovative Biologics Pipelines for UC Treatment in the U.S.

Target	Generic Name	Company	Indications	Status	Date ⁽²⁾
HER2	disitamab vedotin	RemeGen (榮昌生物)	HER2-expressing UC	Phase II	Apr-2020

Major HER2-Targeted Innovative Biologics Pipelines for UC Treatment in China

Target	Generic Name	Company	Indications	Status	Date ⁽²⁾
HER2	disitamab vedotin	RemeGen (榮昌生物)	HER2 low- to non-expressing UC	Phase II	Dec-2019
			HER2 over-expressing UC (IHC 2+/3+)	Pivotal Phase II	Jan-2019

Notes:

- (1) The annual cost refers to the average wholesale acquisition cost for UC patients on a 365-day-basis based on the recommended dosage for each patient.
- (2) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

INDUSTRY OVERVIEW

For the competitive advantages of disitamab vedotin, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Disitamab Vedotin (RC48) – Competitive Advantages of Disitamab Vedotin” in this document.

Breast Cancer

Breast cancer is the second-most common cancer worldwide, with an estimated 2.1 million new cases diagnosed per year. Breast cancer typically is staged (Stage 0-IV) based on the size of the tumor, whether or not the tumor is invasive, whether or not the cancer is in the lymph nodes, and whether or not the cancer has spread (metastasized) to other parts of the body beyond the breast.

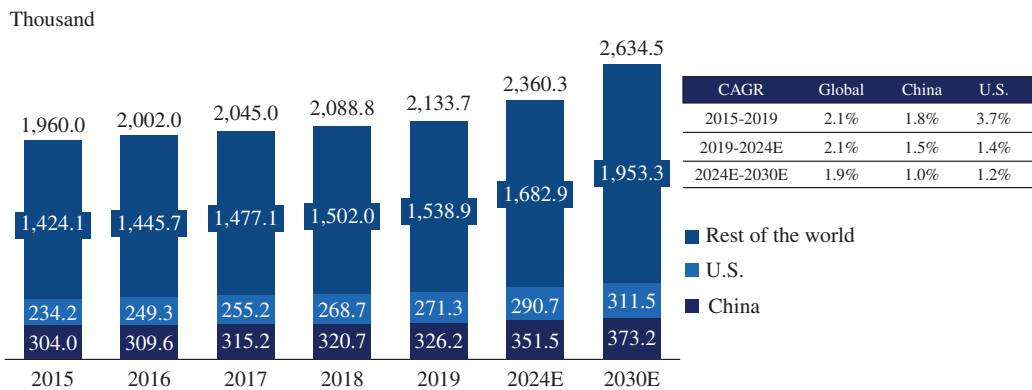
Breast cancer is a heterogeneous disease comprising of several molecular subtypes, which are commonly grouped into clinical subtypes based on receptor status. Receptors that are assessed in standard clinical practice include the estrogen receptor (ER) and progesterone receptor (PgR), collectively the hormone receptors (HR), and HER2. Breast cancers generally are categorized by the presence or absence of these receptors. The most common type of breast cancer is HER2 low-expressing, accounting for approximately 50% of newly diagnosed cases.

Breast cancer is one of the major indications of HER2-targeted therapies that have been approved for marketing or are in clinical development. Most of these therapies target breast cancer patients with a high expression level of HER2. However, approximately 71% of HER2-expressing breast cancer patients have a low HER2 expression level, which presents a large market potential for novel anti-HER2 drug candidates.

Breast Cancer Incidence Globally, in the U.S. and in China

According to Frost & Sullivan, the number of new cases of breast cancer diagnosis globally increased from 2.0 million in 2015 to 2.1 million in 2019 (including approximately 271,300 in the U.S. and approximately 326,200 in China), and it is forecasted to reach 2.3 million by 2024 (including approximately 290,700 in the U.S. and approximately 351,500 in China), and to 2.6 million by 2030 (including approximately 311,500 in the U.S. and approximately 373,200 in China).

Breast Cancer Incidence Globally, in the U.S. and in China (2015-2030E)



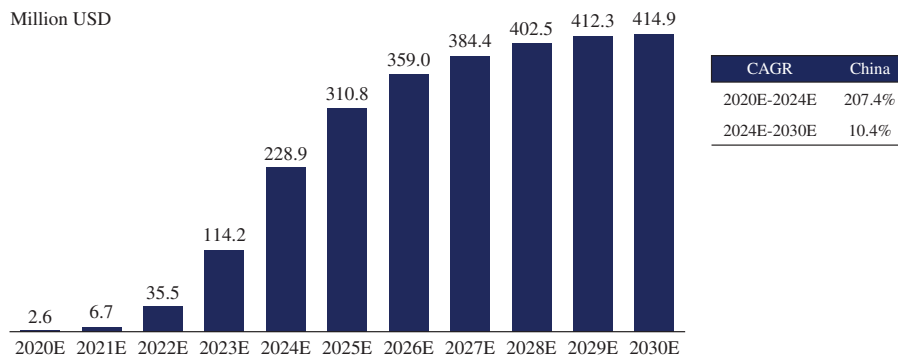
Source: Frost & Sullivan

INDUSTRY OVERVIEW

Market Size of ADCs for HER2-Expressing Breast Cancer in China

The ADCs market for HER2-positive breast cancer is expected to be a fast-growing segment of the breast cancer drug market in China. In January 2020, Kadcylla was approved by NMPA, becoming the first ADC product in China. This market is expected to increase from US\$2.6 million in 2020 to US\$228.9 million in 2024, representing a CAGR of 207.4%, and is expected to reach US\$414.9 million in 2030.

Market Size of ADCs for HER2-Expressing Breast Cancer in China (2020E-2030E)



Source: Frost & Sullivan

Treatment Paradigm for Breast Cancer in the U.S. and in China

In the U.S., ADC drug, trastuzumab emtansine (T-DM1), is considered as the standard second-line treatment for patients with HER2-expressing metastatic breast cancer who previously received trastuzumab, pertuzumab or taxane in the first-line therapy. In comparison, chemo-combo therapies which have been recommended as third-line treatment in the U.S. are still adopted as the second-line in China. Besides Roche’s Kadcylla, which received marketing approval from the NMPA for early HER2 positive/high-expressing breast cancer in January 2020, there has been no other ADC approved in China so far. In particular, there are no treatment options for breast cancer patients that have low to intermediate HER2 expression level.

Competitive Landscape of Biologics Treatment of Breast Cancer in the U.S. and in China

Trastuzumab and pertuzumab were the two most widely prescribed anti-HER2 monoclonal antibodies in the U.S. and in China. There were a number of anti-HER2 innovative biologic drug candidates in clinical trials in the U.S. and in China. A summary of the competitive landscape of Phase II clinical-stage or more advanced HER2-targeted innovative biologics treating breast cancer in the U.S. and in China is set forth below.

INDUSTRY OVERVIEW

Marketed HER2-targeted Breast Cancer Innovative Biologics Treatment in the U.S. and in China

Target	Generic Name	Product	Company	Indications	FDA Approval Date	NMPA Approval Date	Patent Expiration Date
HER2	inetetamab	Cipterbin	Sunshine Guojian (三生國健)	HER2 over-expressing BC (IHC 2+/3+)	–	2020	2029
HER2	ado-trastuzumab emtansine pertuzumab	Kadcyla	Roche	HER2 over-expressing BC (IHC 2+/3+)	2013	2020	2023
HER2		Perjeta	Roche	HER2 over-expressing BC (IHC 2+/3+)	2012	2018	2024
HER2	trastuzumab	Herceptin	Roche	HER2 over-expressing BC (IHC 2+/3+)	1998	2002	2019

Competitive Pipelines of HER2-targeted Breast Cancer Innovative Biologics in the U.S.

Target	Generic Name	Company	Indications	Status	Date ⁽¹⁾
HER2	margetuximab	MacroGenics/ Zai Lab	HER2-expressing BC (IHC 1+/2+)	BLA Submission	Dec-2019
HER2	trastuzumab deruxtecan	Daiichi Sankyo/ AstraZeneca	HER2-expressing BC (IHC 1+/2+/3+)	Phase III	Nov-2018
Immunostimulants, HER2	cancer vaccine E75	Galena Biopharma	HER2-expressing BC (IHC 1+/2+)	Phase III	Nov-2011
HER2	trastuzumab duocarmazine	Byondis	Metastatic BC	Phase III	Aug-2017

Competitive Pipelines of HER2-targeted Breast Cancer Biologics in China

Target	Generic Name	Company	Indications	Status	Date ⁽¹⁾
HER2	–	TOT Biopharm (東曜藥業)	HER2-positive BC (IHC 3+)	Phase III	Jun-2020
HER2	disitamab vedotin	RemeGen (榮昌生物)	HER2-positive BC (IHC 1+/2+)	Phase III	May-2020
HER2	trastuzumab deruxtecan	Daiichi Sankyo, AstraZeneca	HER2-expressing BC (IHC 3+)	Phase III	Sep-2019
HER2	anti-HER2 ADC	Bio-Thera (百奧泰)	HER2-positive BC (IHC 3+)	Phase III	Feb-2018
HER2	margetuximab	MacroGenics/ ZaiLab	HER2-expressing BC (IHC 1+/2+)	Phase II	Feb-2020
HER2	–	Alphamab (康寧傑瑞)	HER2-expressing BC (IHC 1+/2+/3+)	Phase II	Nov-2019

Note:

(1) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

For the competitive advantages of disitamab vedotin, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – Disitamab Vedotin (RC48) – Competitive Advantages of Disitamab Vedotin” in this document.

INDUSTRY OVERVIEW

OPHTHALMOLOGY MARKET

The ophthalmology market is divided into three main treatment segments: ophthalmic drugs, vision care products and surgical/ophthalmic equipment. The ophthalmic drug segment represents a large and growing segment within the ophthalmology market. According to Frost & Sullivan, the global ophthalmic drug market is expected to increase from US\$33.7 billion in 2019 to US\$40.2 billion in 2024, representing a CAGR of 8.0% during this period. China’s ophthalmic drug market is expected to experience similar growth from US\$2.8 billion in 2019 to US\$5.9 billion by 2024, representing a CAGR of 8.0%. The drivers of this growth include the increasing numbers of elderly people and the consequent escalating occurrence of ophthalmic diseases, which is expected to stimulate demand for new ophthalmic product introductions to the market.

Wet Age-related Macular Degeneration

Overexpression of vascular endothelial growth factor (VEGF) in ocular tissues is central to the pathogenesis and clinical manifestations of wet age-related macular degeneration (wet AMD). VEGF is a protein produced by cells that stimulates the formation of new blood vessels, a process called neovascularization, and induces vascular permeability. In wet AMD, fluid that exits from blood vessels causes swelling, or edema, of the retina and loss of vision. This loss of vision can be reversed if treated early with an anti-VEGF agent to suppress VEGF signalling. Delayed treatment or under treatment can result in permanent retinal damage and blindness. To reach effective ocular tissue concentrations, these agents must be injected into the vitreous humor, the jelly-like substance that fills the area between the lens and retina. These injections must occur at regular intervals to maintain anti-VEGF effects. The fibroblast growth factors (FGF) are a family of cell signalling proteins with a wide variety of effects, most notably as crucial elements for vascular endothelial cells, vascular smooth muscle cells, and extracellular fibroblasts development. To date, the mechanism of FGF in wet AMD development has not been fully understood, but it has been observed that FGF stimulates the pathologic neovascular formation on choroid layer, and FGF expression level elevates significantly in ocular neovascular diseases such as wet AMD.

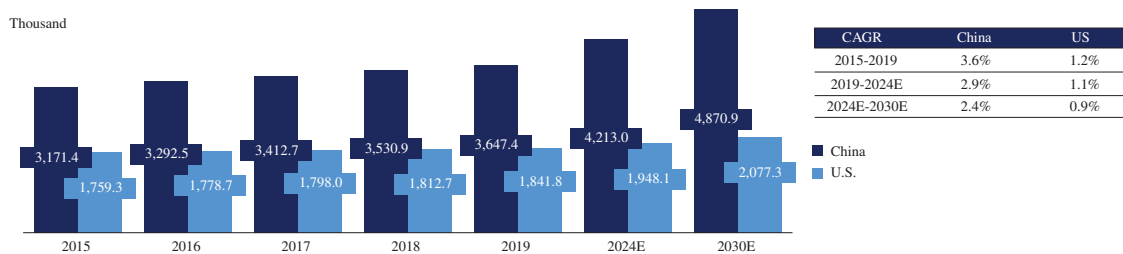
Driven by the improved efficacy of biologic drugs, external eye drops administration and the development of gene therapies, China’s wet AMD drug market is expected to experience growth from US\$0.3 billion in 2019 to US\$0.9 billion by 2024, representing a CAGR of 28.4%.

INDUSTRY OVERVIEW

Prevalence of wet AMD in the U.S. and in China

According to Frost & Sullivan, the number of wet AMD patients in the U.S. was 1.8 million in 2019, and it is forecasted to reach 1.9 million by 2024, and to 2.1 million by 2030. In China, the prevalence of wet AMD grew from 3.2 million in 2015 to 3.6 million in 2019 at a CAGR of 3.6%, and it is expected to further grow to 4.2 million by 2024, representing a CAGR of 2.9% between 2019 and 2024. The following chart sets forth the number of wet AMD patients in the U.S. and China from 2015 to 2030.

Prevalence of wet AMD in the U.S. and in China (2015-2030E)

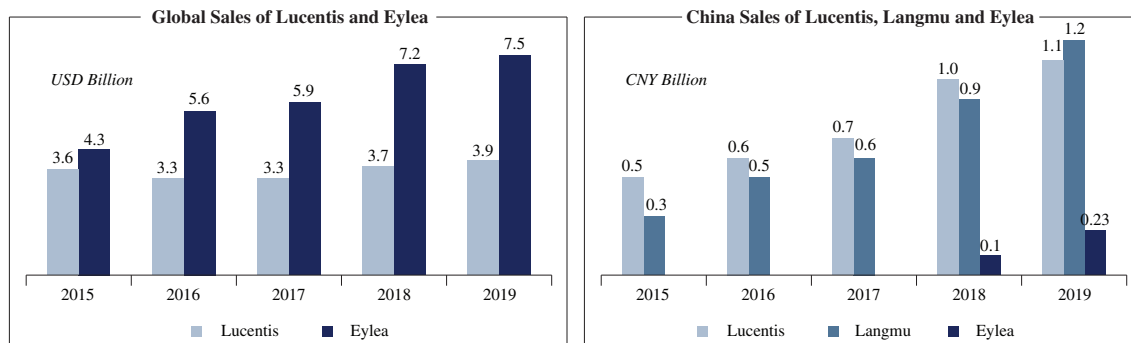


Source: Frost & Sullivan

Market Size of wet AMD Treatment Market Globally, in the U.S. and in China

Annual global sales of Lucentis (ranibizumab) and Eylea (afibercept) for all indications totalled approximately US\$11.5 billion in 2019 (including US\$6.5 billion in the U.S.), a substantial majority of which were in connection with the treatment of wet AMD and DME. Langmu (conbercept) is currently approved and marketed drug for the treatment of wet AMD and DME in China.

The following chart sets forth the sales revenue of Lucentis (ranibizumab) and Eylea (afibercept) globally and the sales revenue of Lucentis (ranibizumab), Langmu (conbercept) and Eylea (afibercept) in China as a treatment for wet AMD from 2015 to 2019:



Note:

(1) Translation from Euro amounts to U.S. dollars was made at the rate of US\$1.1295 to EUR1.00.

Source: Frost & Sullivan

INDUSTRY OVERVIEW

Competitive Landscape of Biologics Treatment of wet AMD in the U.S. and in China

Lucentis (ranibizumab), marketed by Roche in the U.S. and by Novartis outside the U.S., and Eylea (aflibercept), marketed by Regeneron in the U.S. and by Bayer outside the U.S., are anti-VEGF therapies that have become the standard of care for treating wet AMD. Langmu (conbercept) is currently approved and marketed for the treatment of wet AMD in China. The following tables illustrate the competitive landscape of innovative biologics treating wet AMD in the U.S. and in China.

Marketed Innovative Biologics for wet AMD Treatment in the U.S. and in China

Target	Generic Name	Product	Company	FDA Approval Date	Annual Cost in the U.S. ⁽¹⁾	NMPA Approval Date	Annual Cost in China ⁽¹⁾	Patent Expiration Date
					(USD)		(RMB)	
VEGF	ranibizumab	Lucentis	Novartis/	2006	24,540	2011	47,400	2020
VEGF	aflibercept	Eylea	Roche Bayer	2011	17,469	2018	36,900	2020
VEGF	conbercept	Langmu	Kanghong (康弘藥業)	-	-	2013	24,960	2026
VEGF	brovacizumab	Beovu	Novartis	2019	15,528	-	-	2029

Pipeline Innovative Biologics for wet AMD Treatment in the U.S.

Target	Generic Name	Product	Company	Status	Date ⁽²⁾
VEGF-A	abicipar Pegol	AGN-150998	Abbvie	BLA Submission	May-2018
VEGF-A, Ang-2	faricimab	RG7716	Roche	Phase III	Jan-2019
VEGF	conbercept	KH-902	Kanghong (康弘藥業)	Phase III	Aug-2018

Pipeline Innovative Biologics for wet AMD Treatment in China

Target	Generic Name	Product	Company	Status	Date ⁽²⁾
VEGF-A, Ang-2	faricimab	RG7716	Roche	Phase III	Jan-2020
VEGF	brovacizumab	RTH258	Novartis	Phase III	Oct-2019
VEGF, FGF	-	RC28	RemeGen (榮昌生物)	Phase Ib	Jan-2020

Notes:

- (1) The annual cost refers to the average wholesale acquisition cost for wet AMD patients on a 365-day-basis based on the recommended dosage for each patient.
- (2) Date denotes the date on which the relevant status was publicly disclosed.

Source: Frost & Sullivan

For the competitive advantages of RC28, please refer to the paragraphs headed “Business – Our Drug Candidates – Our Core Drug Candidates – RC28 – Competitive Advantages of RC28” in this document.

INDUSTRY OVERVIEW

Diabetic Macular Edema

Diabetic macular edema (DME), a swelling of the retina that is a common cause of vision loss in patients with diabetic retinopathy (DR). DME occurs when fluid and protein deposits collect on or under the macula of the eye (a yellow central area of the retina) and causes it to thicken and swell (edema). The swelling may distort a person’s central vision, because the macula holds tightly packed cones that provide sharp, clear, central vision to enable a person to see detail, form, and color that is directly in the center of the field of view.

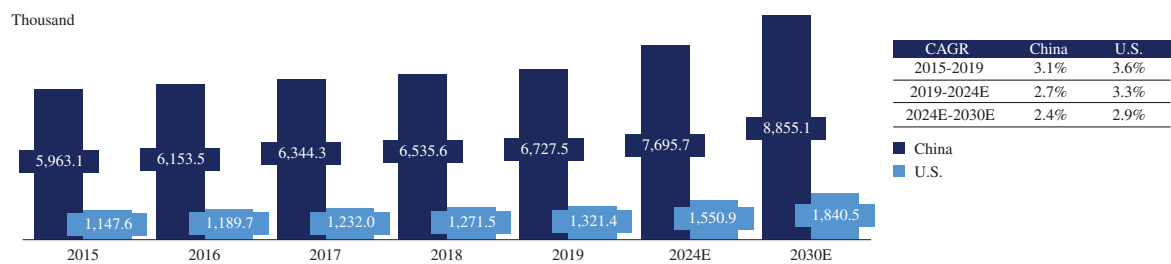
Once DME is present, the standard of care is frequent, monthly or every other month, injections of drugs into the eye that target vascular endothelial growth factor or VEGF. Intravitreal injections of anti-VEGF agents such as Lucentis (ranibizumab) or Eylea (aflibercept) are effective at reducing retinal thickness; however, the fluid and swelling often recur with discontinued therapy. These anti-VEGF therapies rarely provide a complete solution to the underlying vascular problem associated with DME. In addition, both ranibizumab and aflibercept are associated with increased risks of blood clots in the arteries.

There are a number of additional therapies that have been used to treat DME including corticosteroid anti-inflammatories such as triamcinolone, fluocinolone, and dexamethasone, which are all administered via injections into the eye. Novel sustained release corticosteroids such as Illuvien (fluocinolone), marketed by Alimera, and Ozurdex (dexamethasone), marketed by Allergan, have recently been approved for use in DME, which reduce the number of injections required to obtain and maintain clinical responses.

Prevalence of DME in the U.S. and in China

According to Frost & Sullivan, the prevalence of DME in the U.S. grew from 1.1 million in 2015 to 1.3 million in 2019 at a CAGR of 3.5%, and it is expected to further grow to 1.6 million by 2024, representing a CAGR of 3.4% between 2019 and 2023. The number of DME patients in China increased from 6.0 million in 2015 to 6.7 million in 2019, and it is forecasted to reach 7.7 million by 2024, and to 8.9 million by 2030. The following chart sets forth the number of DME patients in the U.S. in China from 2015 to 2030.

Prevalence of DME in the U.S. and in China (2015-2030E)



Source: Frost & Sullivan

INDUSTRY OVERVIEW

Market Size of DME Treatment Market in China

According to Frost & Sullivan, China’s DME therapeutics market reached US\$85.3 million in 2019 and is expected to grow to US\$767.8 million in 2024, representing a CAGR of 55.2%. This market is expected to increase at a CAGR of 23.8% from 2024 to US\$2.8 billion in 2030.

Competitive Landscape of Biologics Treatment of DME in the U.S. and in China

Lucentis (ranibizumab), marketed by Roche in the U.S. and by Novartis outside the U.S., and Eylea (aflibercept), marketed by Regeneron in the U.S. and by Bayer outside the U.S., are anti-VEGF therapies that have become the standard of care for treating severe forms of DME. Langmu (conbercept) has been approved and marketed for the treatment of DME in China.

REPORT COMMISSIONED BY FROST AND SULLIVAN

In connection with the [REDACTED], we have engaged Frost & Sullivan to conduct a detailed analysis and prepare an industry report on the therapeutic biologics market in China and the United States. Frost & Sullivan is an independent global market research and consulting company which was founded in 1961 and is based in the United States. Services provided by Frost & Sullivan include market assessments, competitive benchmarking and strategic and market planning for a variety of industries. The contract sum to Frost & Sullivan is RMB[REDACTED] for the preparation of the Frost & Sullivan Report. The payment of such amount was not contingent upon our successful [REDACTED] or on the results of the Frost & Sullivan Report. Except for the Frost & Sullivan Report, we did not commission any other industry report in connection with the [REDACTED]. We have included certain information from the Frost & Sullivan Report in this document because we believe such information facilitates an understanding of the biologics market for potential investors. Frost & Sullivan prepared its report based on its in-house database, independent third-party reports and publicly available data from reputable industry organizations. Where necessary, Frost & Sullivan contacts companies operating in the industry to gather and synthesize information in relation to the market, prices and other relevant information. Frost & Sullivan believes that the basic assumptions used in preparing the Frost & Sullivan Report, including those used to make future projections, are factual, correct and not misleading. Frost & Sullivan has independently analyzed the information, but the accuracy of the conclusions of its review largely relies on the accuracy of the information collected. Frost & Sullivan research may be affected by the accuracy of these assumptions and the choice of these primary and secondary sources.

REGULATORY OVERVIEW

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

This section summarizes the principal PRC laws, rules and regulations that are relevant to our business.

REGULATORY REGIME

The regulatory authorities of the drug industry in the PRC include: the National Medical Products Administration (國家藥品監督管理局), the National Health Commission (國家衛生健康委員會) and the National Healthcare Security Administration (國家醫療保障局).

The National Medical Products Administration (the “NMPA”), an authority under the State Administration for Market Regulation (國家市場監督管理總局), is the primary regulator for medical products. It is primarily responsible for the supervising and managing drugs, medical devices and cosmetics, including drafting of relevant regulations and policies; undertaking standard management, registration regulation, quality management and post-market risk management for drugs, medical devices and cosmetics; and organizing and guiding the supervision and inspection of drugs, medical devices and cosmetics; undertaking management of qualifications for licensed pharmacists.

The National Health Commission (formerly known as the National Health and Family Planning Commission), is primary national regulator for public health and family planning management. It is primarily responsible for drafting national health policies, supervising and regulating public health, healthcare services, and health emergency systems, coordinating the reform of medical and health system, organizing the formulation of national drug policies and national essential medicine system, launching an early warning mechanism for the monitoring of the use and clinical comprehensive evaluation of medicine as well as the drug shortage, giving suggestions on the pricing policy of national essential medicine, and regulating the operation of medical institutions and practicing of medical personnel.

The National Healthcare Security Administration is an authority directly under the State Council responsible for the management of the healthcare security system. It is primarily responsible for drafting and implementing policies and standards on medical insurance, maternity insurance and medical assistance; supervising and administering the healthcare security funds; organizing the formulation a uniform medical insurance catalogue and payment standards on drugs, medical disposables and healthcare services; and formulating and supervising the implementation of the bidding and tendering policies for drugs and medical disposables.

REGULATORY OVERVIEW

LAWS AND REGULATIONS IN RELATION TO DRUG MANUFACTURER

Drug Manufacturing Permit

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) promulgated by the Standing Committee of the National People’s Congress in September 1984 and lastly amended in August 2019, the state adopts an industry entry permit system for drug manufacturers. the establishment of a drug manufacturer shall be approved and granted with a Drug Manufacturing License (《藥品生產許可證》) by the drug regulatory authority of the people’s government at provincial, autonomous regional or municipal level. The Drug Manufacturing License shall indicate the validity period and the scope of production, and shall be reviewed for renewing upon expiration.

Good Manufacturing Practices

Prior to December 1, 2019, establishment of a new drug manufacturer, construction of new production premise for a drug manufacturer or production of new dosage form are required to submit application for good manufacturing practice certification (GMP certification) with the drug regulatory authority in accordance with the provisions. If the Good Manufacturing Practices are satisfied, a GMP certificate will be issued. Pursuant to the Circular on the Relevant Issues Concerning the Implementation of the Drug Administration Law of the PRC (《關於貫徹實施<中華人民共和國藥品管理法>有關事項的公告》), promulgated by the NMPA on November 29, 2019, and the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》), newly amended in August 2019, since December 1, 2019, the GMP and Good Supply Practice (GSP) certifications have been cancelled, applications for GMP and GSP certifications are no longer accepted, and GMP and GSP certificates are no longer issued. When engaging in drug manufacturing activities, a manufacturer shall comply with the GMP and establish a sound GMP management system, to ensure that the entire process of drug manufacturing maintain to meet the statutory requirements, and meet the GMP requirements enacted by the drug regulatory authority under the State Council in accordance with this law. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The Good Manufacturing Practices (《藥品生產質量管理規範》), promulgated by the Ministry of Health of the PRC (the “MOH”, now known as the National Health Commission) in January 2011, provided guidance for the quality management, organization and staffing, production premises and facilities, equipments, material and products, recognition and inspection, documentation maintenance, manufacture management, quality control and quality assurance, contractual manufacture and contractual inspection for the products, product delivery and recalls of a manufacturer in a systematical manner.

REGULATORY OVERVIEW

LAWS AND REGULATIONS IN RELATION TO NEW DRUG

Application for New Drug Registration

Drug registration refers to an approval process where the NMPA conducts review of the safety, efficacy and quality controllability of the drugs intended for marketing according to the application for drug registration made by an applicant, and decides whether to approve the application. Drug registration applications include new drug application, generic drug application, and imported drug registration application and supplementary application, as well as re-registration application. Pursuant to the provisions of the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), promulgated by the NMPA and came into effect in October 2007, the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) shall apply to applications for drug clinical trials, drug production and drug imports, as well as drug approval, registration inspection and supervision and administration in the PRC.

In accordance with the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), application for new drugs registration refers to application for registration of drugs that have never been previously marketed within the territory of the PRC. Application for changing the dosage form or route of administration, or claiming a new indication for marketed drugs, shall be submitted in compliance with the procedure of a new drug application.

All new drugs must go through four stages before being marketed: non-clinical research and animal testing, application for clinical trial, clinical trial and new drug application.

Non-clinical Research and Animal Testing

The non-clinical safety assessment of drugs for marketing approval shall be conducted in accordance with the Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範》) promulgated by the NMPA in August 2003 and lastly amended in July 2017. The NMPA promulgated the Administrative Measures for the Certification of Good Laboratory Practices for Non-clinical Laboratory Studies (《藥物非臨床研究質量管理規範認證管理辦法》) in April 2007, which specifies the requirements for institutions applying for Good Laboratory Practice (GLP) certification of non-clinical laboratory studies.

According to the Regulations for the Administration of Affairs Concerning Experimental Animals (實驗動物管理條例) promulgated by the State Science and Technology Commission in November 1988 and lastly amended in March 2017 by the State Council, the Administration Measures on Good Practice of Experimental Animals (實驗動物質量管理辦法) jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision in December 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (實驗動物許可證管理辦法(試行)) promulgated by the State Science and Technology Commission and other regulatory authorities in December 2001, performing experimentation on animals requires a Certificate for Use of Laboratory Animals.

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Application for Clinical Trial

After completing the pre-clinical studies, the applicant must obtain approval for clinical trials of drugs (including bioequivalence tests) from the NMPA before the conduction of new clinical drug trials. According to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the NMPA on March 17, 2017, the decision on the approval of clinical trials of drugs enacted by the NMPA can be made by the Center for Drug Evaluation (“CDE”) from May 1, 2017. Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》), latest amended in August 2019, the dossier on a new drug research and development, including the manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data and the samples, shall, in accordance with the regulations of the drug regulatory authority under the State Council be truthfully submitted to the said department for approval before clinical drug trial is conducted. The drug regulatory authority of under State Council shall decide whether to approve the clinical trial application and notify the decision to the clinical trial applicant within 60 business days from the date of accepting the clinical trial application. If the drug regulatory authority of under the State Council fails to do so, the clinical trial application shall be deemed as approval, and if the bioequivalence test is conducted, it is required to report it to the drug regulatory authority under State Council for filing.

Before conducting the clinical trial, the applicant shall file a series of detailed documents with the NMPA, and send a copy to the competent provincial drug administration department. According to the Circular on Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》), which came into effect in September 2013, all clinical trials approved by the NMPA and conducted in the PRC shall complete the clinical trial registration and information disclosure on the Drug Clinical Trial Information Platform. The applicant must complete the initial registration of the trial within one month after obtaining the approval of the clinical trial to obtain the unique registration number of the trial; and complete the subsequent data registration before the first patient is enrolled and submit it for the first time for disclosure.

After obtaining clinical trial approval, the applicant shall choose institutions qualified for clinical trials of the drug to conduct clinical trials. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》), which came into effect in December 2019, if engaging in drug development activities and conducting clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the territory PRC, they shall be conducted in the Drug Clinical Trial Institutions. Drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The national drug regulatory authority is responsible for setting up a filing management information platform for drug clinical trial institutions for registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

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Clinical Trial (Four Phases)

In compliance with the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》), clinical trials are divided into Phase I, Phase II, Phase III and Phase IV:

- Phase I: The preliminary clinical pharmacology and human safety evaluation studies. The purpose is to observe the tolerance degree of human bodies and pharmacokinetics, and to provide a basis for the formulation of dosage regimen.
- Phase II: The preliminary evaluation period on the therapeutic efficacy. The purpose is to preliminarily evaluate the safety and efficacy of a drug on the target patients, including providing the basis for the clinical trial of Phase III and determining a drug administration program. Clinical trial of Phase II may be conducted in various ways including random blind controlled clinical trial complying with the specific study purpose.
- Phase III: The phase to confirm the therapeutic efficacy. The purpose is to further verify the safety and efficacy of a drug for patients with targeted indication, to evaluate the relationship between benefits and risks, and finally to provide sufficient basis for the registration approval of the drug. The trials usually are random, blind and controlled clinical trial with sufficient samples.
- Phase IV: The applicability study period of new drug after been marketed. The objective is to investigate the efficacy and adverse reactions under the conditions of wide use, and to evaluate the relationship between benefits and risks when used by ordinary and special groups of patients and to improve the dosage of the drug.

Clinical trials shall be conducted for the application of new drug registration and shall be implemented in accordance with the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》). The Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) stipulates the criteria for the entire procedure of the clinical trial including pre-clinical trial preparation and the necessary conditions, protection of testees' rights and interests, trial protocols, duties of researchers, duties of sponsors, duties of monitors, trial record and report, data management and statistical analysis, administration of drug products for trial, guarantee for quality, polycentric trials, with reference to the internationally recognized principles.

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New Drug Application

Pursuant to the Administration of Drug Registration (《藥品註冊管理辦法》), upon the completion of Phases I, II, III clinical trials, the applicant can submit application to the NMPA for a new drug manufacture and the NMPA then determines whether to approve the application according to applicable laws and regulations. Applicants must obtain a new drug manufacture approval before they can manufacture the drug and sell it in the PRC market.

- after completion of the clinical trials of drugs, the applicant shall complete the Application Form for Drug Registration, and submit the application materials for production to the drug regulatory authorities at provincial, autonomous regional, or municipal level where it is located, and at the same time, submit the raw materials used for the production of standard products and the related research data of standard materials to the National Institute for Food and Drug Control (“NIFDC”).
- the drug regulatory authorities at provincial, autonomous regional, or municipal level shall conduct formal review over the application materials. If the requirements are satisfied, they will issue an acceptance notice of the drug registration application; if the requirements are not satisfied, they will issue a non-acceptance notice of the drug registration application and explain the reason.
- the drug regulatory authorities at provincial, autonomous regional, or municipal level shall organise an on-site verification of the clinical trial and related original data, conduct a preliminary review of the application materials and give review opinions, all within five days from the date of acceptance of the application. For other drugs in addition to the biological products, it is necessary to take three batches of samples and send a standard review notice to the NIFDC.
- the drug regulatory authorities at provincial, autonomous regional, or municipal level shall submit the review opinion, verification reports and the application materials to the CDE and notify the applicant within the prescribed time.
- the NIFDC shall review the declared drug standards and submit the review opinions to the CDE within the prescribed time, and at the same time, send copies to the competent drug regulatory authority at provincial, autonomous regional, or municipal level and the applicant.
- after receiving the application materials, the CDE shall arrange for pharmaceutical, medical or other professionals within the prescribed time to conduct a review on the application materials and request for supplemental materials and explanations, if necessary.

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- if the requirements are satisfied upon the review, the CDE shall notify the applicant to apply for a production site inspection and report to the Drug Certification Administration Centre (“DCAC”) of the NMPA; if the requirements are not satisfied upon the review, the CDE shall submit the review opinions and relevant materials to the NMPA, and the NMPA shall make a decision of disapproval based on the technical review opinions and issue a Notice of Approval Opinion and explain the reason.
- the applicant shall apply to the DCAC for a site inspection within six months after receiving the notice of production site inspection.
- the DCAC shall arrange an on-site inspection of the facilities for the mass production of the new drug within 30 days after receiving the application for inspection of the production site, to confirm the feasibility of the approved production process. The DCAC also shall take one batch of samples (three batches of samples for the biological products) and send them to the NIFDC to conduct standard review of the drug for inspection, and send the report on production site inspection to the CDE within 10 days after completion of the site inspection.
- the NIFDC shall inspect the collected samples according to approved drug standards, and submit the drug registration and inspection report to the CDE within the prescribed time, and at the same time, send a copy to the drug regulatory authorities at provincial, autonomous regional or municipal level and the applicants.
- the CDE shall form a comprehensive opinion based on the technical review opinion, the report on sample production site inspection and the result of sample examination, and submit to the NMPA together with relevant materials. The NMPA will make an approval decision based on the comprehensive opinion. If the requirements are satisfied, it will issue a New Drug Certificate. If the applicant already holds a Drug Production Permit and meets the production conditions, it will also issue a drug approval number; if the requirements are not satisfied, it will issue a notice of approval opinion and explain reason.

New drug certificate shall not be issued upon approval of application for changing the dose form, but no change on administration route and claiming a new indication for marketed drugs, except for special dose forms including targeted preparation, slow-release and controlled-release preparation.

Reform of Evaluation and Approval System for Drugs

In August 2015, the State Council promulgated the Opinions on the Reform of Evaluation and Approval System for Drugs and Medical Devices and Equipment (關於改革藥品醫療器械審評審批制度的意見) (the “Reform Opinions”), which provides a framework for reforming the evaluation and approval system for drugs and indicates enhancing the standard of approval for drug registration and accelerating the evaluation and approval process for innovative drugs.

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In November 2015, the CFDA (which was cancelled in the institutional reform of the State Council in 2018, its functions of drug supervision and management were inherited by the NMPA, which was established at the same time) promulgated the Circular on Certain Policies for Drug Registration, Evaluation and Approval (《關於藥品註冊審評審批若干政策的公告》) (the “Certain Policies Announcement”), which further clarifies the measures and policies on simplifying and accelerating the approval process on the basis of the Reform Opinions.

Pursuant to the Decision on Adjusting the Approval Procedures of Certain Administrative Approval Items for Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) promulgated by the SFDA in March 2017, the clinical trial approval decisions on drugs (including domestic and imported) can be directly made by the CDE in the name of the SFDA; decisions on approval of drug supplementary applications (including domestic and imported); decisions on approval of re-registration of imported drugs.

The Opinions on Implementing Priority Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》) (the “Encourage Opinions”) promulgated by the SFDA in December 2017 replaces the Opinions on Implementing Priority Review and Approval to Solve the Backlog of Drug Registration Applications (《關於解決藥品註冊申請積壓實行優先審評審批的意見》) promulgated in February 2016, which further clarified that a fast track clinical trial approval or drug registration pathway will be available to innovative drugs.

In addition, the NMPA and National Health Commission jointly promulgated the Circular on Issues Concerning Optimizing Drug Registration Review and Approval (《關於優化藥品註冊審評審批有關事宜的公告》) in May 2018, which further simplified and accelerated the clinical trial approval process.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》) as latest amended in August 2019, the state implements the drug marketing authorization holder system for drug management. The drug marketing authorization holder refers to an enterprise or a drug development institution that has obtained the drug registration certificate. The drug marketing authorization holder shall be responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the law. Other units and individuals engaged in drug development, production, operation, storage, transportation, use and other activities shall bear corresponding responsibilities pursuant to the law.

The drug marketing authorization holder shall establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. The drug marketing authorization holder shall regularly review the quality management system of the drug manufacturer and the drug distributor, and supervise its continuous quality assurance and control capabilities. A drug marketing authorization holder who manufactures drugs on its own shall obtain a drug production license in accordance with

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the law; if it is entrusted with manufacturing, it shall entrust a qualified drug manufacturer. The drug marketing authorization holder and the entrusted manufacturer shall sign the entrustment agreement and quality agreement, and strictly fulfill the obligations stipulated in the agreement. The drug regulatory authority of the State Council has formulated guidelines for the quality of pharmaceuticals entrusted manufacturing, to guide and supervise the drug marketing authorization holder and the entrusted manufacturer to fulfill their drug quality assurance obligations. Blood products, narcotic drugs, psychotropic drugs, medical toxic drugs, and pharmaceutical precursor chemicals shall not be commissioned for manufacturing; except as otherwise provided by the drug regulatory authority of the State Council. Where a drug marketing authorization holder, a drug manufacturer or a drug distributor are entrusted to store or transport drugs, it shall evaluate the trustee's quality assurance capabilities and risk management capabilities, sign a trust agreement with them, agree on drug quality responsibilities and operating procedures, and supervise the trustee.

The drug marketing authorization holder, drug manufacturers, drug distributors and medical institutions shall establish and implement a drug traceability system, provide traceability information in accordance with regulations and ensure that drugs are traceable. The drug marketing authorization holder shall establish an annual reporting system to report the drug production and sales, post-marketing research and risk management to the drug regulatory department of the people's government of the province, autonomous region or municipality in accordance with regulations every year. With the approval of the drug regulatory authority of the State Council, drug marketing authorization holder can transfer drug marketing authorization. The transferee shall have the capabilities of quality management, risk prevention and control and liability compensation to ensure the safety, effectiveness and quality controllability of the drug and fulfill the obligations of the drug marketing authorization holder.

Gathering, Collection and Filing of Human Genetic Resources

The Ministry of Science and Technology and the Ministry of Health promulgated the Interim Measures for the Management of Human Genetic Resources (《人類遺傳資源管理暫行辦法》) in June 1998. The Interim Measures for the Management of Human Genetic Resources set out rules for the protection and use of human genetic resources in China. Pursuant to the Service Guide for Administrative Licensing of Gathering, Collection, Deal, Export and Exit Approval of Human Genetic Resources of Human genetic resources (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) promulgated by the Ministry of Science and Technology in July 2015 and the Notice on the Implementation of the Administrative License for the Gathering, Collection, Deal, Export and Exit of Human Genetic Resources (《關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知》) promulgated by the Ministry of Science and Technology in August 2015, foreign investment sponsors who gather and collect human genetic resources through clinical trials should file a record with the China Human Genetic Resources Management Office through an online system. The Ministry of Science and Technology promulgated the Notice on Optimizing the Administrative Examination and Approval Process of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017, which has simplified the approval process for the gathering and collection of human genetic resources for the listing of drugs in China.

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Pursuant to the Regulations on the Management of Human Genetic Resources of the People’s Republic of China (《中華人民共和國人類遺傳資源管理條例》) promulgated by the State Council in May 2019 and came into effect on July 1, 2019, the state supports the rational use of human genetic resources for scientific research, development of the biomedical industry, improvement of diagnosis and treatment technology, improvement of China’s ability to guarantee biosafety and improvement of the level of people’s health. Foreign organizations, individuals and institutions established or actually controlled by them shall not gather or preserve Chinese genetic resources in China, or provide Chinese genetic resources to foreign countries. In addition, the gathering, preservation, utilization and external provision of Chinese genetic resources shall conform to ethical principles and conduct ethical review in accordance with relevant regulations.

Good Clinical Practice Certification and Compliance with the Good Clinical Practice (GCP)

To improve the quality of clinical trials, the State Food and Drug Administration promulgated the Good Clinical Practice for Drug Trials (《藥物臨床試驗質量管理規範》) (the “GCP”) in August 2003, which aims to ensure that the clinical trials of drugs are standardized and the results are scientific and reliable, protecting the rights and safety of human subjects. The GCP are standard provisions for the entire clinical trial process, including protocol design, organization and implementation, monitoring, auditing, recording, analysing and summarizing and reporting. Pursuant to the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) promulgated by the general offices of the Chinese Communist Party Central Committee and the State Council in October 2017, the qualification of clinical trial institutions shall be subject to record management. Clinical trials should follow GCP and protocols approved by the ethics committee of each research center. Pursuant to the Administrative Regulations for Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) promulgated by the NMPA and National Health Commission and came into effect in December 2019, if engaging in drug development activities and conducting clinical trials of drugs (including bioequivalence test conducted after filing) approved by the NMPA within the territory PRC, they shall be conducted in the Drug Clinical Trial Institutions. Drug clinical trial institutions shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The national drug regulatory authority is responsible for setting up a filing management information platform for drug clinical trial institution for registration and filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

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Administrative Protection and Monitoring Periods for New Drugs

Pursuant to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) and drug classification reform plan, for the purpose of protecting public health, the NMPA may provide for an administrative monitoring period of five years commencing from the date of approval for Type 1 new drugs that have been approved for production to continuously monitor their safety. During the monitoring period of new drug, the NMPA will not accept applications from other applicants for registration of the same product. The only exception is that the NMPA will continue to handle any application if, prior to the commencement of the monitoring period, the NMPA has already approved the applicant’s clinical trial for a similar new drug. If such application conforms to the relevant provisions, the NMPA may approve such applicant to manufacture.

OTHER LAWS AND REGULATIONS IN RELATION TO MEDICAL INDUSTRY

Laws and Regulations in relation to Basic Medical Insurance

Basic Medical Insurance Policy

Pursuant to the Decision on the Establishment of the Urban Employee Basic Medical Insurance Programme (《關於建立城鎮職工基本醫療保險制度的決定》) promulgated by the State Council on December 14, 1998 and the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》) promulgated by the National Development and Reform Commission (the “NDRC”), the Ministry of Human Resources and Social Security (formerly the Ministry of Labor and Social Security), the Ministry of Finance, the Ministry of Health, the NMPA and the State Administration of Traditional Chinese Medicine and came into effect on May 12, 1999, all employers in cities and towns, including enterprises (state-owned enterprises, collective enterprises, foreign-invested enterprises, private enterprises, etc.), institutions, public institutions, social organizations, private non-enterprise units and their employees are required to participate in basic medical insurance. Pursuant to the Guiding Opinions on the Pilot of Basic Medical Insurance for Urban Residents (《關於開展城鎮居民基本醫療保險試點的指導意見》) promulgated by the State Council on July 10, 2007, urban residents (not urban employees) in the pilot areas can voluntarily participate in the basic medical insurance for urban residents. Pursuant to the Opinions on the Integration of the Basic Medical Insurance System for Urban and Rural Residents (《關於整合城鄉居民基本醫療保險制度的意見》) promulgated by the State Council on January 3, 2016, a unified basic medical insurance system for urban and rural residents was established, including the existing urban residents’ medical insurance and all the insured personnel of NCMS, covering all urban and rural residents except those who should be covered by the employee’s basic medical insurance.

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Medical Insurance Catalogue

Pursuant to the Tentative Measures for the Administration of the Scope of Medical Insurance Coverage for Pharmaceutical Products for Urban Employee (《城鎮職工基本醫療保險用藥範圍管理暫行辦法》), the scope of medical insurance coverage for pharmaceutical products needs to be managed through the formulation of the Medical Insurance Catalogue. A pharmaceutical product listed in the Medical Insurance Catalogue must be clinically needed, safe, effective, reasonably priced, easy to use, available in sufficient quantity, and must meet the following requirements: it is set forth in the Pharmacopoeia of the People's Republic of China (current edition) (《中華人民共和國藥典》(現行版)); it meets the standards promulgated by the NMPA; and if imported, it is approved by the NMPA for import. Medical Insurance Catalogue are divided into Category A and Category B. Category A is uniformly formulated by the state and shall not be adjusted in various places. Category B is formulated by the state, and each autonomous region or municipality may make appropriate adjustments based on local economic levels, medical needs and medication habits. The sum of the increased and decreased varieties shall not exceed 15% of the total number of Category B medicines formulated by the state. Expenses incurred by the participant using medicines included in Category A shall be paid in accordance with the provisions of the basic medical insurance. Expenses incurred by the participant using medicines included in Category B shall be paid by the participant as to a certain percentage first, and then paid in accordance with the provisions of the basic medical insurance. Therefore, Category B medicines in the Medical Insurance Catalogue in various provinces in the PRC may differ from region to region, and as the specific reimbursement ratio for Category B medicines is formulated by local authorities, inconsistency also exist in the specific proportion of individual outlays. In October 2018, the National Medical Insurance Bureau (NMIB) announced that the Catalogue B was expanded to include 17 anti-cancer drugs. In November 2019, NMIB further announced 70 new therapies to be added to the NRDL.

The Medical Insurance Catalogue was first promulgated since 2000. After several adjustments, the currently effective one is the National Insurance Drug List for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2019 Version) (《國家基本醫療保險、工傷保險和生育保險藥品目錄(2019年版)》) adjusted by the National Healthcare Security Administration and the Ministry of Human Resources and Social Security in 2019 and came into effective since January 1, 2020. Pursuant to the Work Plan for 2019 National Medical Insurance Drug Catalogue Adjustment (《2019年國家醫保藥品目錄調整工作方案》) promulgated by the National Healthcare Security Administration, in the adjustment of the national basic medical insurance in 2019, priority will be given to national essential drugs, drugs for the treatment of major diseases such as cancer and rare diseases, drugs for chronic diseases, drugs for children and drugs for emergency rescue.

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Drug Price

Pursuant to the Drug Administration Law of the PRC (《中華人民共和國藥品管理法》), for drug products with market-regulated prices in accordance with the law, the drug marketing authorization holder, the drug manufacturer, the drug distributor and medical institution shall determine the price pursuant to the principles of fairness, reasonableness, integrity and trustworthiness as well as quality for value in order to supply drug users with reasonably priced drug products; and shall comply with the requirements relating to drug price administration promulgated by the State Council’s pricing authorities, determine and clearly mark the retail prices of drug products. Pursuant to the Notice on Issuing Opinions on Promoting Drug Price Reform (《關於印發推進藥品價格改革意見的通知》) jointly promulgated by NDRC, NHC, the Ministry of Human Resources and Social Security, Ministry of Industry and Information Technology, the Ministry of Finance, the Ministry of Commerce and the CFDA on May 4, 2015 from June 1, 2015, except for narcotic drugs and first-class psychotropic drugs, the price of drugs set by the government will be cancelled.

Drug Technology Transfer

Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer as the transferee and the application for drug registration by the drug manufacturer as the transferee pursuant to the provisions under Technology Transfer Regulations. On August 19, 2009, the NMPA promulgated the Administrative Regulations for Technology Transfer Registration of Drugs (《藥品技術轉讓註冊管理規定》), to standardise the registration process of drug technology transfer, which includes application for, evaluation, review, approval and supervision of drug technology transfer registration. Drug technology transfer includes new drug technology transfer and drug production technology transfer. An application for drug technology transfer must be submitted to the provincial drug regulatory authority, and the SFDA will ultimately make an approval decision based on the comprehensive opinions of the drug review center. Eligible applications will receive a letter of approval and a drug approval number for the supplementary application.

Advertising of Pharmaceutical Products and Insert Sheet, Labels and Packaging of Pharmaceutical Products

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), which came into effect on March 1, 2020, advertisements for drugs, medical devices, health food and formula food for special medical purposes shall be true and legitimate, and shall not contain any false or misleading contents. Holders of registration certificates or filing certificates of drugs, medical devices, health food and formula food for special medical purposes as well as the production enterprises and operating enterprises authorized by such holders of certificates shall be applicants for advertising (hereinafter referred to as the “applicants”). Applicants may entrust agents to apply for the review of advertisements for drugs, medical devices, health food and formula food for special medical purposes. Applicants may submit their applications at the

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acceptance windows of advertisement review authorities, or may submit their applications for advertisements for drugs, medical devices, health food and formula food for special medical purposes via letters, faxes, e-mails or e-government platforms. The advertisement review authorities shall review the materials submitted by the applicant and shall complete the review within ten working days from the date of acceptance. After review, for that advertisements that are in line with laws, administrative regulations and these Measures, approval decisions of review shall be made and advertisement approval numbers shall be issued. The validity period of the advertisement approval number for drugs, medical devices, health food and formula food for special medical purposes shall be consistent with the shortest validity period of the product registration certificate, filing certificate or production license. If no valid period is prescribed in the product registration certificate, filing certificate or production license, the valid period of the advertisement approval number shall be two years.

Pursuant to the Measures for the Administration of the Insert Sheets and Labels of Drugs (《藥品說明書和標籤管理規定》), which came effective on June 1, 2006, the insert sheets and labels of drugs should be reviewed and approved by the NMPA. A drug insert sheet should include the important scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug's name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, description, indication or function, strength, dose and usage, adverse reaction, contraindications, precautions, storage, production date, batch number, expiry date, approval number and drug manufacturer.

Pursuant to the Measures for The Administration of Pharmaceutical Packaging (《藥品包裝管理辦法》) which came effective on September 1, 1988, pharmaceutical packaging must comply with the national and professional standards. If no national or professional standards are available, the enterprise can formulate its standards and put into implementation after obtaining the approval of the food and drug administration or bureau of standards at provincial level. The enterprise shall reapply with the relevant authorities if it needs to change its packaging standard. Drugs that without packing standards must not be sold or traded (except for drugs for the military).

LAWS AND REGULATIONS IN RELATION TO ADMINISTRATION OF PATHOGENIC MICROORGANISM LABORATORIES

According to the Regulations on the Bio-safety Management of Pathogenic Microbe Laboratories (《病原微生物實驗室生物安全管理條例》) (effective in November 2004 and latest amended in March 2018) promulgated by State Council, the pathogenic microorganism laboratories are classified into Level 1, Level 2, Level 3 and Level 4 in accordance with its biosafety level for pathogenic microorganisms and the national standards for the bio-safety. Laboratories at Bio-safety Level 1 and Level 2 are forbidden to conduct experimental activities relating to any highly pathogenic microbes. Laboratories at Bio-safety Level 3 and Level 4 shall meet certain requirements to conduct experimental activities relating to any highly pathogenic microbes. Newly building, rebuilding or expanding of Bio-safety Level 1 or Level

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2 laboratories shall file with the relevant health administrative department or veterinary administrative department in the municipal people’s government of the place where it is built. The laboratories of Bio-safety Level 3 and Level 4 shall be subject to the state accreditation for laboratories. Laboratories passing accreditation will be granted with Certificates for Bio-safety Laboratories at corresponding level. The certificate will be effective for five years.

REGULATIONS IN RELATION TO INTELLECTUAL PROPERTY

Patent

Patents in the PRC are mainly protected by the Patent Law of the PRC (《中華人民共和國專利法》), which was promulgated by the Standing Committee of the National People’s Congress on March 12, 1984 and latest amended on December 27, 2008, and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), which were promulgated by the State Council on June 15, 2001 and latest amended on January 9, 2010. The Patent Law and its Implementation Rules provide for three types of patents, namely “invention”, “utility model” and “design”. “Invention” refers to any new technical solution relating to a product, a process or improvement thereof; “utility model” refers to any new technical solution relating to the shape, structure, or their combination, of a product, which is suitable for practical use; and “design” refers to any new design of the shape, pattern, color or the combination of any two of them, of a product, which creates an aesthetic feeling and is suitable for industrial application. The duration of a patent right for “invention” is 20 years, and the duration of a patent right for “utility model” or “design” is 10 years, from the date of application. According to the Patent Law, for the purpose of public health, the patent administrative department of the State Council may grant mandatory licensing for patented drugs manufactured and exported to countries or regions which comply with the provisions of the relevant international treaty participated by the PRC.

Trademarks

Registered trademarks in the PRC are mainly protected by the Trademark Law of the PRC (《中華人民共和國商標法》), which was promulgated by the Standing Committee of the National People’s Congress on August 23, 1982 and latest amended on April 23, 2019, and the Implementation Rules of the Trademark Law of the PRC (《商標法實施條例》), which were promulgated by the State Council on August 3, 2002 and latest amended on April 29, 2014. The Trademark Office is responsible for the registration and administration of trademarks throughout China and grants a term of 10 years to registered trademarks. When it is necessary to continue using the registered trademark upon expiration of period of validity, a trademark registrant shall make an application for renewal within 12 months before the expiration in accordance with the requirements. If such an application cannot be filed within that period, an extension period of six months may be granted. The period of validity for each renewal of registration shall be 10 years as of the next day of the previous period of validity. If the formalities for renewal have not been handled upon expiration of period of validity, the registered trademarks will be deregistered.

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Copyright

Copyright in the PRC is protected by the Copyright Law of the PRC (《中華人民共和國著作權法》), which was promulgated by the Standing Committee of the National People’s Congress on September 7, 1990 and latest amended on February 26, 2010, and Implementation Regulations of the Copyright Law of PRC (《中華人民共和國著作權法實施條例》), which was promulgated by the State Council on August 2, 2002 and latest amended on January 30, 2013. These laws and regulations provide provisions on the classification of works and the obtaining and protection of copyright.

REGULATIONS IN RELATION TO FOREIGN DIRECT INVESTMENT

Since January 1, 2020, the Foreign Investment Law of the People’s Republic of China (the “Foreign Investment Law”) promulgated by the National People’s Congress has come into effect. The Law of the People’s Republic of China on Sino-Foreign Equity Joint Ventures and the Law of the People’s Republic of China on Wholly Foreign-Owned and Law of the People’s Republic of China on Sino-Foreign Cooperative Joint Ventures abolished at the same time. Since then, the Foreign Investment Law has become the basic law regulating foreign-invested enterprises wholly or partially invested by foreign investors. While the organization form, institutional framework and standard of conduct of foreign-invested enterprises shall be subject to the provisions of the Company Law of the PRC and other laws. The PRC government will implement the management system of pre-entry national treatment and the Negative List for foreign investment abolished the original approval and filing administration system for the establishment and change of foreign-invested enterprises. Pre-entry national treatment refers to the treatment accorded to foreign investors and their investments at the stage of investment entry which is no less favourable than the treatment accorded to domestic investors and their investments. Negative List refers to a special administrative measure for the entry of foreign investment in specific sectors as imposed by the PRC. The PRC accords national treatment to foreign investment outside of the Negative List. The current Negative List is the Special Management Measures (Negative List) for the Access of Foreign Investment (2019 Revision) (《外商投資准入特別管理措施(負面清單)(2019年版)》) issued by the NDRC and the Ministry of Commerce on June 30, 2019, which lists the special management measures for foreign investment access for industries regulated by the Negative List, such as equity requirements and senior management requirements.

While strengthening investment promotion and protection, the Foreign Investment Law further regulates foreign investment management and proposes the establishment of a foreign investment information reporting system that replaces the original foreign investment enterprise approval and filing system of the Ministry of Commerce. The foreign investment information reporting is subject to the Foreign Investment Information Reporting Method (《外商投資信息報告辦法》) jointly developed by the Ministry of Commerce and the State Administration for Market Regulation, which came into effect on January 1, 2020. According to the Foreign Investment Information Reporting Method, the Ministry of Commerce is responsible for coordinating and guiding the reporting of foreign investment information nationwide. The competent commercial department of the local people’s government at or

REGULATORY OVERVIEW

above the county level, as well as the relevant agencies of the Pilot Free Trade Zone and the National Economic and Technological Development Zone, are responsible for reporting information on foreign investment in the region. Foreign investors who directly or indirectly carry out investment activities in China shall submit investment information to the competent commercial department through the enterprise registration system and the National Enterprise Credit Information Publicity System and the reporting methods include initial reports, change reports, cancellation reports, and annual reports. Foreign investors who establish foreign-invested enterprises in China or acquire domestic non-foreign-invested enterprises through equity merger and acquisition shall submit initial reports through the enterprise registration system when applying for the registration of the establishment of foreign-invested enterprises or applying for the registration of the change of the acquired enterprises. If the change in the information of initial reports involves registration or filing of the change of enterprises, foreign-invested enterprises shall submit change reports through the enterprise registration system when applying for the registration or filing of change of enterprises. If the change in the information of initial reports does not involve registration or filing of the change of enterprises, foreign-invested enterprises shall submit change reports through the enterprise registration system within 20 working days after the change. Foreign-invested listed companies may report information on changes in investors and their shareholdings only when the cumulative change in the foreign investors’ shareholding ratio exceeds 5% or the foreign parties’ shareholding or relative holding status have changed.

REGULATIONS IN RELATION TO PRODUCT LIABILITY

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), promulgated by the Standing Committee of the National People’s Congress on February 22, 1993 and latest amended on December 29, 2018 (the “Product Quality Law”), is the principal governing law relating to the supervision and administration of product quality. According to the Product Quality Law, manufacturers shall be liable for the quality of products produced by them and sellers shall take measures to ensure the quality of the products sold by them. A manufacturer shall be liable to compensate for any bodily injuries or damage to property other than the defective product itself resulting from the defects in the product, unless the manufacturer is able to prove that: (1) the product has never been circulated; (2) the defects causing injuries or damage did not exist at the time when the product was circulated; or (3) the science and technology at the time when the product was circulated were at a level incapable of detecting the defects. A seller shall be liable to compensate for any bodily injuries or damage to property of others caused by the defects in the product if such defects are attributable to the seller. A seller shall pay compensation if it fails to indicate neither the manufacturer nor the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim for compensation from the manufacturer or the seller.

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REGULATIONS IN RELATION TO PRODUCTION SAFETY

The Production Safety Law of the PRC (《中華人民共和國安全生產法》), promulgated by the Standing Committee of the National People’s Congress on June 29, 2002 and latest amended on December 1, 2014, is the basic law for governing production safety. It provides that, any entity whose production safety conditions do not meet the above requirements may not engage in production and business operation activities. The production and business operation entities shall educate and train employees regarding production safety so as to ensure that the employees have the necessary knowledge of production safety, are familiar with the relevant regulations and rules for safe production and the rules for safe operation, master the skills of safe operation in their own positions, understand the emergency measures, and know their own rights and duties in terms of production safety. Employees who fail the education and training programmes on production safety may not commence working in their positions. Safety facilities of new building, rebuilding or expanding project (the “construction project”) shall be designed, constructed and put into operation simultaneously with the main body of the project. Investment in safety facilities shall be included in the budget of the construction project.

REGULATIONS IN RELATION TO ENVIRONMENTAL PROTECTION

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), promulgated by the Standing Committee of the National People’s Congress on December 26, 1989 and latest amended on April 24, 2014, the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the Standing Committee of the National People’s Congress on October 28, 2002 and latest amended on December 29, 2018, and the Administrative Regulations on the Environmental Protection of Construction Project (《建設項目環境保護管理條例》), promulgated by the State Council on November 29, 1998 and latest amended on July 16, 2017, enterprises which plan to construct projects shall engage qualified professionals to provide the assessment reports, assessment form, or registration form on the environmental impact of such projects. The assessment reports, assessment form, or registration form shall be filed with or approved by the relevant environmental protection bureau prior to the commencement of any construction work.

According to the Administrative Measures on Pollutant Emission Permits (Trial) (《排污許可管理辦法(試行)》), promulgated by the Ministry of Environmental Protection on January 10, 2018 and latest amended on August 22, 2019, enterprises, institutions and other producers and operators (the “pollutant discharge enterprises”) that have been included in the Classification Management List for Fixed Source Pollution Permits shall apply for and obtain a discharge permit in accordance with the prescribed time limit. According to the Classification Management List for Fixed Source Pollution Permits (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), the manufacturing of biological drugs and products falls into the classification management scope for fixed source pollution permits.

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REGULATIONS IN RELATION TO PREVENTION AND CONTROL OF OCCUPATIONAL DISEASES

The Prevention and Control of Occupational Diseases Law of the PRC (《中華人民共和國職業病防治法》), which was promulgated by the Standing Committee of the National People’s Congress on October 27, 2001 and latest amended on December 29, 2018 (the “Prevention and Control of Occupational Diseases Law”), is the basic law for the prevention and control of occupational diseases. According to the Prevention and Control of Occupational Diseases Law, budget for facilities for the prevention and control of occupational diseases of a construction project shall be included in the budget of the project and those facilities shall be designed, constructed and put into operation simultaneously with the main body of the project. The entity that takes charge of the project should carry out the assessment of the effectiveness of measures for the prevention and control of occupational diseases before the final acceptance of the construction project. In addition, employers shall take required administrative measures to prevent and control occupational diseases in work.

REGULATIONS IN RELATION TO IMPORT AND EXPORT OF GOODS

According to the Administrative Provisions on the Registration of Customs Declaration Entities of the PRC (《中華人民共和國海關報關單位註冊登記管理規定》), promulgated by the General Administration of Customs of the PRC on March 13, 2014, latest amended on July 1, 2018, import and export of goods shall be declared by the consignor or consignee itself, or by a customs declaration enterprise entrusted by the consignor or consignee and duly registered with the customs authority. Consignors and consignees of imported and exported goods shall go through customs declaration entity registration formalities with the competent customs departments in accordance with the applicable provisions. After completing the registration formalities with the customs, consignors and consignees of the imported and exported goods may handle their own customs declarations at customs ports or localities where customs supervisory affairs are concentrated within the customs territory of the PRC.

REGULATIONS IN RELATION TO LABOR PROTECTION

The Labor Contract Law of the PRC (《中華人民共和國勞動合同法》), which was promulgated by the Standing Committee of the National People’s Congress on June 29, 2007 became effective on January 1, 2008, latest amended on December 28, 2012 and became effective on July 1, 2013, governs the relationship between employers and employees, and provides for specific provisions in relation to the terms and conditions of an employment contract. The Labor Contract Law stipulates that employment contracts must be in writing and signed. It imposes more stringent requirements on employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees.

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According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), which was promulgated by the Standing Committee of the National People’s Congress on October 28, 2010 and latest amended on December 29, 2018, and the Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》), which was amended by the State Council on March 24, 2019, employers and/or employees are required to contribute to a number of social security funds, including funds for basic pension insurance, employment insurance, basic medical insurance, occupational injury insurance, maternity leave insurance, and to housing provident funds. These payments are made to local administrative authorities and employers who fail to contribute may be fined and ordered to rectify within a stipulated time limit.

LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

LAWS AND REGULATIONS IN RELATION TO NEW DRUG

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the FDCA, its implementing regulations and biologics under the FDCA and the Public Health Service Act (the “PHSA”) and their implementing regulations. Both drugs and biologics also are subject to other federal, state and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA’s refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

Once a product candidate is identified for development, it enters pre-clinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Pre-clinical testing is conducted in accordance with FDA’s Good Laboratory Practice regulations. A sponsor of an IND must submit the results of the pre-clinical tests, manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance.

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All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board (“IRB”), must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB’s requirements or if the product has been associated with unexpected serious harm to subjects.

Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap.

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.
- Phase II clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further PK and PD information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.
- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor’s initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

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Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with cGMP, requirements. The process of obtaining regulatory approvals and compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions.

U.S. Review and Approval Processes

The results of product development, pre-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a BLA. Unless deferred or waived, BLAs, or supplements must contain data adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of a BLA is subject to the payment of a substantial user fee and an annual prescription drug product program fee.

Within 60 days of its receipt, the FDA reviews the BLA to ensure that it is sufficiently complete for substantive review before it accepts the BLA for filing. After accepting the BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Before approving the BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

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The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase IV clinical trials, to further assess a product’s safety and effectiveness after BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

Accelerated Approval

Under FDA’s accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough Designation

Another program available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product’s marketing application, including by meeting with the sponsor throughout the product’s development, providing timely advice to the sponsor to ensure that the development program to gather pre-clinical and clinical data is as efficient as practicable.

REGULATORY OVERVIEW

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstance.

Post-Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as “off-label use”) and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy (“REMS”), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP.

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Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval of the product if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or
- injunctions or the imposition of civil or criminal penalties.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product’s testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is

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eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a BLA has not been submitted.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OVERVIEW

We are a commercial-ready biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics for the treatment of autoimmune, oncology and ophthalmic diseases with unmet medical needs in China and globally. Our history traces back to 2008 when Yantai Rongchang Pharmaceutical Co., Ltd. (煙台榮昌製藥股份有限公司), a company led by Mr. Wang, and Dr. Fang jointly founded RemeGen, Ltd. (formerly known as RC Biotechnologies Ltd. (煙台榮昌生物工程有限公同)), the predecessor of our Company. We were established as a limited liability company under the laws of the PRC on July 4, 2008 and were converted into a joint stock limited company under the laws of the PRC on May 12, 2020. For the details of the background and experience of Mr. Wang and Dr. Fang, please refer to the section headed “Directors, Supervisors and Senior Management” in this document.

Prior to the Reorganization, our predecessor was wholly-owned by RC Pharma, a leading platform based in the PRC with subsidiaries engaging in the pharmaceutical industry focusing on the research and development of small molecule drugs and Chinese medicines, sale of drugs, CDMO and biomedical incubation businesses in China and the U.S. As of the Latest Practicable Date, RC Pharma and our Company was controlled by the Concert Parties as to approximately 63.93% and 56.35%, respectively. The Concert Parties include Mr. Wang, Dr. Fang, Dr. Wang Liqiang and Mr. Lin Jian who are our Directors, Mr. Wen Qingkai, our senior management member, five other individuals and three companies through which they hold equity interests in our Company.

MILESTONES

The following table illustrates the key milestones of our business development:

Time	Milestone
2008	Our predecessor was established in July
2010	We filed the first IND application for telitacicept (RC18) in May
2011	We obtained the IND approval from the NMPA for telitacicept for the treatment of autoimmune disease in April
2015	We obtained IND approval for disitamab vedotin (RC48) in September. Disitamab vedotin became the first novel antibody-drug conjugate (ADC) to obtain IND approval in the PRC
2017	We obtained IND approval from the NMPA for telitacicept for the treatment of NMOSD in April
	We initiated a Phase II clinical trial for disitamab vedotin for the treatment of UC in December

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Time	Milestone
2018	<p>We initiated a Phase III clinical trial for the treatment of NMOSD in January</p> <p>We initiated a registrational clinical trial for disitamab vedotin for the treatment of GC in July</p> <p>We obtained IND approval from the NMPA for telitacept for the treatment of four indications, namely, IgAN, MG, SS and MS in May, and were officially approved to carry out Phase II clinical trials for these indications</p> <p>We obtained the IND approval from the NMPA for RC28 for the treatment of three indications, namely, wet AMD, DME and DR in July</p> <p>We obtained the IND approval from the NMPA for RC88 for the treatment of advanced multiple solid tumours in November and were officially approved to carry out a Phase I clinical trial</p> <p>We initiated a Phase II registrational clinical trial for disitamab vedotin for the treatment of UC in December</p>
2019	<p>We completed our multi-center, randomized, double-blinded and placebo-controlled Phase IIb registrational clinical trial for telitacept in SLE patients in June</p> <p>The FDA approved our Phase II clinical trial for telitacept in the U.S. in August</p> <p>The NMPA accepted our new drug application (NDA) for telitacept for the treatment of SLE in November and granted us priority review status in December</p> <p>Our Reorganization was completed in December</p> <p>We completed our 2019 Subscription by PAG Growth Prosperity Holding I (HK) Limited (“PAG I”) in December</p>
2020	<p>The FDA approved our Phase III clinical trial for telitacept for the treatment of SLE in the U.S. in January</p> <p>We completed our 2020 Subscription and raised approximately USD105 million in March</p> <p>The FDA approved our Phase II clinical trial for disitamab vedotin for the treatment of UC patients in the U.S. in April</p> <p>The FDA granted the Fast Track designation to telitacept in April</p>

CORPORATE DEVELOPMENT

The following sets forth the corporate history and shareholding changes of our Company.

Incorporation of our Company

Pursuant to a subscription by technology agreement (技術入股協議) dated May 23, 2008 entered into between RC Pharma and Dr. Fang, RC Pharma and Dr. Fang agreed to establish RemeGen, Ltd. (formerly known as RC Biotechnologies Ltd. (煙台榮昌生物工程)), our predecessor, with an initial registered capital of USD2,213,700. RC Pharma contributed to USD1,438,800 of the registered capital, representing 65% equity interest, by way of cash and transfer of assets including factory building and equipment. Dr. Fang contributed to the remaining USD774,900 of the registered capital, representing 35% equity interest, by way of transfer of certain technologies and intellectual property rights. RemeGen, Ltd. was established on July 4, 2008.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Subsequent Capital Increase and Equity Transfer

On October 30, 2013, the board of directors of our Company resolved to increase the registered capital of our Company from USD2,213,700 to RMB70,000,000. RC Pharma, Dr. Fang and Yantai Jianchang Biotechnology Co., Ltd. (煙台健昌生物技術有限公司) (“Yantai Jianchang”) subscribed for the increased registered capital of RMB31,074,200, RMB16,665,000 and RMB7,000,000 at par value, respectively. Yantai Jianchang was a limited company established in the PRC and was owned as to 65% and 35% by RC Pharma and Dr. Fang, respectively. Upon completion of the increase and subscription of registered capital on March 19, 2014, our Company was owned as to 58.5%, 31.5% and 10.0% by RC Pharma, Dr. Fang and Yantai Jianchang, respectively.

Pursuant to an equity transfer agreement dated October 27, 2015 entered into by Dr. Fang and Yantai Rongchang Technology Co., Ltd. (煙台榮昌科技有限公司) (“Rongchang Technology”), Dr. Fang transferred his unpaid registered capital of our Company of RMB16,660,000, representing 23.8% equity interest, to Rongchang Technology at nil consideration. Rongchang Technology was a limited company established in the PRC and was owned as to 40%, 30% and 30% by Mr. Wang Yuxiao, Mr. Lin Jian and Ms. Xiong Xing. Mr. Wang Yuxiao is the son of and has acted according to the instructions of Mr. Wang and Ms. Xiong Xing is the daughter of and has acted according to the instructions of Mr. Xiong Xiaobin. All of Mr. Wang, Mr. Lin Jian and Mr. Xiong Xiaobin belong to the Concert Parties Group. For details of the arrangement of the Concert Parties Group, please refer to the paragraph headed “– Concert Party Arrangement” in this section. Upon completion of the equity transfer on January 18, 2016, our Company was owned as to 58.5%, 23.8%, 10.0% and 7.7% by RC Pharma, Rongchang Technology, Yantai Jianchang and Dr. Fang, respectively.

Pursuant to an equity transfer agreement dated February 1, 2016 entered into between Rongchang Technology and RC Pharma, Rongchang Technology transferred its unpaid registered capital of our Company of RMB16,660,000, representing 23.8% equity interest, to RC Pharma at nil consideration. Pursuant to another equity transfer agreement dated February 3, 2016 entered into between Dr. Fang and Huijian Life Sciences Co., Ltd. (惠健生命科學有限公司) (“Huijian”), Dr. Fang transferred his remaining registered capital of our Company of RMB5,390,000, representing 7.7% equity interest, to Huijian at a consideration of RMB1,500,000. Huijian was a limited company incorporated in Hong Kong and was then indirectly wholly-owned by Dr. Fang. The consideration was determined with reference to the then book value of the patent and technologies contributed by Dr. Fang. Upon completion of the aforementioned equity transfers on March 17, 2016, our Company was owned as to 82.3% by RC Pharma, 10.0% by Yantai Jianchang and 7.7% by Huijian, respectively.

Pursuant to an equity transfer agreement dated March 10, 2016 entered into between Yantai Jianchang and RC Pharma, Yantai Jianchang transferred its registered capital of our Company of RMB7,000,000, representing 10.0% equity interest, to RC Pharma at par value. Upon completion of the equity transfer on June 30, 2016, our Company was owned as to 92.3% by RC Pharma and 7.7% by Huijian, respectively.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Pursuant to an equity transfer agreement dated September 23, 2016 entered into between Huijian and RC Pharma, as the consideration to subscribe for the increased registered capital of RMB2,156,000, Huijian transferred its registered capital of our Company of RMB5,390,000, representing 7.7% equity interest, to RC Pharma. The consideration was determined with reference to the net asset value of RC Pharma of approximately RMB225 million as at May 31, 2016 pursuant to a valuation report issued by a third party valuer. Upon completion of the equity transfer, our Company became a wholly-owned subsidiary of RC Pharma.

On July 23, 2019, as part of the internal restructuring between RC Pharma and our Company, the registered capital of our Company was increased from RMB70,000,000 to RMB165,912,935, RC Pharma subscribed for the increased registered capital of our Company of RMB95,912,935, by way of capitalization of shareholder’s loans provided by RC Pharma to our Company at a total amount of RMB600,000,000. The premium amount of RMB504,087,065 was credited to the capital reserve of our Company.

As part of the Reorganization, RC Pharma transferred its 100% equity interest in our Company to its shareholders or their offshore/onshore affiliates in proportion to their respective shareholdings in RC Pharma pursuant to the reorganization agreement dated October 8, 2019 entered into by and amongst our Company, RC Pharma and the then shareholders of RC Pharma (the “Reorganization Agreement”). For details, please refer to the paragraph headed “—Reorganization” in this section.

Pursuant to the second supplemental agreement of the share subscription agreement dated July 15, 2019 entered into by and between, amongst others, PAG I, RC Pharma and our Company, PAG I agreed to subscribe for the increased share capital of RMB2,741,117 or 1.6521% of the registered capital of our Company at a consideration of RMB90 million. As such, the registered share capital of our Company was increased from RMB165,912,935 to RMB168,654,052. For details, please refer to the paragraph headed “—Pre-[REDACTED] Investments—2019 Subscription” in this section.

Pursuant to an investment agreement dated February 25, 2020 entered into by and between, amongst others, our Company and the Pre-[REDACTED] Investors, the registered capital of our Company was increased from RMB168,654,052 to RMB182,645,092 and the Pre-[REDACTED] Investors agreed to subscribe for the increased registered capital of RMB13,991,040 of our Company at a total consideration of USD105,355,440. For details, please refer to the paragraph headed “—Pre-[REDACTED] Investments—2020 Subscription” in this section.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

REORGANIZATION

Prior to the Reorganization, our Company was a wholly-owned subsidiary of RC Pharma. As part of the strategic restructuring of the businesses of entities owned by RC Pharma and for the purpose of the [REDACTED], our Group carried out the Reorganization which included the steps set forth below.

Immediately prior to the Reorganization, the shareholding structure of RC Pharma was as follows:

Shareholders	Registered Capital (RMB)	Equity interest (%)
Yantai Rongchang Enterprise Management Center (Limited Partnership) (煙台榮昌企業管理中心(有限合夥))	47,429,000	28.11
Dr. Fang	30,420,000	18.03
Yantai Hengrong Enterprise Management Center (Limited Partnership) (煙台恒榮企業管理中心(有限合夥))	9,653,770	5.72
Yantai Jianshun Enterprise Management Center (Limited Partnership) (煙台健順企業管理中心(有限合夥))	7,836,231	4.65
Yantai Yida Enterprise Management Center (Limited Partnership) (煙台頤達企業管理中心(有限合夥))	6,000,000	3.56
Yantai Jichang Enterprise Management Center (Limited Partnership) (煙台濟昌企業管理中心(有限合夥))	4,287,540	2.54
Huijian Life Sciences Co., Ltd. (惠健生命科學有限公司)	4,000,000	2.37
Total equity interests held by the Concert Parties and employee incentive platforms	109,626,541	64.98
Fund for the transformation of National Science and Technology Major Project (國投(上海)科技成果轉化創業投資基金企業(有限合夥))	10,451,885	6.20
Yiliwuyouen Equity Investment Partnership (Limited Partnership) (伊犁烏尤恩股權投資合夥企業(有限合夥))	7,059,500	4.18
PAG Growth Prosperity Holding I (HK) Limited	6,967,913	4.13
Gaotoumingli Venture Investment Co., Ltd. (高投名力成長創業投資有限公司)	5,344,086	3.17
Shenzhen Capital Group Co.,Ltd. (深圳市創新投資集團有限公司)	5,225,943	3.10
Lu Thai Textile Co., Ltd. (魯泰紡織股份有限公司)	5,000,000	2.96
SDIC Chuanghe National Leading Fund of Emerging Industries VC (Limited Partnership) (國投創合國家新興產業創業投資引導基金(有限合夥))	3,483,962	2.07
Beijing Lapam Healthcare Investment Center LLP (北京龍磐健康醫療投資中心(有限合夥))	3,483,962	2.07

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shareholders	Registered Capital	Equity interest
	(RMB)	(%)
Yantai Venture Investment Co., Ltd. (煙台市創業投資有限公司)	2,381,000	1.41
Nanjing Huatai Healthcare Investment I (LLP) (南京華泰大健康一號股權投資合夥企業(有限合夥))	1,606,184	0.95
TIBET Lapam Yijing Venture Capital Center LLP (西藏龍磐怡景創業投資中心(有限合夥))	1,393,583	0.83
Hangzhou Chuanghe Select Venture Capital (Limited Partnership) (杭州創合精選創業投資合夥企業(有限合夥))	1,393,583	0.83
Shandong Jifu Jingu New Kinetic Energy Equity Investment Fund Partnership (Limited Partnership) (山東吉富金穀新動能股權投資基金合夥企業(有限合夥)) (formerly known as Jinan Jifu Jingu Equity Investment Fund Partnership (Limited Partnership) (濟南吉富金穀 股權投資基金合夥企業(有限合夥))	1,219,385	0.72
Weihai Luxin Fuwei Equity Investment Fund Partnership (Limited Partnership) (威海魯信福威股權投資基金合夥企業(有限合夥))	1,219,385	0.72
Small Medium Enterprises Development Fund (Shenzhen)LLP (中小企業發展基金(深圳)有限合夥)	1,045,189	0.62
Jiangyin Changjiang Investment Group Co., Ltd. (江陰長江投資集團有限公司)	965,414	0.57
Qingdao Zhongtaihuiyin Investment Management Partnership (Limited Partnership) (青島中泰匯銀投資管理合夥企業(有限合夥))	696,792	0.41
Nanjing Huatai Healthcare Investment II (LLP) (南京華泰大健康二號股權投資合夥企業(有限合夥))	110,050	0.07
Nanjing Daoxin Management Center GP (南京道興投資管理中心(普通合夥))	25,744	0.02
Total	168,700,101	100.00

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Transfers of equity interest

To achieve a separate legal structure for the [REDACTED] and pursuant to the Reorganization Agreement, RC Pharma has transferred its 100% equity interests in our Company to its then shareholders or their offshore/onshore affiliates in proportion to their respective shareholdings in RC Pharma in December 2019. As part of the Reorganization, certain shareholders have also transferred their shareholdings in our Company to their offshore/onshore affiliates.

Pursuant to an asset valuation report dated August 5, 2019 issued by an independent third party valuer, the net asset value of the Company as at June 30, 2019 amounted to RMB6,809,800. After arm’s length negotiations amongst the parties with reference to the said valuation, the effective valuation of the Company for the purposes of the equity transfers was determined to be RMB7,254,104 and the consideration for the equity transfers were determined based on such effective valuation of the Company.

First round: transfer of equity interests to Dr. Fang and PAG

As the first round of the equity transfers, RC Pharma transferred a total of RMB36,770,211 registered capital in the Company to I-NOVA Limited, Dr. Fang and PAG I. Details of the transfer were as follows:

Transferee	Corresponding shareholder of RC Pharma	Ownership in RC Pharma (%)	Ownership in our Company after equity transfer (%)	Amount of registered capital in our Company (RMB)	Consideration (RMB)
I-NOVA Limited	Dr. Fang	18.03	10.85	18,000,000	787,002
Dr. Fang			7.18	11,917,418	521,058
PAG I	PAG I	4.13	4.13	6,852,793	299,620

The abovementioned equity transfers were completed on December 2, 2019.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Second round: transfer of equity interests to employee incentive platforms and onshore institutional shareholders

As the second round of the equity transfers, RC Pharma transferred a total of RMB129,142,724 registered capital in the Company to the Concert Parties (except Dr. Fang), the Onshore ESOP Platforms and certain onshore institutional shareholders or their offshore holding entities. Details of the transfer were as follows:

Transferee	Corresponding shareholder(s) of RC Pharma	Ownership in RC Pharma held by the corresponding shareholder(s) of RC Pharma	Ownership in our Company after equity transfer	Amount of registered capital in our Company	Consideration
		(%)	(%)	(RMB)	(RMB)
Yantai Rongda Venture Capital Center (Limited Partnership) (煙台榮達創業投資中心(有限合夥)) (“Rongda”)	Yantai Rongchang Enterprise Management Center (Limited Partnership) (煙台榮昌企業管理中心(有限合夥)) (27.28%), Yantai Hengrong Enterprise Management Center (Limited Partnership) (煙台恒榮企業管理中心(有限合夥)) (0.65%), Yantai Jichang Enterprise Management Center (Limited Partnership) (煙台濟昌企業管理中心(有限合夥)) (0.02%) and Yantai Jianshun Enterprise Management Center (Limited Partnership) (煙台健順企業管理中心(有限合夥)) (0.09%)	28.05	28.05	46,537,223	2,034,717
<p><i>Note:</i> The 28.05% equity interest in our Company transferred by RC Pharma to Rongda represents 27.28% equity interest indirectly owned by Yantai Rongchang Enterprise Management Center (Limited Partnership) (煙台榮昌企業管理中心(有限合夥)), 0.65% equity interest indirectly owned by Yantai Hengrong Enterprise Management Center (Limited Partnership) (煙台恒榮企業管理中心(有限合夥)), 0.02% equity interest indirectly owned by Yantai Jichang Enterprise Management Center (Limited Partnership) (煙台濟昌企業管理中心(有限合夥)) and 0.09% equity interest indirectly owned by Yantai Jianshun Enterprise Management Center (Limited Partnership) (煙台健順企業管理中心(有限合夥)).</p>					
RongChang Holding Group LTD. (“RongChang Holding”)	Yantai Rongchang Enterprise Management Center (Limited Partnership) (煙台榮昌企業管理中心(有限合夥)) (0.83%) and Huijian Life Sciences Co., Ltd. (惠健生命科學有限公司) (2.37%)	3.20	3.20	5,310,784	232,200
<p><i>Note:</i> The 3.20% equity interest in our Company transferred by RC Pharma to RongChang Holding represents 0.83% equity interest indirectly owned by Yantai Rongchang Enterprise Management Center (Limited Partnership) (煙台榮昌企業管理中心(有限合夥)) and 2.37% equity interest indirectly owned by Huijian Life Sciences Co., Ltd. (惠健生命科學有限公司).</p>					

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Transferee	Corresponding shareholder(s) of RC Pharma	Ownership in RC Pharma held by the corresponding shareholder(s) of RC Pharma	Ownership in our Company after equity transfer	Amount of registered capital in our Company	Consideration
		(%)	(%)	(RMB)	(RMB)
Yantai Rongshi Enterprise Management Center (煙台榮實企業管理中心(有限合夥)) (“Rongshi”)	Yantai Jichang Enterprise Management Center (Limited Partnership) (煙台濟昌企業管理中心(有限合夥)) (2.52%)	2.52	2.52	4,177,365	182,644
Yantai Rongyi Enterprise Management Center (Limited Partnership) (煙台榮益企業管理中心(有限合夥)) (“Rongyi”)	Yantai Jianshun Enterprise Management Center (Limited Partnership) (煙台健順企業管理中心(有限合夥)) (4.56%)	4.56	4.56	7,559,244	330,508
Yantai Rongqian Enterprise Management Center (Limited Partnership) (煙台榮謙企業管理中心(有限合夥)) (“Rongqian”)	Yantai Hengrong Enterprise Management Center (Limited Partnership) (煙台恒榮企業管理中心(有限合夥)) (5.07%)	5.07	5.07	8,412,449	367,812
Yantai Rongjian Enterprise Management Center (Limited Partnership) (煙台榮建企業管理中心(有限合夥)) (“Rongjian”)	Yantai Yida Enterprise Management Center (Limited Partnership) (煙台頤達企業管理中心(有限合夥)) (3.56%)	3.56	3.56	5,900,871	258,000
Total equity interests held by the Concert Parties (except Dr. Fang) and our Onshore ESOP Platforms		46.96	46.96	77,897,936	-
Fund for the transformation of National Science and Technology Major Project (國投(上海)科技成果轉化創業投資基金企業(有限合夥)) (“SDIC Venture”)	Fund for the transformation of National Science and Technology Major Project (國投(上海)科技成果轉化創業投資基金企業(有限合夥))	6.20	6.20	10,279,205	449,431
Wholly Sunbeam Limited	Yiliwuyouen Equity Investment Partnership (Limited Partnership) (伊犁烏尤恩股權投資合夥企業(有限合夥))	4.18	4.18	6,942,867	303,559
Gaotoumingli Venture Investment Co., Ltd. (高投名力成長創業投資有限公司) (“Gaotoumingli”)	Gaotoumingli Venture Investment Co., Ltd. (高投名力成長創業投資有限公司)	3.17	3.17	5,255,794	229,796
Shenzhen Capital Group Co., Ltd. (深圳市創新投資集團有限公司) (“SCGC”)	Shenzhen Capital Group Co., Ltd. (深圳市創新投資集團有限公司)	3.10	3.10	5,139,603	224,716

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Transferee	Corresponding shareholder(s) of RC Pharma	Ownership in RC Pharma held by the corresponding shareholder(s) of RC Pharma (%)	Ownership in our Company after equity transfer (%)	Amount of registered capital in our Company (RMB)	Consideration (RMB)
Lu Thai Textile Co., Ltd. (魯泰紡織股份有限公司) (“Lu Thai”)	Lu Thai Textile Co., Ltd. (魯泰紡織股份有限公司)	2.96	2.96	4,917,393	21,500
SDIC Chuanghe National Leading Fund of Emerging Industries VC (Limited Partnership) 國投創合國家新興產業創業投資引導基金(有限合夥) (“SDIC Chuanghe”)	SDIC Chuanghe National Leading Fund of Emerging Industries VC (Limited Partnership) 國投創合國家新興產業創業投資引導基金(有限合夥)	2.07	2.07	3,426,402	149,810
Beijing Lapam Healthcare Investment Center LLP (北京龍磐健康醫療投資中心(有限合夥)) (“Beijing Lapam”)	Beijing Lapam Healthcare Investment Center LLP (北京龍磐健康醫療投資中心(有限合夥))	2.07	2.07	3,426,402	149,810
Yantai Venture Investment Co., Ltd. (煙台市創業投資有限公司) (“Yantai Venture”)	Yantai Venture Investment Co., Ltd. (煙台市創業投資有限公司)	1.41	1.41	2,341,662	102,383
Nanjing Huatai Healthcare Investment I (LLP) (南京華泰大健康一號股權投資合夥企業(有限合夥)) (“Nanjing Huatai I”)	Nanjing Huatai Healthcare Investment I (LLP) (南京華泰大健康一號股權投資合夥企業(有限合夥))	0.95	0.95	1,579,648	69,066
TIBET Lapam Yijing Venture Capital Center LLP (西藏龍磐怡景創業投資中心(有限合夥)) (“TIBET Lapam”)	TIBET Lapam Yijing Venture Capital Center LLP (西藏龍磐怡景創業投資中心(有限合夥))	0.83	0.83	1,370,559	59,924
Hangzhou Chuanghe Select Venture Capital (Limited Partnership) (杭州創合精選創業投資合夥企業(有限合夥)) (“Hangzhou Chuanghe”)	Hangzhou Chuanghe Select Venture Capital (Limited Partnership) (杭州創合精選創業投資合夥企業(有限合夥))	0.83	0.83	1,370,559	59,924
Weihai Luxin Fuwei Equity Investment Fund Partnership (Limited Partnership) (威海魯信福威股權投資基金合夥企業(有限合夥)) (“Weihai Luxin”)	Weihai Luxin Fuwei Equity Investment Fund Partnership (Limited Partnership) (威海魯信福威股權投資基金合夥企業(有限合夥))	0.72	0.72	1,199,239	52,434
Shandong Jifu Jingu New Kinetic Energy Equity Investment Fund Partnership (Limited Partnership) (山東吉富金毅新動能股權投資基金合夥企業(有限合夥)) (“Shandong Jifu”)	Shandong Jifu Jingu New Kinetic Energy Equity Investment Fund Partnership (Limited Partnership) (山東吉富金毅新動能股權投資基金合夥企業(有限合夥))	0.72	0.72	1,199,239	52,434

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Transferee	Corresponding shareholder(s) of RC Pharma	Ownership in RC Pharma held by the corresponding shareholder(s) of RC Pharma (%)	Ownership in our Company after equity transfer (%)	Amount of registered capital in our Company (RMB)	Consideration (RMB)
Small Medium Enterprises Development Fund (Shenzhen) LLP (中小企業發展基金(深圳有限合伙)) (“SME Development Fund”)	Small Medium Enterprises Development Fund (Shenzhen) LLP (中小企業發展基金(深圳有限合伙))	0.62	0.62	1,027,921	44,943
Jiangyin Changjiang Investment Group Co., Ltd. (江陰長江投資集團有限公司) (“Jiangyin Changjiang”)	Jiangyin Changjiang Investment Group Co., Ltd. (江陰長江投資集團有限公司)	0.57	0.57	949,464	41,513
Senming Capital Limited	Qingdao Zhongtaihuiyin Investment Management Partnership (Limited Partnership) (青島中泰匯銀投資管理合夥企業(有限合伙))	0.41	0.41	685,280	29,962
Nanjing Huatai Healthcare Investment II (LLP) (南京華泰大健康二號股權投資合夥企業(有限合伙)) (“Nanjing Huatai II”)	Nanjing Huatai Healthcare Investment II (LLP) (南京華泰大健康二號股權投資合夥企業(有限合伙))	0.07	0.07	108,232	4,732
Nanjing Daoxin Management Center GP (南京道興投資管理中心(普通合伙)) (“Nanjing Daoxin”)	Nanjing Daoxin Management Center GP (南京道興投資管理中心(普通合伙))	0.02	0.02	25,319	1,107

The abovementioned equity transfers were completed on December 5, 2019.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Third round: equity transfers between employee incentive platforms and by existing shareholders to their affiliates

RC-Biology Investment Ltd. was incorporated in the British Virgin Islands as part of our employee incentive arrangement for our employees who are not Chinese citizens. Further, certain of our then existing shareholders transferred their equity interests in our Company to their offshore/onshore affiliates pursuant to the Reorganization Agreement. Details of such transfers were as follows:

Transferor	Transferee	Transferred Ownership in our Company (%)	Consideration (RMB)
Rongjian	RC-Biology Investment Ltd. (“RC-Biology”)	2.96	21,500
Gaotoumingli	Metroplus International Limited (“Metroplus”)	1.93	140,247
	Govtor Capital Co., Ltd. (江蘇高科技投資集團有限公司) (“Govtor”)	0.65	46,850
	Jiangsu International Trust Corporation Limited (江蘇省國際信託有限責任公 司) (“Jiangsu International Trust”)	0.59	42,699
Yantai Venture	Metroplus	0.22	15,877
	Govtor	0.07	5,304
	Jiangsu International Trust	0.068	4,834
	Jiangyin Changjiang	0.06	4,700
	Yantai Economic Development Investment Company (煙台市 經濟發展投資公司) (“Yantai Economic Development”)	0.56	40,953
	Yan Tai Hong Da Investment Limited (煙台鴻大投資有限公司) (“Hong Da”)	0.42	30,715
Nanjing Daoxin	Nanjing Daoan Management Center GP (南京道安企業管理中心(普通 合夥)) (“Nanjing Daoan”)	0.02	1,107

The abovementioned equity transfers were completed on December 13, 2019.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the Reorganization, the shareholding structure of our Company was as follows:

Shareholders	Registered Capital (RMB)	Equity interest (%)
Rongda	46,537,223	28.05
I-NOVA Limited	18,000,000	10.85
Dr. Fang	11,917,418	7.18
Rongqian	8,412,449	5.07
Rongyi	7,559,244	4.56
RongChang Holding	5,310,784	3.20
Rongshi	4,177,365	2.52
Rongjian	983,479	0.60
Total equity interests held by the Concert Parties and Onshore ESOP Platforms	102,897,962	62.03
SDIC Venture	10,279,205	6.20
Wholly Sunbeam Limited	6,942,867	4.18
PAG I	6,852,793	4.13
SCGC	5,139,603	3.10
RC-Biology	4,917,392	2.96
Lu Thai	4,917,393	2.96
Metroplus	3,570,805	2.15
SDIC Chuanghe	3,426,402	2.07
Beijing Lapam	3,426,402	2.07
Nanjing Huatai I	1,579,648	0.95
TIBET Lapam	1,370,559	0.83
Hangzhou Chuanghe	1,370,559	0.83
Shandong Jifu	1,199,239	0.72
Weihai Luxin	1,199,239	0.72
Govtor	1,192,847	0.72
Jiangsu International Trust	1,087,152	0.66
Jiangyin Changjiang	1,056,952	0.63
SME Development Fund	1,027,921	0.62
Yantai Economic Development	936,665	0.56
Hong Da	702,499	0.42
Senming Capital Limited	685,280	0.41
Nanjing Huatai II	108,232	0.07
Nanjing Daoan	25,319	0.02
Total	165,912,935	100.00

Our PRC Legal Advisor has confirmed that the increases of registered capital and equity transfers in respect of our Company as described above have been properly and legally completed and all regulatory approvals have been obtained in accordance with PRC laws and regulations.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shareholders’ rights

Prior to the Reorganization, the shareholders of RC Pharma were granted certain shareholders’ rights at the level of RC Pharma. As part of the Reorganization, it was agreed between such shareholders and our Company that our Company should grant corresponding shareholders’ rights at the level of our Company to the shareholders or their affiliates which will be entities holding equity interests in our Company after the Reorganization. As such, on October 8, 2019, our Company and, amongst others, the then shareholders of RC Pharma or their affiliates (together, the “Old Shareholders”) entered into a shareholders’ agreement and a supplemental shareholders’ agreement (together, the “Old Shareholders’ Agreement”) to provide for such corresponding shareholders’ rights. Save for the redemption rights as described below, all other shareholders’ rights were automatically terminated prior to the submission of the [REDACTED] of our Company.

On June 23, 2020, the Old Shareholders have agreed that in the event that (i) the planned listing of the Domestic Shares in the PRC is not completed within 36 months after the [REDACTED]; and (ii) the Shares held by the Old Shareholders cannot be traded on the Hong Kong Stock Exchange within 36 months after the [REDACTED], the Old Shareholders are entitled to request RC Pharma or members of the Concert Parties Group to repurchase the Domestic Shares held by the Old Shareholders in part or in full (the “Redemption Right”). The redemption price will be the higher of (i) 80% of the investment amount paid by each of the Old Shareholders when they subscribe for the shares of RC Pharma plus redemption interest calculated at a specified interest rate; or (ii) a share price of approximately RMB21.46 times the number of Domestic Shares held by such Old Shareholders, or, if the Redemption Right is triggered because the Company does not use reasonable efforts to apply for the planned listing of the Domestic Shares or to assist the Old Shareholders in their conversion of Domestic Shares into H Shares, the redemption price shall be three times of 80% of the investment amount paid by each of the Old Shareholders when they subscribe for the share of RC Pharma. The Old Shareholders agreed that the Redemption Right with respect to the Unlisted Foreign Shares or H Shares held by them is terminated and shall only be exercisable if [REDACTED] does not take place and Redemption Right is restored if the [REDACTED] does not take place before December 31, 2021. The Redemption Right with respect to the Domestic Shares shall cease if the relevant Domestic Shares are qualified to be traded on the Hong Kong Stock Exchange or if the conversion of the Domestic Shares into H Shares is approved by the CSRC.

JOINT-STOCK REFORM

Pursuant to the shareholders’ resolutions and the Promoters’ agreement dated May 11, 2020, the then existing Shareholders of our Company agreed to convert our Company into a joint stock limited liability company with a registered capital of RMB401,819,202. According to the audit report prepared by Ernst & Young Hua Ming LLP, as at March 31, 2020, the net asset value of our Company amounted to RMB427,630,845, of which RMB401,819,202 has been converted into 401,819,202 Shares of RMB1.0 par value each, and issued to the then

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shareholders of our Company in proportion to their capital contribution to our Company at the ratio of 1:2.2. The remaining amount of RMB25,811,643 was converted to capital reserve. Upon the completion of registration with the Yantai Administration for Market Regulation (煙台市市場監督管理局) on May 12, 2020, our Company was converted into a joint stock company with limited liability, and renamed as RemeGen Co., Ltd. (榮昌生物製藥(煙台)股份有限公司).

SUBSIDIARIES OF OUR COMPANY

As of the Latest Practicable Date, we have four wholly-owned subsidiaries and their details are as set forth below:

Entity	Date and place of incorporation	Share capital/Registered capital	Principal business activities
Ruimeijing (Beijing) Pharmaceutical Technology Co., Ltd. (瑞美京(北京)醫藥科技有限公司) (“Ruimeijing”)	PRC; August 14, 2019	RMB1,000,000	Research and development
RemeGen Medical Research (Shanghai) Co., Ltd. (榮昌生物醫藥研究(上海)有限公司)	PRC; May 20, 2020	RMB8,000,000	Research and development
RemeGen Biosciences, Inc. (formerly known as RC Biotechnologies, Inc.)	US; April 18, 2011	1,500 common shares	Research and development, registration and business development
RemeGen Hong Kong Limited	Hong Kong; September 26, 2019	USD4,000,000	Research and development and business development

CONCERT PARTY ARRANGEMENT

Pursuant to a concert party agreement dated April 16, 2020 entered into by and amongst Mr. Wang, Dr. Fang, Mr. Lin Jian (林健), Mr. Xiong Xiaobin (熊曉濱), Dr. Wang Liqiang (王荔強), Mr. Wang Xudong (王旭東), Mr. Deng Yong (鄧勇), Mr. Wen Qingkai (溫慶凱), Ms. Yang Minhua (楊敏華) and Mr. Wei Jianliang (魏建良), Rongda, RongChang Holding Group LTD. and I-NOVA Limited (together, the “Concert Parties”), the Concert Parties confirmed that they have acted in concert in the management, decision-making and all major decisions of our Group during the Track Record Period, and they have agreed to continue to act in concert and reach consensus on any proposal presented to the general meeting of the Shareholders of our Company for voting. In the event they fail to reach such consensus, each of the Concert Parties shall exercise their respective indirect voting rights in accordance with majority vote amongst the Concert Parties.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Rongda is a limited partnership established in the PRC and wholly-owned by the individual members of the Concert Parties Group (except Dr. Fang), Mr. Wang Yuxiao, Mr. Lin Yongqing and Ms. Xiong Xing. RongChang Holding Group LTD. is a company incorporated in the British Virgin Islands and wholly-owned by the individual members of the Concert Parties Group (except Dr. Fang and Mr. Xiong Xiaobin). I-NOVA Limited is a company incorporated in the British Virgin Islands and is wholly-owned by Dr. Fang. Pursuant to the confirmation dated June 8, 2020 executed by each of Mr. Wang Yuxiao, Mr. Lin Yongqing and Ms. Xiong Xing, each of them confirms that they have acted and will continue to act according to the instructions of Mr. Wang, Mr. Lin Jian and Mr. Xiong Xiaobin, respectively, in exercising their shareholders' rights.

EMPLOYEE INCENTIVE SCHEMES

In recognition of the contributions of our employees and to incentivize them to further promote our development, Rongqian, Rongshi, Rongyi, Rongjian were established in the PRC as our Onshore ESOP Platforms. Further, RC-Biology was incorporated in the British Virgin Islands as our offshore employee incentive platform.

Yantai Rongqian Enterprise Management Center (Limited Partnership) (煙台榮謙企業管理中心(有限合夥))

Rongqian was established in the PRC as a limited partnership on August 2, 2019. Mr. Wang is the sole executive partner of Rongqian and is responsible for the management of Rongqian. As of the Latest Practicable Date, Rongqian had 30 limited partners, including Dr. Wang Liqiang, our non-executive Director, and 29 other individuals, including employees of our Group and individuals who were indirect shareholders of RC Pharma prior to the Reorganization.

Yantai Rongshi Enterprise Management Center (Limited Partnership) (煙台榮實企業管理中心(有限合夥))

Rongshi was established in the PRC as a limited partnership on August 2, 2019. Mr. Wang is the sole executive partner of Rongshi and is responsible for the management of Rongshi. As of the Latest Practicable Date, Rongshi had 33 limited partners, including employees of our Group and individuals who were indirect shareholders of RC Pharma prior to the Reorganization.

Yantai Rongyi Enterprise Management Center (Limited Partnership) (煙台榮益企業管理中心(有限合夥))

Rongyi was established in the PRC as a limited partnership on August 1, 2019. Mr. Wang is the sole executive partner of Rongyi and is responsible for the management of Rongyi. As of the Latest Practicable Date, Rongyi had 39 limited partners, including Yantai Rongchang Enterprise Management Center (Limited Partnership) (煙台榮昌企業管理中心(有限合夥)),

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

employees of our Group and individuals who were indirect shareholders of RC Pharma prior to the Reorganization. Yantai Rongchang Enterprise Management Center (Limited Partnership) (煙台榮昌企業管理中心(有限合夥)) is the holding vehicle of individual members (other than Dr. Fang) among the Concert Parties.

Yantai Rongjian Enterprise Management Center (Limited Partnership) (煙台榮建企業管理中心(有限合夥))

Rongjian was established in the PRC as a limited partnership on July 26, 2019. Mr. Wang is the sole executive partner of Rongjian and is responsible for the management of Rongjian. As of the Latest Practicable Date, Rongjian had 23 limited partners, including Yantai Rongchang Enterprise Management Center (Limited Partnership) (煙台榮昌企業管理中心(有限合夥)), employees of our Group and individuals who were indirect shareholders of RC Pharma prior to the Reorganization.

RC-Biology Investment Ltd.

RC-Biology was incorporated in the British Virgin Islands as a limited company on July 29, 2019. Dr. Fang and Mr. Li Ruoshun (李若順), an employee of the Company and a supervisor of our subsidiary, Ruimeijing, are the directors and shareholders of RC-Biology and are jointly responsible for the management of RC-Biology. The equity interests held by RC-Biology are reserved for employee incentive purpose for our employees who are not PRC residents.

PRE-[REDACTED] INVESTMENTS

2019 Subscription

Pursuant to a share subscription agreement and a share purchase agreement, both dated August 11, 2017, entered into by, amongst others, PAG I and RC Pharma, PAG I has subscribed for the then increased share capital of RC Pharma and purchased certain equity interests in RC Pharma from Rongchang Technology and became a shareholder of RC Pharma. Pursuant to the supplemental agreement of the share subscription agreement dated August 11, 2017 entered into by and between, amongst others, PAG I and RC Pharma, PAG I was granted a right to subscribe for registered capital of RC Pharma at a subscription price of RMB35.879 per share for a total consideration of RMB100 million (the “PAG Subscription Right”).

Pursuant to the second supplemental agreement of the share subscription agreement dated July 15, 2019 (the “Second Supplemental Agreement”) entered into by and between, amongst others, PAG I, RC Pharma and our Company, it was agreed that PAG I was entitled to subscribe for 1.6521% equity interest in RC Pharma for a total consideration of RMB100 million should it then exercise the PAG Subscription Right. Considering the Reorganization and the respective valuations in the proportion of 1:9 of RC Pharma and its subsidiaries and our Group after the Reorganization, it was agreed under the Second Supplemental Agreement that PAG I would exercise the PAG Subscription Right in RC Pharma and our Group simultaneously to subscribe

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

for approximately 1.6521% of the registered capital of each of RC Pharma and our Group at a consideration of RMB10 million and RMB90 million, respectively. As such, PAG I subscribed for the increased registered capital of RMB2,741,117 of our Company at a consideration of RMB90 million and the registered capital of our Company was increased from RMB165,912,935 to RMB168,654,052 (the “2019 Subscription”). The premium amount of RMB87,258,883 was credited to the capital reserve of our Company.

Upon completion of the increase and subscription of registered capital on December 25, 2019, the shareholding structure of our Company was as follows:

Shareholders	Registered Capital (RMB)	Equity interest (%)
Rongda	46,537,223	27.59
I-NOVA Limited	18,000,000	10.67
Dr. Fang	11,917,418	7.07
Rongqian	8,412,449	4.99
Rongyi	7,559,244	4.48
RongChang Holding	5,310,784	3.15
Rongshi	4,177,365	2.48
Rongjian	983,479	0.58
Total equity interests held by the Concert Parties and the Onshore ESOP Platforms	102,897,962	61.01
SDIC Venture	10,279,205	6.09
PAG I	9,593,910	5.69
Wholly Sunbeam Limited	6,942,867	4.12
SCGC	5,139,603	3.05
RC-Biology	4,917,392	2.92
Lu Thai	4,917,393	2.92
Metroplus	3,570,805	2.12
SDIC Chuanghe	3,426,402	2.03
Beijing Lapam	3,426,402	2.03
Nanjing Huatai I	1,579,648	0.94
TIBET Lapam	1,370,559	0.81
Hangzhou Chuanghe	1,370,559	0.81
Shandong Jifu	1,199,239	0.71
Weihai Luxin	1,199,239	0.71
Govtor	1,192,847	0.71
Jiangsu International Trust	1,087,152	0.64
Jiangyin Changjiang	1,056,952	0.63
SME Development Fund	1,027,921	0.61
Yantai Economic Development	936,665	0.55
Hong Da	702,499	0.42
Senming Capital Limited	685,280	0.40
Nanjing Huatai II	108,232	0.06
Nanjing Daoan	25,319	0.02
Total	168,654,052	100.00

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

2020 Subscription

Pursuant to a capital increase agreement dated February 25, 2020 entered into by and between, among others, our Company and the investors set out in the table below (together with PAG I, the “Pre-[REDACTED] Investors”), the registered capital of our Company was increased from RMB168,654,052 to RMB182,645,092 and the Pre-[REDACTED] Investors agreed to subscribe for the increased registered capital of RMB13,991,040 of our Company at a total consideration of USD105,355,440 (the “2020 Subscription”). The consideration for the 2020 Subscription was determined based on arm’s length negotiations amongst the Company and the Pre-[REDACTED] Investors, taking into account various factors including the expected commercialization timeline of telitacicept and disitamab vedotin, the indications they cover, the number of patients suffering from such indications in the PRC and globally, as well as the pricing and expected market shares of telitacicept and disitamab vedotin. The premium amount of approximately RMB721,835,000 was credited to the capital reserve of our Company.

The respective subscription amounts and considerations paid by the Pre-[REDACTED] Investors were as follows:

Pre-[REDACTED] Investors	Registered capital subscribed for	Consideration paid	Equity interest (upon completion of the 2020 Subscription)
	(RMB)	(USD)	(%)
LAV Remegen Limited	1,991,977	15,000,000	1.09
Suzhou Lirui Equity Investment Center (Limited Partnership) (蘇州禮瑞股權投資中心(有限合夥)) (“Suzhou Lirui”)	663,992	5,000,000*	0.36
Suzhou Likang Equity Investment Center (Limited Partnership) 蘇州禮康股權投資中心(有限合夥)) (“Suzhou Likang”)	1,327,985	10,000,000*	0.73
LBC Sunshine Healthcare Fund L.P. (“LBC Sunshine”)	2,058,376	15,500,000	1.13
Vivo Capital Fund IX, L.P. (“Vivo Capital”)	2,058,376	15,500,000	1.13
Janchor Partners Pan-Asian Master Fund (“Janchor Partners”)	1,726,380	13,000,000	0.95
OrbiMed Partners Master Fund Limited (“OrbiMed Partners”)	1,062,388	8,000,000	0.58
OrbiMed Genesis Master Fund, L.P. (“OrbiMed Genesis”)	265,597	2,000,000	0.15
Hudson Bay Master Fund LTD (“Hudson Bay Capital”)	929,589	7,000,000	0.51
PAG Growth Holding IV (HK) Limited (“PAG IV”)	762,552	5,742,176*	0.42
TIBET Lapam	381,276	2,871,088*	0.21
Hong Da	285,957	2,153,316*	0.16
Shandong Jifu	285,957	2,153,316*	0.16
Wholly Sunbeam Limited	190,638	1,435,544*	0.10

Note:

* denotes payment of consideration in RMB

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Upon completion of the 2020 Subscription on March 20, 2020, the shareholding structure of our Company was as follows:

Shareholders	Registered Capital (RMB)	Equity interest (%)
Rongda	46,537,223	25.48
I-NOVA Limited	18,000,000	9.86
Dr. Fang	11,917,418	6.52
Rongqian	8,412,449	4.61
Rongyi	7,559,244	4.14
RongChang Holding	5,310,784	2.91
Rongshi	4,177,365	2.29
Rongjian	983,479	0.54
Total equity interests held by the Concert Parties and the Onshore ESOP Platforms	102,897,962	56.35
SDIC Venture	10,279,205	5.63
PAG I	9,593,910	5.25
PAG IV	762,552	0.42
Wholly Sunbeam Limited	7,133,505	3.91
SCGC	5,139,603	2.81
RC-Biology	4,917,392	2.69
Lu Thai	4,917,393	2.69
Metroplus	3,570,805	1.96
SDIC Chuanghe	3,426,402	1.88
Beijing Lapam	3,426,402	1.88
LBC Sunshine	2,058,376	1.13
Vivo Capital	2,058,376	1.13
LAV Remegen Limited	1,991,977	1.09
TIBET Lapam	1,751,835	0.96
Janchor Partners	1,726,380	0.95
Nanjing Huatai I	1,579,648	0.85
Shandong Jifu	1,485,196	0.81
Hangzhou Chuanghe	1,370,559	0.75
Suzhou Likang	1,327,985	0.73
Weihai Luxin	1,199,239	0.66
Govtor	1,192,847	0.65
Jiangsu International Trust	1,087,152	0.59
Jiangyin Changjiang	1,056,952	0.58
OrbiMed Partners	1,062,388	0.58
SME Development Fund	1,027,921	0.56
Hong Da	988,456	0.54
Yantai Economic Development	936,665	0.51
Hudson Bay Capital	929,589	0.51
Senming Capital Limited	685,280	0.37
Suzhou Lirui	663,992	0.36
OrbiMed Genesis	265,597	0.15
Nanjing Huatai II	108,232	0.06
Nanjing Daoan	25,319	0.01
Total	182,645,092	100.00

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Principal terms of the Pre-[REDACTED] Investments and Pre-[REDACTED] Investors’ Rights

The below table summarizes the principal terms of the Pre-[REDACTED] Investments:

	<u>2019 Subscription</u>	<u>2020 Subscription</u>
Amount of registered capital increased	RMB2,741,117	RMB13,991,040
Amount of registered capital after joint stock reform	RMB6,030,457.4	RMB30,780,288
Amount of consideration paid	RMB90,000,000	USD105,355,440
Post-money valuation of our Company¹	RMB5,537 million	USD1.38 billion
Date of agreement	Second supplemental agreement of the share purchase agreement dated July 15, 2019	Capital increase agreement dated February 25, 2020
Date of payment of full consideration	December 25, 2019	March 16, 2020
Cost per Share paid under the pre-[REDACTED] investment¹	RMB14.92	RMB23.84
Discount to the [REDACTED]²	approximately [REDACTED]%	approximately [REDACTED]%
Use of proceeds and whether they have been fully utilized	the proceeds raised have been fully utilized for the repayment of the loan from RC Pharma and the Company’s operations and research and development activities	the proceeds raised are used for the Company’s operations, and the research and development activities of the Company, such as pre-clinical studies and clinical studies of our Core Products. As of the Latest Practicable Date, approximately 80% of the net proceeds from the 2020 Subscription were utilized
Lock-up	subject to a lock-up period of 12 months following the [REDACTED] pursuant to the PRC Company Law	
Strategic benefits to our Company	Our Directors believe that the Pre-[REDACTED] Investments have provided support for our research and development activities as well as our daily operations.	

Notes:

1. Calculated based on the currency conversion rate of USD1 = RMB6.966. The fluctuation in valuations was mainly due to the advancement in the research and development, especially the clinical trials, of telitacicept and disitamab vedotin.
2. Calculated on the basis of the [REDACTED] of HK\$[REDACTED], the mid-point of the proposed range of the [REDACTED].

The considerations of all the pre-[REDACTED] investments were determined based on an arm’s length negotiation between the parties taking into consideration of the timing of the investments and the status of our business and operating entities.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Rights of the Pre-[REDACTED] Investors

The Pre-[REDACTED] Investors were granted customary special rights, including but not limited to redemption right, financial compensation right, pre-emptive right, information right and anti-dilution rights. Except for the redemption right as described below, all other special rights shall cease to be effective and be discontinued upon the [REDACTED].

Redemption right

Each Pre-[REDACTED] Investor is given the right to, upon the occurrence of specified redemption events, request that our Controlling Shareholders redeem the Shares each Pre-[REDACTED] Investor then holds at the specified redemption price. Such redemption events include: (a) a failure on the part of our Company or our Controlling Shareholders to rectify a material breach of laws or regulations or provisions under the transaction documents for the 2020 Subscription which results in a material adverse effect; (b) our Company cannot complete the [REDACTED] by December 31, 2021; (c) our Company fails to submit the application for listing of the Domestic Shares in the PRC within 12 months after the [REDACTED] and refuse to assist the Pre-[REDACTED] Investors to apply for conversion of their Shares into H Shares; (d) we fail to obtain the registration certificate and manufacturing permit for telitacipt in China by June 30, 2021; (e) the sale of telitacipt is withdrawn by the Company; or (f) exercise of redemption right by any other Shareholders of the Company (together, “Redemption Conditions” and each a “Redemption Condition”).

Pursuant to a supplemental agreement dated June 10, 2020 entered into by and between, among others, our Company and each of our Pre-[REDACTED] Investors (the “Supplemental Agreement”), our Pre-[REDACTED] Investors which hold our Unlisted Foreign Shares agreed to terminate the abovementioned redemption right with respect to Redemption Conditions (a), (c) to (f) with effect from the day prior to submission of the [REDACTED] application by our Company, and that the redemption right with respect to Redemption Condition (b) shall only be exercisable if the [REDACTED] is not completed by December 31, 2021 and will terminate upon [REDACTED].

Pursuant to the Supplemental Agreement, our Pre-[REDACTED] Investors which hold our Domestic Shares agreed to terminate the abovementioned redemption right with respect to Redemption Conditions (a), (d) to (f) above with effect from the day prior to submission of the [REDACTED] application by our Company, and that the redemption right with respect to Redemption Condition (b) above shall only be exercisable if the [REDACTED] is not completed by December 31, 2021 and will terminate upon [REDACTED]. For the redemption right with respect to Redemption Condition (c), it remains effective and exercisable by our Pre-[REDACTED] Investors which hold our Domestic Shares. The redemption price will be equal to the investment amount paid by the Pre-[REDACTED] Investors plus 11% compound interest per annum from the date of settlement of the investment amount to the date of payment of the redemption price.

The redemption rights terminated pursuant to the Supplemental Agreement shall be restored upon the earlier of (a) the withdrawal of the [REDACTED] application by our Company; (b) the rejection of the [REDACTED] application by the Stock Exchange; or (c) failure on the part of our Company to complete the [REDACTED] by December 31, 2021.

Following the [REDACTED] and prior to the completion of our planned listing of Domestic Shares in the PRC, the share capital of our Company will comprise H Shares, Unlisted Foreign Shares and Domestic Shares, which carry different right and are regarded as different classes of Shares under the Articles of Association. Whereas H Shares will be freely transferable on the Hong Kong Stock Exchange after the [REDACTED], Domestic Shares and Unlisted Foreign Shares which are not converted into H Shares are not tradeable publicly.

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As such, our Shareholders which hold Domestic Shares and cannot apply for conversion of such Shares into H Shares are subject to significantly different risks, relating to the lack of liquidity of such Domestic Shares they invested in if our planned listing of Domestic Shares in the PRC does not proceed and we refuse to assist them in their application for conversion of Domestic Shares into H Shares, compared to investors in the [REDACTED] who invest in H Shares. Redemption Condition (c) was retained to cater for such risks which investors in the [REDACTED] are not subject to. In addition, our Controlling Shareholders bear the corresponding redemption obligation and such redemption will not be funded by our Company. Therefore, the redemption right with respect to Redemption Condition (c) do not fall within Guidance Letter HKEX-GL43-12 issued in October 2012 by the Hong Kong Stock Exchange and can survive the [REDACTED].

Information about our Pre-[REDACTED] Investors

Our Pre-[REDACTED] Investors are mainly sophisticated investors, such as dedicated healthcare funds and biotech funds as well as established funds with a focus on investments in the biopharmaceutical sector, including the following:

1. **PAG:** PAG I, a sophisticated investor, and PAG IV are both limited companies incorporated in Hong Kong, and wholly-owned subsidiaries of funds managed by PAG. Founded in 2002, PAG is today one of Asia’s largest independent alternative investment managers, focusing on private equity, real estate and absolute returns, with over US\$35 billion under management as of December 31, 2019. PAG employs a thematic approach to investing in private equity, seeking to back businesses with leading market positions, proven performance, committed management teams and great potential. Biotech and healthcare have been core focus sectors of PAG, and it has invested in a number of companies in such areas.
2. **LAV:** LAV Remegen Limited is a company incorporated in the British Virgin Islands with limited liability. Each of Suzhou Lirui and Suzhou Likang is a limited partnership established in the PRC. Each of the abovementioned entities are investment arms of Lilly Asia Ventures (“LAV”), a leading Asia-based life science investment firm with portfolios covering all major sectors of the biomedical and healthcare industry including biopharmaceuticals, medical devices, diagnostics and healthcare services. Founded in 2008, LAV is one of the biomedical venture firms with the longest histories in China. To date, LAV manages committed capital of over USD1.2 billion, and has invested in 78 portfolio companies worldwide. Currently, LAV is managed by a team of professionals with substantial biomedical domain expertise, as well as extensive investing experiences in China. LAV has offices in Shanghai, Hong Kong and California, USA.
3. **Lake Bleu:** LBC Sunshine Healthcare L.P. (“LBC Sunshine”) is managed by Lake Bleu Capital (Hong Kong) Limited. LBC Sunshine, an exempted limited partnership registered in the Cayman Islands, specializes in investing in late-stage healthcare companies in Asia/Greater China. The investment scope includes pharmaceuticals, biotech, medical devices, and healthcare services. LBC GP Limited, an exempted company incorporated in the Cayman Islands, acts as the general partner of the LBC Sunshine.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

4. **Vivo:** Vivo Capital is an investment fund organized under the laws of Delaware, US and has been dedicated to investing in companies and assets in the healthcare sector in primarily the U.S. and the Greater China, which are two of the largest healthcare markets in the world. Vivo Capital IX, LLC is the general partner of Vivo Capital.
5. **Janchor:** Janchor Partners is a company incorporated under the laws of the Cayman Islands that is managed and controlled by Janchor Partners Limited, a company licensed by the SFC to conduct asset management business (together, “Janchor Partners”). Established in 2009, Janchor Partners is a long-term industrialist investor, partnering with companies that have superior business models, favorable growth prospects and the potential to be part of long-term positive structural dynamics of Asia countries and economies. Janchor is an experienced institutional investor with a track record of investing in healthcare companies.
6. **OrbiMed:** OrbiMed Partners is a company incorporated under the laws of Bermuda, and OrbiMed Genesis is an exempted limited partnership incorporated under the laws of the Cayman Islands. Both OrbiMed Partners and OrbiMed Genesis are under common control of Sven Borho, Carl Gordon and Jonathan Silverstein. OrbiMed is a leading healthcare investment firm dedicated exclusively to the healthcare sector, with over US\$14 billion in assets under management. OrbiMed invests globally across a spectrum of healthcare companies, from start-ups to large multinational corporations, utilizing a range of private equity funds, public equity funds, royalty/credit funds and other investment vehicles. OrbiMed maintains its headquarters in New York City, with additional offices in San Francisco, Shanghai, Mumbai, Herzliya and Hong Kong. OrbiMed seeks to be a capital provider of choice, providing tailored financing solutions and global team support to help build world-class healthcare companies.
7. **Hudson Bay Capital:** Hudson Bay Capital (“HBC”) is a multi-billion dollar asset management firm operating in New York and London. With over 80 employees, HBC has been managing assets on behalf of outside investors since 2006. The firm invests across multiple strategies by utilizing rigorous fundamental analysis, and seeks to identify value and growth opportunities that are uncorrelated to each other and market indices. HBC promotes an integrated team culture emphasizing collaboration and cross-pollination of ideas across sectors and strategies. HBC’s dedicated investment team seeks to achieve outstanding performance by investing in companies that are poised for growth or are undervalued while maintaining a focus on risk management.
8. **Lapam Capital:** TIBET Lapam is a limited partnership established in the PRC and an investment arm of Lapam Capital, which is a leading healthcare-focused venture capital firm in China and manages 3 funds with over RMB2 billion in capital under management. Lapam Capital targets start-up, early-stage and fast-growing companies that have innovative and disruptive healthcare technologies, including small-molecule therapies, biologics, and medical devices. Lapam Capital has invested in over 30 biopharmaceutical companies and 10 medical device companies to date.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

9. **Shandong Jifu:** Shangdong Jifu is a limited partnership established in the PRC in November 2017 and whose executive partner is Shandong Jifu Gaoxing Equity Investment Management Co., Ltd. (山東吉富高新股權投資管理有限公司). Shandong Jifu is principally engaged in the equity investments in private company, private placements of shares of listed companies and relevant consultation services.
10. **Hong Da:** Hong Da is a limited company incorporated in the PRC and is an investment company focusing on equity investments using its own funds. Hong Da is indirectly owned by seven individuals who are Independent Third Parties.
11. **Wholly Sunbeam Limited:** Wholly Sunbeam Limited is a limited company incorporated in the British Virgin Islands and is wholly-owned by an individual who is an Independent Third Party.

Compliance with Interim Guidance and Guidance Letters

The Joint Sponsors confirm that the investments by the Pre-[REDACTED] Investors are in compliance with the Guidance Letter HKEX-GL29-12 issued on January 2012 and updated in March 2017 by the Stock Exchange and the Guidance Letter HKEX-GL43-12 issued in October 2012 and updated in July 2013 and in March 2017 by the Stock Exchange.

THE A SHARE LISTING

We plan to conduct the offering and listing of A shares at an appropriate time after the [REDACTED]. As of the Latest Practicable Date, we have not determined the size and scope of the contemplated A share offering and have not made any application to any recognized stock exchange in the PRC for approval for the listing of any A shares. There is no assurance we will conduct an A share offering in the future.

PUBLIC FLOAT

The 265,512,611 Shares held by Rongda, Dr. Fang, Rongshi, Rongyi, Rongqian, Rongjian, SDIC Venture, SCGC, SDIC Chuanghe, Beijing Lapam, Suzhou Likang, Suzhou Lirui, Lu Thai, TIBET Lapam, Nanjing Huatai I, Shandong Jifu, Hangzhou Chuanghe, Weihai Luxin, Govtor, Jiangsu International Trust, SME Development Fund, Hong Da, Yantai Economic Development, Shanghai Tanying Investment Partnership (Limited Partnership) (上海檀英投資合夥企業(有限合夥)), Nanjing Huaitai II and Nanjing Daoan, representing approximately 66.08% of our total issued Shares as of the Latest Practicable Date, or approximately [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), will not be considered as part of the public float as the Shares are Domestic Shares and Unlisted Foreign Shares which will not be converted into H Shares and listed following the completion of the [REDACTED].

The 62,101,987 Shares held by I-NOVA Limited, RongChang Holding and RC-Biology, representing approximately 15.46% of our total issued Shares as of the Latest Practicable Date, or approximately [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), are Unlisted Foreign Shares which [will be] converted into H Shares and listed following the completion of the [REDACTED]. As of the Latest Practicable Date, Mr. Wang, our executive Director, is the sole director of RongChang Holding and Dr. Fang, our executive Director, is the sole shareholder of I-NOVA Limited. Also, Dr. Fang and Mr. Li Ruoshun, a supervisor of our subsidiary, Ruimeijing, are the directors of RC-Biology. As these individuals and entities are core connected persons of our Company upon [REDACTED], the Shares held by them will not be counted towards the public float for the purpose of Rule 8.08 of the Listing Rule after [REDACTED].

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

The 74,204,604 Shares held by PAG I, PAG IV, Wholly Sunbeam Limited, Metroplus, LBC Sunshine, LAV Remegen Limited, Vivo Capital, Janchor Partners, MINTU Infrastructure Development Holdings Co., Limited, OrbiMed Partners, OrbiMed Genesis, Hudson Bay Capital, Senming Capital Limited and CRF Investment Holdings Company Limited, representing approximately 18.47% of our total issued Shares as of the Latest Practicable Date, or [REDACTED]% of our total issued Shares upon [REDACTED] (assuming the [REDACTED] is not exercised), are Unlisted Foreign Shares which will be converted into H Shares and listed following the completion of the [REDACTED]. As these entities will not be core connected persons of the Company upon [REDACTED], are not accustomed to take instructions from core connected persons in relation to the acquisition, disposal, voting or other disposition of their Shares and their acquisition of Shares were not financed directly or indirectly by core connected persons, the Shares held by them will be counted towards the public float for the purpose of Rule 8.08 of the Listing Rule after [REDACTED].

Immediately upon completion of the [REDACTED], assuming that (i) [REDACTED] H Shares are issued and sold in the [REDACTED]; (ii) the [REDACTED] is not exercised; and (iii) [REDACTED] Shares are issued and outstanding upon completion of the [REDACTED], based on an [REDACTED] of HK\$[REDACTED] per Share (being the low-end of the indicative [REDACTED] range), the Company will have a market capitalization of at least HK\$[REDACTED] held by public.

The below table is a summary of the capitalization of our Company as of the date of this document and the [REDACTED]:

Shareholders	Number of Shares	Ownership percentage as of the date of this document	Ownership percentage as of the [REDACTED]
Yantai Rongda Venture Capital Center (Limited Partnership) (煙台榮達創業投資中心(有限合夥)) ^(A)	102,381,891	25.48%	[REDACTED]%
I-NOVA Limited ^(B)	39,600,000	9.86%	[REDACTED]%
Dr. Fang ^(B)	26,218,320	6.52%	[REDACTED]%
Yantai Rongqian Enterprise Management Center (Limited Partnership) (煙台榮謙企業管理中心(有限合夥)) ^(A)	18,507,388	4.61%	[REDACTED]%
Yantai Rongyi Enterprise Management Center (煙台榮益企業管理中心(有限合夥)) ^(A)	16,630,337	4.14%	[REDACTED]%
RongChang Holding Group LTD. ^(B)	11,683,725	2.91%	[REDACTED]%
Yantai Rongshi Enterprise Management Center (Limited Partnership) (煙台榮實企業管理中心(有限合夥)) ^(A)	9,190,203	2.29%	[REDACTED]%
Yantai Rongjian Enterprise Management Center (煙台榮建企業管理中心(有限合夥)) ^(A)	2,163,655	0.54%	[REDACTED]%
Total equity interests held by the Concert Parties and the Onshore ESOP Platforms	226,375,519	56.35%	[REDACTED]%
Fund for the transformation of National Science and Technology Major Project (國投(上海)科技成果轉化創業投資基金企業(有限合夥)) ^{(5)(A)}	24,732,556	6.16%	[REDACTED]%
PAG Growth Prosperity Holding I (HK) Limited ^(B)	21,106,602	5.25%	[REDACTED]%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shareholders	Number of Shares	Ownership percentage as of the date of this document	Ownership percentage as of the [REDACTED]
PAG Growth Holding IV (HK) Limited ^{(4)(B)}	2,002,231	0.50%	[REDACTED]%
Wholly Sunbeam Limited ^(B)	15,693,711	3.91%	[REDACTED]%
Shenzhen Capital Group Co., Ltd. (深圳市創新投資集團有限公司) ^{(8)(A)}	12,813,478	3.19%	[REDACTED]%
RC-Biology Investment Ltd. ^(B)	10,818,262	2.69%	[REDACTED]%
Metroplus International Limited ^(B)	7,855,771	1.96%	[REDACTED]%
SDIC Chuanghe National Leading Fund of Emerging Industries VC (Limited Partnership) (國投創合國家新興產業創業投資引導基金(有限合夥)) ^(A)	7,538,084	1.88%	[REDACTED]%
Beijing Lapam Healthcare Investment Center LLP (北京龍磐健康醫療投資中心(有限合夥)) ^(A)	7,538,084	1.88%	[REDACTED]%
LBC Sunshine Healthcare Fund L.P. ^{(3)(B)}	4,723,198	1.18%	[REDACTED]%
LAV Remegen Limited ^{(2)(B)}	4,593,351	1.14%	[REDACTED]%
Suzhou Likang Equity Investment Center (Limited Partnership) (蘇州禮康股權投資中心(有限合夥)) ^{(2)(A)}	3,062,235	0.76%	[REDACTED]%
Suzhou Lirui Equity Investment Center (Limited Partnership) (蘇州禮瑞股權投資中心(有限合夥)) ^{(2)(A)}	1,531,116	0.38%	[REDACTED]%
Vivo Capital Fund IX, L.P. ^(B)	4,528,427	1.13%	[REDACTED]%
Lu Thai Textile Co., Ltd. (魯泰紡織股份有限公司) (1)(2)(3)(4)(5)(6)(7)(8)(A)	4,218,265	1.05%	[REDACTED]%
Janchor Partners Pan-Asian Master Fund ^{(1)(B)}	3,927,884	0.98%	[REDACTED]%
TIBET Lapam Yijing Venture Capital Center LLP (西藏龍磐怡景創業投資中心(有限合夥)) ^(A)	3,854,037	0.96%	[REDACTED]%
Nanjing Huatai Healthcare Investment I LLP (南京華泰大健康一號股權投資合夥企業(有限合夥)) ^(A)	3,475,226	0.85%	[REDACTED]%
Shandong Jifu Jingu New Kinetic Energy Equity Investment Fund Partnership (Limited Partnership) (山東吉富金谷新動能股權投資基金合夥企業(有限合夥)) ^(A)	3,267,431	0.81%	[REDACTED]%
Hangzhou Chuanghe Select Venture Capital (Limited Partnership) (杭州創合精選創業投資合夥企業(有限合夥)) ^(A)	3,015,230	0.75%	[REDACTED]%
Weihai Luxin Fuwei Equity Investment Fund Partnership (Limited Partnership) (威海魯信福威股權投資基金合夥企業) ^(A)	2,638,326	0.66%	[REDACTED]%
Govtor Capital Co., Ltd. (江蘇高科技投資集團有限公司) ^(A)	2,624,263	0.65%	[REDACTED]%
Jiangsu International Trust Corporation Limited (江蘇省國際信託有限責任公司) ^(A)	2,391,734	0.59%	[REDACTED]%

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

Shareholders	Number of Shares	Ownership percentage as of the date of this document	Ownership percentage as of the [REDACTED]
MINTU Infrastructure Development Holdings Co., Limited (民圖基礎設施發展控股有限公司) ^{(9)(B)}	2,325,294	0.58%	[REDACTED]%
OrbiMed Partners Master Fund Limited ^(B)	2,337,254	0.58%	[REDACTED]%
OrbiMed Genesis Master Fund, L.P. ^(B)	584,313	0.15%	[REDACTED]%
Small Medium Enterprises Development Fund (Shenzhen) LLP (中小企業發展基金(深圳有限合夥)) ^(A)	2,261,426	0.56%	[REDACTED]%
Yan Tai Hong Da Investment Limited (煙台鴻大投資有限公司) ^(A)	2,174,603	0.54%	[REDACTED]%
Yantai Economic Development Investment Company (煙台市經濟發展投資公司) ^(A)	2,060,663	0.51%	[REDACTED]%
Hudson Bay Master Fund LTD ^(B)	2,045,096	0.51%	[REDACTED]%
Senming Capital Limited ^(B)	1,507,616	0.37%	[REDACTED]%
CRF Investment Holdings Company Limited ^{(6)(B)}	973,856	0.24%	[REDACTED]%
Shanghai Tanying Investment Partnership (Limited Partnership) (上海檀英投資合夥企業(有限合夥)) ^{(7)(A)}	930,248	0.23%	[REDACTED]%
Nanjing Huatai Healthcare Investment II LLP (南京華泰大健康二號股權投資合夥企業(有限合夥)) ^(A)	238,110	0.06%	[REDACTED]%
Nanjing Daoan Management Center GP 南京道安企業管理中心(普通合夥) ^(A)	55,702	0.01%	[REDACTED]%
Total	401,819,202	100.00%	[REDACTED]%

Notes:

- (1) Lu Thai transferred RMB59,022 registered capital in our Company to Janchor Partners on March 23, 2020 for a total consideration of USD400,000.
- (2) Lu Thai transferred RMB95,910, RMB31,970 and RMB63,940 registered capital in our Company to LAV Remgen Limited, Suzhou Lirui and Suzhou Likang for a consideration of USD650,000, USD216,667 and USD433,333 on March 23, 2020, respectively.
- (3) Lu Thai transferred RMB88,532 registered capital in our Company to LBC Sunshine on March 23, 2020 for a total consideration of USD600,000.
- (4) Lu Thai transferred RMB147,553 registered capital in our Company to PAG IV on March 23, 2020 for a total consideration of RMB6,965,960.
- (5) Lu Thai transferred RMB962,866 registered capital in our Company to SDIC Venture on March 23, 2020 for a total consideration of RMB45,456,791.
- (6) Lu Thai transferred RMB442,662 registered capital in our Company to CRF Investment Holdings Company Limited on March 23, 2020 for a total consideration of USD3,000,000.
- (7) Lu Thai transferred RMB422,840 registered capital in our Company to Shanghai Tanying Investment Partnership (Limited Partnership) (上海檀英投資合夥企業(有限合夥)) on March 23, 2020 for a total consideration of RMB19,962,235.
- (8) Lu Thai transferred RMB684,705 registered capital in our Company to SCGC on March 23, 2020 for a total consideration of RMB32,324,826.
- (9) Jiangyin Changjiang transferred its RMB1,056,952 registered capital in our Company to its subsidiary, MINTU Infrastructure Development Holdings Co., Limited (“MINTU”) on March 16, 2020.

Remarks:

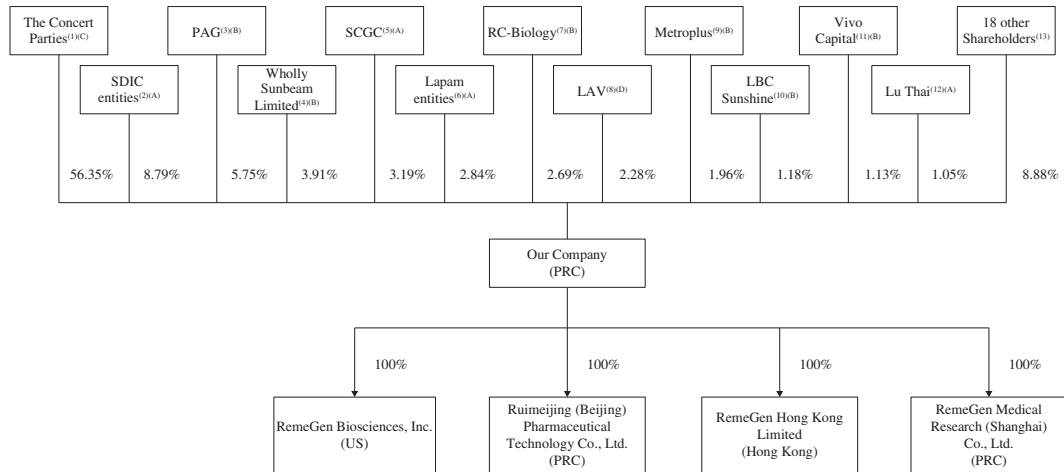
- (A) The Shares held by these Shareholders are Domestic Shares.
- (B) The Shares held by these Shareholders are Unlisted Foreign Shares.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

OUR SHAREHOLDING AND CORPORATE STRUCTURE

Immediately Before Completion of the [REDACTED]

The chart below sets out the shareholding structure of our Company immediately before completion of the [REDACTED]:



Notes:

- (1) Our Concert Parties are interested in 56.35% equity interest in our Company through the 25.48%, 9.86%, 6.52%, 4.61%, 4.14%, 2.91%, 2.29% and 0.54% equity interests held by Rongda, I-NOVA Limited, Dr. Fang, Rongqian, Rongyi, RongChang Holding, Rongshi and Rongjian. Amongst which Rongqian, Rongyi, Rongshi and Rongjian are the Onshore ESOP Platforms, where Mr. Wang acts as the sole executive partner and whose shareholders are Independent Third Parties save for being employees of the Group.
- (2) SDIC entities include SDIC Venture, SDIC Chuanghe and Hangzhou Chuanghe which hold 6.16%, 1.88% and 0.75% equity interest, respectively, in our Company. SDIC Venture is a limited partnership established in the PRC whose executive partner is SDIC (Shanghai) Venture Capital Management Co., Ltd. (國投(上海)創業投資管理有限公司). Both of SDIC Chuanghe and Hangzhou Chuanghe are limited partnerships established in the PRC and whose executive partner is or is wholly-owned by SDIC Unity Capital Co., Ltd. (國投創合基金管理有限公司). State Development & Investment Corporation (國家開發投資集團有限公司), a state-owned entity incorporated in the PRC, indirectly controls the executive partner of each of SDIC Venture, SDIC Chuanghe and Hangzhou Chuanghe. To the best knowledge of our Directors, SDIC entities and their ultimate beneficial owners are Independent Third Parties.
- (3) Each of PAG I and PAG IV is our Pre-[REDACTED] Investor and is a limited company incorporated in Hong Kong and holds 5.25% and 0.50% equity interest, respectively, in our Company. PAG Growth I LP, an Independent Third Party, indirectly controls each of PAG I and PAG IV.
- (4) Wholly Sunbeam Limited is a limited company incorporated in the British Virgin Islands and is wholly-owned by an Independent Third Party who is a natural person.
- (5) SCGC is a limited liability company established in August 1990 under PRC laws, under the sponsorship from the Shenzhen government, who still holds a 28.2% equity interest as its largest shareholder. To the best knowledge of our Directors, SCGC and its ultimate beneficial owners are Independent Third Parties.
- (6) Lapam entities include Beijing Lapam and TIBET Lapam which hold 1.88% and 0.96% equity interest, respectively, in our Company. TIBET Lapam is the general partner of Beijing Lapam, both of which are limited partnership established in the PRC. To the best knowledge of our Directors, Lapam entities and their ultimate beneficial owners are Independent Third Parties.
- (7) RC-Biology is a limited company incorporated in the British Virgin Islands and is an offshore employee incentive platform of our Company and whose shareholders are Independent Third Parties save for being employees of the Group.
- (8) LAV includes LAV RemeGen Limited, Suzhou Lirui and Suzhou Likang hold 1.14%, 0.76% and 0.38% equity interest, respectively, in our Company. LAV RemeGen Limited is a limited company incorporated in the British Virgin Islands and each of Suzhou Lirui and Suzhou Likang is a limited partnership established in the PRC. LAV RemeGen Limited, Suzhou Lirui and Suzhou Likang are our Pre-[REDACTED] Investors. To the best knowledge of our Directors, LAV RemeGen, Suzhou Lirui and Suzhou Likang and their ultimate beneficial owners are Independent Third Parties.

HISTORY, DEVELOPMENT AND CORPORATE STRUCTURE

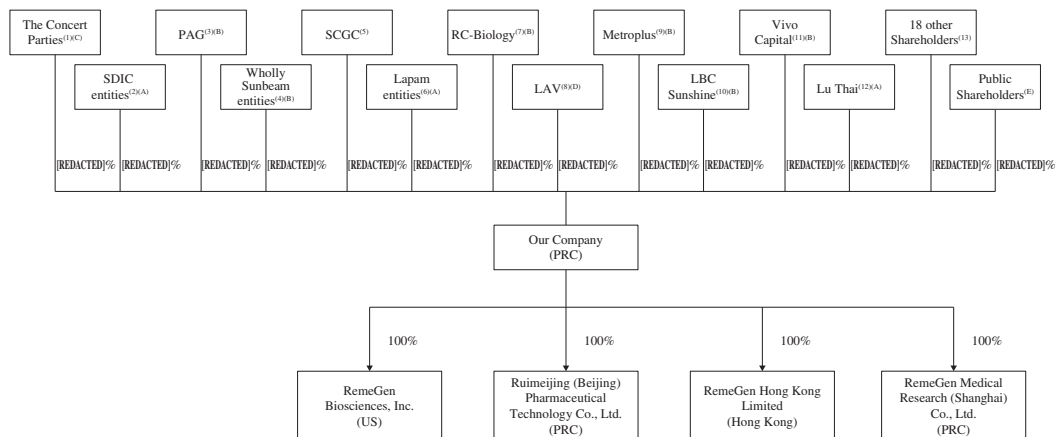
- (9) Metroplus International Limited is a company incorporated in Hong Kong, which is owned by an Independent Third Party to the best knowledge of our Directors.
- (10) LBC Sunshine is a limited partnership established in the Cayman Islands and is one of our Pre-[REDACTED] Investors. To the best knowledge of our Directors, LBC Sunshine and its ultimate beneficial owners are Independent Third Parties.
- (11) Vivo Capital is a limited partnership established in the U.S. and is one of our Pre-[REDACTED] Investors. To the best knowledge of our Directors, Vivo Capital and its ultimate beneficial owners are Independent Third Parties.
- (12) Lu Thai is a company incorporated in the PRC and its A shares are listed on the Shenzhen Stock Exchange (000726.SZ), which is controlled by Independent Third Parties to the best knowledge of our Directors.
- (13) Janchor Partners^(B), Nanjing Huatai I^(A), Shandong Jifu^(A), Weihai Luxin^(A), Govtor^(A), Jiangsu International Trust^(A), MINTU^(B), OrbiMed Partners^(B), OrbiMed Genesis^(B), SME Development Fund^(A), Hong Da^(A), Yatai Economic Development^(A), Hudson Bay Capital^(B), Senming Capital Limited^(B), CRF Investment Holdings Company Limited^(B), Shanghai Tanying Investment Partnership (Limited Partnership)^(A), Nanjing Huatai II^(A), Nanjing Daoan^(A) hold 0.98%, 0.85%, 0.81%, 0.66%, 0.65%, 0.59%, 0.58%, 0.58%, 0.15%, 0.56%, 0.54%, 0.51%, 0.51%, 0.37%, 0.24%, 0.23%, 0.06%, 0.01% equity interest, respectively, in our Company and are Independent Third Parties to the best knowledge of our Directors.

Remarks:

- (A) The Shares held by these Shareholders are Domestic Shares.
- (B) The Shares held by these Shareholders are Unlisted Foreign Shares.
- (C) The Shares held by Rongda, Rongqian, Rongyi, Rongshi and Rongjian are Domestic Shares. The Shares held by I-NOVA Limited, Dr. Fang and RongChang Holding are Unlisted Foreign Shares.
- (D) The Shares held by LAV Remegen Limited are Unlisted Foreign Shares. The Shares held by Suzhou Lirui and Suzhou Likang are Domestic Shares.

Immediately After Completion of the [REDACTED]

The chart below sets out the shareholding structure of our Company immediately after completion of the [REDACTED] (assuming the [REDACTED] is not exercised):



Notes:

Please refer to notes 1-13 in the paragraphs headed “Our Shareholding and Corporate Structure – Immediately Before Completion of the [REDACTED]” in this section.

Remarks:

Please refer to remarks A-D in the paragraphs headed “Our Shareholding and Corporate Structure – Immediately Before Completion of the [REDACTED]” in this section.

- (E) The Shares held by these Shareholders are H Shares (excluding the portion of Unlisted Foreign Shares converting into H Shares).

BUSINESS

OVERVIEW

We are a commercial-ready biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics for the treatment of autoimmune, oncology and ophthalmic diseases with unmet medical needs in China and globally. Our vision is to become a leading player in the global biopharmaceutical industry.

Since our inception in 2008, we have been dedicated to the research and development of biologics with novel targets, innovative design and breakthrough potential to address global unmet clinical needs. Through more than ten years of meticulous efforts, we have built a fully-integrated, end-to-end therapeutics platform encompassing all the key biologic drug development functionalities, including discovery, pre-clinical pharmacology, process and quality development, clinical development, and GMP manufacturing. Leveraging our strong R&D platforms, we have discovered and developed a robust pipeline of more than ten drug candidates. Among our drug candidates, five are in clinical development stage targeting 17 indications and more than five are in IND-enabling stage. Two of our clinical-stage candidates, telitacicept (RC18) and disitamab vedotin (RC48), are in registrational trials targeting six indications in China and the U.S. Our new drug application (NDA) for telitacicept in China for SLE was accepted by the NMPA in November 2019 and was granted priority review the following month. We expect to receive approval from the NMPA to market telitacicept in China for SLE in the fourth quarter of 2020.

The following chart illustrates our pipeline and summarizes the development status of our clinical-stage drug candidates and selected IND-enabling stage candidates as of the Latest Practicable Date:

	Drug Candidates	Target (Modality)	Indication	Status (Clinical Sites Indicated on Status Bar)					NDA/BLA submission date	Commercial Rights			
				Pre-clin.	IND	Ph I	Ph II	Pivotal/Ph III					
Autoimmune Diseases	Telitacicept (RC18)*	BLYS/APRIL (fusion protein)	Systemic Lupus Erythematosus	China					NDA Filed	October 2019	Global		
			Systemic Lupus Erythematosus	US									
			Neuromyelitis Optica Spectrum Disorder	China								In registrational trial**	
			Rheumatoid Arthritis	China									
			IgA Nephritis	China									
			Sjogren's Syndrome	China									
			Multiple Sclerosis	China									
Myasthenia Gravis	China						In registrational trial**						
Oncology	Disitamab Vedotin (RC48)*	HER2 (ADC)	HER2-Expressing* Gastric Cancer	China					3	Q3 of 2020	Global		
			HER2-Expressing Urothelial Cancer	China					4	1H of 2021			
			HER2-Expressing Urothelial Cancer	US									
			HER2-Expressing Gastric Cancer	US									
			HER2 Low-Expressing* Breast Cancer	China						In registrational trial**			
			HER2 Low- to Non-Expressing* Urothelial Cancer	China									
			HER2-Expressing Biliary Tract Carcinoma	China									
			HER2-Expressing Non-Small-Cell Lung Cancer	China									
			RC88	Mesothelin (ADC)	Multiple Solid Tumors	China							Global
			RC98	PD-L1 (mAb)	Multiple Solid Tumors	China							Global
			RC108	c-MET (ADC)	Multiple Solid Tumors	China							Global
RC118	Confidential (ADC)	Multiple Solid Tumors	China						Global				
RC138	Confidential (HiBody)	Multiple Solid Tumors	China						Global				
RC148	Confidential (HiBody)	Multiple Solid Tumors	China						Global				
RC158	Confidential (HiBody)	Multiple Solid Tumors	China						Global				
Ophthalmology	RC28*	VEGF/FGF (fusion protein)	Wet Age-Related Macular Degeneration	China					7		Global		
			Diabetic Macular Edema	China					8				
			Diabetic Retinopathy	China					9				

* Denotes our core drug candidates.

Abbreviations: 1H = first half; ADC = antibody drug conjugate; HiBody = a novel bifunctional antibody; mAb = monoclonal antibody; Q3 = third quarter

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Notes:

- (1) The FDA has provided clearance for us to proceed with the Phase III clinical trial of telitacicept for SLE in the U.S in January 2020 and granted telitacicept Fast Track designation in April 2020.
- (2) HER2-expressing refers to a HER2 status of tumor cells identified with a test score of IHC 1+ or above. HER2 low-expressing refers to a HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+/FISH-. HER2 non-expressing refers to HER2 status of tumor cells identified with a test score of IHC 0.
- (3) In China, we are (i) finalizing a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) gastric cancer (GC), and (ii) conducting a Phase I clinical trial to evaluate distamab vedotin in combination with PD-1 inhibitor for the treatment of HER2 over-expressing GC.
- (4) In China, we are conducting (i) a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) urothelial cancer (UC), and (ii) a Phase Ib/II trial to evaluate disitamab vedotin in combination with PD-1 inhibitor for the treatment of UC.
- (5) The FDA has provided clearance for us to proceed with the Phase II clinical trial of disitamab vedotin in the U.S in April 2020.
- (6) We have initiated pre-IND discussion with the FDA to obtain their consents for disitamab vedotin’s Phase II clinical trial in GC in the U.S.
- (7) We have completed a Phase I trial of RC28 in wet age-related macular degeneration (wet AMD) in August 2019 in China, of which the primary endpoint of safety was met. In July 2018, we obtained the NMPA’s approval for us to conduct Phase I, II and III trials of RC28 according to our clinical development plan and progress, and the NMPA has not raised any objections towards our clinical trials of RC28 since then. We are currently conducting a Phase Ib trial of RC28 to further evaluate its efficacy and safety for the treatment of wet AMD.
- (8) We plan to initiate a Phase II trial for RC28 in diabetic macular edema in the second half of 2020 in China.
- (9) We plan to initiate a Phase II trial for RC28 in diabetic retinopathy in the second half of 2020 in China.
- (10) Registrational trial, or pivotal trial, means the clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval.

Our pipeline features three highly-differentiated core drug candidates, and we are developing them for autoimmune, oncology and ophthalmic diseases, respectively:

- **Telitacicept (RC18)** is a first-in-class NDA-filed late-stage innovative TACI-Fc fusion protein targeting two important cell-signaling molecules, BLYS and APRIL, implicated in B cell-mediated autoimmune diseases. We are carrying out a broad clinical development program for this drug candidate targeting a variety of B cell-mediated autoimmune diseases with unmet or underserved medical needs.

Systemic lupus erythematosus (SLE) is the lead indication of telitacicept. In SLE, we have completed a Phase IIb registrational study in China, where telitacicept showed robust efficacy and a favorable safety profile, and has supported best-in-class potential in treating SLE. Based on the results of this trial, the NMPA accepted our NDA for conditional approval of telitacicept for SLE in November 2019 and granted it priority review based on the significant unmet medical need in December 2019. The approval will be conditional on a commitment to complete a confirmatory Phase III trial in SLE post the commercial launch, and we are currently in the process of enrolling patients in this Phase III trial. We expect to receive marketing approval in China and commence commercialization activities in the fourth quarter of 2020. In addition to SLE, we are actively developing telitacicept for six other B cell-mediated autoimmune diseases in late-stage clinical trials in China, including (i) two registrational studies in neuromyelitis optica spectrum disorder (NMOSD) and in rheumatoid arthritis (RA), (ii) two Phase II studies in indications with large patient populations but few efficacious treatments available, including IgA nephropathy (IgAN) and Sjögren’s syndrome (SS), and (iii) two additional Phase II studies in hard-to-treat rare diseases, including multiple sclerosis (MS) and myasthenia gravis (MG).

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Based on the encouraging clinical trial results in China and our clearly defined U.S. clinical development strategy, telitacicept has the potential to become the first created-in-China first-in-class biologic drug to be approved for marketing in the U.S. Among other efforts, we obtained the FDA’s consent for entry into a registrational trial for the treatment of SLE in the U.S. in January 2020, and the FDA granted telitacicept Fast Track designation in April 2020. We expect to initiate the global Phase III clinical trials covering multiple jurisdictions, including the U.S., Europe and other countries, in the first half of 2021. For further details, please refer to “Summary—Impact of the COVID-19 Outbreak.”

- **Disitamab vedotin (RC48)** is a late-stage anti-HER2 antibody-drug conjugate (ADC) targeting prevalent cancers with significant unmet medical needs, and it is the first domestically-developed ADC in China to have entered clinical development. We are implementing a differentiated development and commercial strategy for disitamab vedotin, targeting prevalent HER2-expressing indications that are currently underserved, including both (i) HER2-expressing cancer (IHC 1+ or above) indications beyond BC, such as gastric cancer (GC) and urothelial carcinoma (UC) (both currently in registrational trials in China), and (ii) HER2 low-expressing cancer (IHC 2+/FISH- or IHC 1+) indications, such as HER2 low-expressing BC (currently in a registrational trial in China). These therapeutic areas represent a less crowded but underserved field for HER2-targeted therapies, and a broad addressable patient population for disitamab vedotin.

Based on its design advantages, disitamab vedotin has demonstrated superior anti-tumor activity and good tolerability in a registrational study in GC and a Phase II study in UC. We plan to file NDAs with the NMPA for disitamab vedotin in the third quarter 2020 for GC and in the first half of 2021 for UC.

Leveraging the promising efficacy and safety data observed in our clinical trials in China so far, we are actively exploring overseas trial opportunities for disitamab vedotin. In the U.S., disitamab vedotin has received orphan drug designation from the FDA for GC, and the FDA has cleared its IND application for a Phase II study in the U.S. for UC. We plan to initiate U.S. studies of disitamab vedotin in UC and GC patients in 2021.

- **RC28** is a potential first-in-class VEGF/FGF dual-targeting fusion protein for the treatment of eye diseases. Compared to single-target VEGF inhibitors, RC28 has the potential to more effectively inhibit the abnormal blood vessel growth implicated in various eye diseases through both VEGF and FGF pathways, and potentially allows for a better dosing profile. RC28 has demonstrated good safety in a Phase I dose escalation study in patients with wet age-related macular degeneration (wet AMD) in China. We have initiated a Phase Ib study in wet AMD and plan to initiate Phase II clinical studies in diabetic macular edema (DME) and diabetic retinopathy (DR) in the second half of 2020 in China.

Our fully-integrated platform is driven by a proprietary R&D engine, which consists of three specialized platforms, including (i) an antibody and fusion protein platform, based on which we are internally developing telitacicept, RC28 and RC98 (a clinical-stage PD-L1 antibody); (ii) an ADC platform, based on which we are internally developing disitamab vedotin, RC88 (a clinical-stage anti-mesothelin ADC) and two IND-enabling stage ADCs

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(RC108 and RC118); and (iii) a bifunctional antibody (HiBody) platform, based on which we are internally developing three IND-enabling stage HiBody compounds (RC138, RC148 and RC158).

Our Co-Founder, CEO and CSO, Dr. Jianmin Fang, is one of the few founders in China’s biopharmaceutical industry with a successful track record of progressing novel biological drugs from discovery through development and commercialization. A Harvard-trained scientist, Dr. Fang is a visionary leader in translating biomedical discovery into therapeutics. He invented many molecules in our pipeline and is the key driving force for our continual innovation. Furthermore, we have assembled an experienced senior management team with an average of more than 20 years of industry experience (mostly in the U.S.) and proven track records of innovative drug R&D, clinical development and commercialization.

Another key driver of our success has been our strong clinical development capability and insights in regulatory affairs. Led by our Chief Medical Officer, Dr. Ruyi He, our clinical development function has approximately 200 employees and carries out our global clinical development plan through both rigorous trial design and trial operational excellence. More importantly, our clinical development team discovers and explores often unanticipated clinical opportunities, which has organically stimulated the growth and expansion of our clinical development programs. Leveraging Dr. He’s nearly 20 years of unique policy-making and managerial experience at the FDA in the U.S. and the NMPA in China, we have accumulated substantial expertise in and familiarity with regulatory review requirements and approval processes in China, the U.S. and beyond. Since our inception, we have submitted ten IND applications for five drug candidates and have obtained approvals for all applications, including two applications which received clearance from the FDA in the U.S. for telitacicept and disitamab vedotin. In addition, we have submitted an NDA in China for our telitacicept and have obtained priority review status.

Our global GMP-compliant manufacturing facilities houses six 2,000L disposable bag bioreactors for a total capacity of 12,000L. With these capabilities and experiences, we have established a successful track record of manufacturing five drug candidates in-house. We are building new manufacturing facilities and plan to expand our total production capacity to 36,000L by the end of 2021. To support our near-term launch of telitacicept, we have assembled the sales leadership team and expect to build a strong sales and marketing team of around 100 members with rich sales experience in the autoimmune areas, which is expected to further expand to 200 members in the second 12-month period after the commercial launch.

We build and operate our fully-integrated platform with a global vision. In addition to designing and implementing our global clinical development programs for our innovative drug candidates, our regulatory affairs and commercialization teams have invested significant resources in seeking regulatory filings, marketing approvals and eventually successful commercial launches for these products in major markets both in and outside China. We also have been actively seeking strategic partnership opportunities with global leading pharmaceutical companies to maximize the clinical and commercial value of these potential first-in-class and/or best-in-class drug products.

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OUR STRENGTHS

First-in-class registrational-stage fusion protein telitacept (RC18) with impressive therapeutic efficacy in B cell-mediated autoimmune diseases

Telitacept is a first-in-class late-stage innovative recombinant TACI-Fc fusion protein we have internally developed for the treatment of B cell-mediated autoimmune diseases. Telitacept targets and neutralizes two important cell-signaling molecules implicated in B cell-mediated autoimmune diseases, and has shown a robust efficacy with a favorable safety profile. Its demonstrated advantages have enabled us to carry out a broad clinical development program for this product targeting a variety of B cell-mediated autoimmune diseases with unmet or underserved medical needs, and have allowed us to continue to explore and expand the range of its treatment indications.

SLE, currently the lead trial indication for telitacept, is a hard-to-treat systemic autoimmune disorder that causes widespread immune attack in the human body, which inflicts tissue damage in multiple organs, and has one of the highest mortality and disability rates among autoimmune diseases. Most prevalent among females between the ages of 15 and 44, SLE patients can lose part of their physical and mental capabilities, causing a significant socioeconomic burden on patients’ social functions and quality of life.

To this day, there is no effective cure for SLE, while the currently available treatments to control the disease are either limited in efficacy or can cause severe side effects. As SLE often occurs in young patients who usually require lifelong treatment to control the chronic disease conditions, the medical needs for effective SLE therapeutics are huge, which has been underserved in the long history of SLE drug development.

We believe that telitacept has the potential to become the best-in-class therapy in this growing and yet largely untapped global SLE market. Telitacept’s fundamental design-based advantages and differentiation in comparison with competing drugs (especially biologics) lie in: (i) its dual-targeting mechanism and bioinformatics-optimized structure design, which enhance its biological activity, promote molecular stability, and facilitate our production; and (ii) its full human amino acid sequence, which minimizes undesired potential immunogenicity.

Results from our recently completed Phase IIb registrational trial of telitacept in China have demonstrated a superior clinical efficacy and good safety profile supporting a best-in-class potential in SLE. The primary endpoint of this trial was the proportion of patients achieving SRI-4 response at week 48. Telitacept treatment groups at multiple doses in this trial had statistically significantly higher SRI-4 response rates (70% to 79%) than the placebo group (32%), which indicates significant reduction in SLE disease activity in the telitacept treatment groups. In general, telitacept was well tolerated by patients in this trial, with a serious adverse event (SAE) rate ranging from 13% to 16% across the treatment groups for dose levels ranging from 80mg to 240mg, comparing to the placebo group which had an SAE rate of 16%.

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For SLE alone, we are implementing a comprehensive clinical development plan for telitacept both in and outside China. In China, we submitted our NDA for conditional approval of telitacept for the treatment of SLE in October 2019. The NMPA accepted our NDA in November 2019 and granted us priority review in December 2019. The approval will be conditional on a commitment to complete a confirmatory Phase III trial in SLE post the commercial launch, and we are currently in the process of enrolling patients in this Phase III trial. We expect to receive marketing approval in China and commence commercialization activities in the fourth quarter of 2020. In the U.S., we completed an end-of-Phase II meeting with the FDA in January 2020, and received the FDA’s consent for entry into a registrational trial in the U.S. for the treatment of SLE. In April 2020, the FDA granted telitacept Fast Track designation, which could expedite the FDA’s review and potential approval process. We expect to initiate global Phase III clinical trials covering multiple jurisdictions, including the U.S., Europe and other countries, in the first half of 2021, which is expected to commence under the supervision of Dr. Joan Merrill, our clinical program coordinator and a world-renowned rheumatologist. We plan to make a BLA filing for telitacept in the U.S. for SLE treatment if the registrational trial meets the primary endpoints.

In order to facilitate the successful global registrations and commercial launches of telitacept, to which we own worldwide development and commercialization rights, we plan to collaborate with global leading biopharmaceutical companies for the potential co-development or out-license of telitacept and its commercialization outside China.

Telitacept’s promising efficacy in treating SLE has lent support to our belief that it will also be effective in treating other B-cell mediated autoimmune diseases. We are managing a broad clinical development program for telitacept in six other autoimmune diseases besides SLE, and we expect to further expand its range of indications as we continue to advance our clinical research. Among other indications, we are currently conducting registrational studies of telitacept in neuromyelitis optica spectrum disorder (NMOSD) and rheumatoid arthritis (RA). We are also conducting Phase II studies in indications with large patient populations but few efficacious treatments, including IgA neuropathy (IgAN) and Sjögren’s syndrome (SS), as well as hard-to-treat rare diseases, including multiple sclerosis (MS) and myasthenia gravis (MG). Given its potential clinical value in these and additional indications, we see a tremendous overall addressable market of telitacept and significant commercial potential.

Late-stage anti-HER2 antibody-drug conjugate disitamab vedotin (RC48) targeting prevalent cancers with significant unmet medical needs

Antibody-drug conjugates (ADCs) are one of the classes of oncology therapeutics attracting significant attention and investment of its therapeutic potential. ADCs, which consist of a monoclonal antibody linked to a cytotoxic drug, can selectively deliver a highly potent anti-cancer drug into tumor cells while sparing healthy cells, thus generating a wide therapeutic window. Our disitamab vedotin, a novel anti-HER2 ADC, is the first domestically-developed ADC drug to have entered clinical studies in China. With global development and commercialization rights to the candidate, we are evaluating disitamab vedotin in clinical trials for various HER2-expressing (including HER2 low-expressing) solid tumors, including three registrational studies for the treatment of gastric cancer (GC), urothelial carcinoma (UC) and HER2 low-expressing breast cancer (BC). In these cancer types, disitamab vedotin has the potential to become the first-to-market ADC in China and is well-positioned to capture the largely unmet market needs.

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HER2 is an important biomarker commonly expressed in many different tissues, and its overexpression has been recognized as a genetic driver of multiple cancer types. While HER2 has emerged as one of the main targets for the ADCs developed by global pharmaceutical companies in recent years, HER2-positive/high-expressing BC (IHC 2+/FISH+ or IHC 3+) continues to be the most heavily investigated, and the only approved, cancer type for the use of anti-HER2 ADC. However, HER2-expression at various levels (including low expression levels) is also observed in a number of other cancer types, such as GC, UC, biliary tract cancer (BTC) and non-small cell lung cancer (NSCLC), and low-level HER2 expression (IHC 2+/FISH- or IHC 1+) is observed in around 50% of BC cases, indicating a large therapeutic potential and opportunity for anti-HER2 ADCs beyond HER2 high-expressing BC.

We are strategically developing disitamab vedotin to meet these needs of an underserved market, and we are currently conducting its lead trials in GC, UC and HER2 low-expressing BC in China. These therapeutic areas represent a less crowded but underserved field for HER2-targeted therapies, and a large addressable patient population for disitamab vedotin.

Disitamab vedotin’s fundamental advantages and differentiation in comparison with competing drugs and drug candidates lie in its “quality by design” molecular structure. In particular, disitamab vedotin features a novel humanized antibody (disitamab) with high HER2 affinity, which enables a strong anti-tumor effect on HER2 low-expressing cancers. It features a potent and highly membrane-permeable cytotoxic drug that allows for a strong bystander-killing effect on surrounding tumor cells (regardless of their HER2 expression levels). It also features a cleavable linker with no lysosomal resistance and enables release of the cytotoxic payload in lysosomes after the internalization of disitamab vedotin by the targeted HER2-expressing tumor cells.

Indeed, disitamab vedotin has demonstrated strong anti-tumor activity in clinical trials for GC and UC patients. In our Phase II registrational trial for GC, disitamab vedotin delivered an independent review committee (IRC)-assessed confirmed objective response rate (ORR) of 24.4%, median progression-free survival (PFS) of 4.1 months and median overall survival (OS) of 7.6 months in 127 patients with HER2 over-expressing (IHC 2+ or IHC 3+) GC or GEJ cancer post to second lines of prior chemotherapy treatment as of June 22, 2020. In June 2019, we presented positive clinical data from our initial Phase II study of disitamab vedotin in second-line UC at ASCO 2019 held in Chicago, Illinois. In this study with 43 HER2 over-expressing (IHC 2+ or IHC 3+) second line UC patients, disitamab vedotin generated best ORR of 60.5% (26/43), confirmed ORR of 51.2%, and median PFS of 6.9 months. In comparison, in reported studies, the second line UC patients on PD-1/PD-L1 therapy had ORR of 20-30% and median PFS of two to three months. Although these were not head-to-head studies, we believe that valuable insight can nonetheless be drawn from the comparison. These results revealed a clinically meaningful response to our disitamab vedotin among GC and UC patients whose previous treatment failed, which is a population with high unmet medical needs. In addition, disitamab vedotin has also demonstrated favorable safety profile in these trials.

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We are executing a comprehensive set of clinical development programs for disitamab vedotin targeting a variety of HER2-expressing cancer types. In China, we are currently evaluating disitamab vedotin in registrational studies in both GC and UC. We plan to file NDAs with the NMPA for disitamab vedotin in the third quarter of 2020 for GC and in the first half of 2021 for UC. In addition, we have the NMPA’s approval for conducting a Phase III trial of disitamab vedotin in HER2 low-expressing BC and are currently in the process of enrolling patients in this trial.

Leveraging the robust efficacy and favorable safety data observed in our trials in China so far, we are actively exploring overseas trial opportunities for disitamab vedotin. In the U.S., the FDA has already provided clearance for us to proceed with a Phase II trial of disitamab vedotin in UC in the U.S. and we plan to initiate this Phase II trial in the first quarter of 2021. Disitamab vedotin has also received orphan drug designation from the FDA for GC. In the meantime, we plan to initiate a bridging trial in GC patients in the first half of 2021 in the U.S. to seek expedited approval.

Late-stage HER2-targeted ADC drugs, especially the few (including our disitamab vedotin) that target a broad range of solid tumors at varied HER2 expression levels, represent substantial commercial value, in light of AstraZeneca’s commitment in March 2019 to pay up to US\$6.9 billion to its Japanese partner Daiichi-Sankyo for the right to co-develop and co-commercialize trastuzumab-deruxtecan (DS-8201), which is a HER2-targeting ADC and received FDA approval for HER2-positive/high-expressing BC in December 2019. To support our global strategy for the development and commercialization of disitamab vedotin, and given its large addressable patient population globally, we may consider pursuing international partnership opportunities in regions outside China.

Potential first-in-class VEGF/FGF dual-targeting fusion protein (RC28) targeting ophthalmic diseases with huge market potential

RC28 is a potential first-in-class fusion protein targeting both vascular endothelial growth factor (VEGF) and fibroblast growth factor (FGF). We are developing RC28 for the treatment of hard-to-treat ocular diseases, including wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and diabetic retinopathy (DR). As the current standard of care treatments for wet AMD and DME are all VEGF single-targeted agents, we believe that RC28 has the potential to be a best-in-class biologics for these diseases by inhibiting VEGF and FGF pathways simultaneously.

AMD is a medical condition characterized by the abnormal growth of blood vessels in the retina. Wet AMD is the most serious form of AMD and is a leading cause of blindness among senior patients globally. According to Frost & Sullivan, the number of wet AMD patients in China and the U.S. reached 3.6 million and 1.8 million in 2019, respectively, and the number is estimated to grow to 4.9 million and 2.1 million by 2030, respectively. With the global aging population, this therapeutic area represents a sizable market with significant growth potential. The current biological treatment approved for wet AMD in China and the U.S. include ranibizumab, aflibercept, conbercept and brolucizumab, all of which are VEGF single-targeted biologics.

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Our Co-Founder, CEO and CSO, Dr. Jianmin Fang, is the inventor of conbercept, an anti-VEGF fusion protein and the first domestically-developed biologic drug approved for wet AMD in China. Conbercept achieved RMB1.2 billion in sales in 2019, according to Frost & Sullivan. Leveraging Dr. Fang’s successful experience in developing conbercept, we have designed and differentiated RC28 and have gained its competitive advantages through:

- (i) dual-targeting mechanism that overcomes the major challenge faced by single-target VEGF antagonists, which is the upregulated expression of other pro-angiogenic factors when the VEGF pathway alone is inhibited; and
- (ii) potentially less frequent dosing schedule due to a long half-time pharmacokinetic profile that could translate to reduction in treatment costs and improved compliance.

In a Phase I study in China, RC28 has demonstrated its good safety in wet AMD patients up to single dose of 2 mg. Based on the encouraging results from this Phase I study, we have initiated a Phase Ib trial in wet AMD patients and plan to further evaluate RC28 for the treatment of other prevalent ocular indications, such as DME and DR, to address the medical needs of larger population.

A proprietary R&D engine pursuing breakthrough science to generate innovative and best-/first-in-class therapeutics

We have built a world-class innovative proprietary R&D engine that spans biology discovery, target selection and validation, drug discovery, research and development. Our R&D engine consists of three specialized platforms enabling a variety of novel biological therapeutics. These include:

- (1) an antibody and fusion protein platform, featuring generation of novel monoclonal antibodies and fusion proteins through our internal studies. We can generate high affinity monoclonal antibodies in house using various technologies, including murine hybridoma, human B cell cDNA phage-display library and llama nanobody phage-display library. We have extensive capabilities in bioinformatics-aided protein design and engineering for Fc fusion proteins. We humanize antibody sequences to generate murine antibodies by hybridoma technology. We have generated a number of monoclonal antibody molecules using these technologies, some of which have been advanced to preclinical development stage as our drug candidates or for the use in companion diagnostic kits;
- (2) an ADC platform, featuring fully-integrated in-house capabilities covering the whole process of ADC development and manufacturing, including the syntheses of antibody, linker and chemotherapy payload. For each ADC drug candidate, we screen a large panel of combinations of conjugation methods, linkers and payloads to optimize molecular composition. We developed a proprietary Thiel-bridge conjugation technology to yield more homogeneous ADC products that can improve pharmacodynamics and increase therapeutic window. We also have global GMP-compliant manufacturing facility for entire ADC manufacturing process, including antibody production, syntheses of payloads, linkers, and payload-linkers, ADC conjugation, and fill/finish; and

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- (3) a bifunctional antibody (HiBody) platform, featuring cutting-edge design and engineering capabilities for next-generation bifunctional antibodies with significant potential for future exploration. This bifunctional antibody (HiBody) technology is based on novel molecular format and is versatile in generating various bispecific antibodies. Using this novel molecular format, we have constructed a number of bifunctional antibodies and have three IND-enabling drug candidates in pipeline (RC138, RC148, and RC158). For many bispecific platforms, manufacturability is a key issue that often results in project failure. Our HiBody products have shown high expression level in our system and have constantly had product yield similar to conventional antibodies. The products from this HiBody platform is homogeneous and easy to adapt to our manufacturing process. We have filed an invention patent application for the molecular format of HiBody with broad claims.

Leveraging our proprietary R&D platforms, our team is strategically focused on the research and development of novel biologic drugs with first-in-class and/or best-in-class potential. We have established a new R&D center in Shanghai, a main hub for new drug research and development in China, which helps us to tap and leverage China's best R&D talent pool. We also plan to establish an early-stage drug R&D center in California of the United States, which will help us to scout for and develop the most cutting-edge early-stage programs. These R&D centers will work and interact closely with our headquarters and R&D center in Yantai, and will allow us to strengthen and flex our innovative drug development prowess on a global scale. Led by Dr. Fang with his successful track record of innovative biologic drug development at renowned research institutions and biopharmaceutical companies, our R&D team consists of over 280 members, spanning all the key biologic drug development functionalities as of the Latest Practicable Date. As of the Latest Practicable Date, 55% of our R&D team members hold masters or doctorate degrees in life science related majors.

Utilizing our proprietary platforms, our R&D team has developed a robust pipeline of more than ten novel biologic drug candidates targeting hard-to-treat therapeutic areas of autoimmune diseases, oncology and ophthalmology with significant unmet medical needs both in China and globally. Among these candidates, we have developed five clinical-stage assets, and they are in different stages of clinical development stages that ensure a steady stream of market launches in the coming years. These five drug candidates had been or are currently in over 30 clinical trials spanning 17 indications. In addition to our three core drug candidates (telitacept, disitamab vedotin and RC28), we are also conducting early clinical studies to evaluate RC88 (an anti-mesothelin ADC) and RC98 (an innovative PD-L1 monoclonal antibody), both targeting solid tumors with the potential for combination therapies.

Our R&D engine has enabled us to develop pre-clinical drug candidates that feature both target and design novelty and offer us foreseeable upside potential going forward. Three of our pre-clinical assets are innovative bifunctional antibodies discovered and developed on our proprietary HiBody platform. The most advanced asset among them, RC138, is a next-generation bifunctional fusion protein composed of a monoclonal antibody and a decoy receptor, and it is being developed for the treatment of a variety of solid tumors. We expect to file an IND application for RC138 in China in 2021.

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Furthermore, we actively seek and leverage partnership opportunities with preeminent academic researchers and institutions as we pursue and transfer cutting-edge biological and medical sciences. Since January 2011, we have established academic partnerships and entered into a joint development agreement with Tongji University, a top research institution in China, for the research and development of our RC28. Through this collaboration, we developed and optimized the VEGF/FGF dual-targeting fusion protein and solved many challenges during development. RC28 is now being studied in a Phase Ib clinical trial in wet AMD in China.

Integrated in-house capabilities that well position us for biomedical innovation from bench to bedside

We have built a fully-integrated, end-to-end biological therapeutics platform that encompasses all the key biologic drug development functionalities, including not only early-stage drug discovery and development, but also clinical development, regulatory affairs, manufacturing and commercialization. The full integration of these functionalities allows us to bring our drug candidates efficiently from bench to bedside, and it also enables us to identify and address potential clinical, manufacturing and commercial opportunities as well as issues early in the development process, so we can direct our efforts towards molecules with the best potential to become clinically active, cost-effective and commercially viable drugs. Our platform also allows us to carry out process validation and product manufacturing, maintain consistent quality control, and redeploy resources quickly to prioritize our more promising assets and development programs.

Our success has in a large part been driven by our strong clinical development capability and outstanding clinical results of our innovative drugs. We have achieved these through both rigorous trial design and trial operational excellence. Led by our Chief Medical Officer, Dr. Ruyi He, the clinical development function of our fully-integrated platform consists of approximately 200 employees as of the Latest Practicable Date. The team manages our clinical trials and carries out a comprehensive suite of clinical development activities, including clinical trial design, implementation, and the collection and analysis of trial data. We maintain control and oversight over these key functions of clinical trials while partnering with globally reputable CROs for trial execution. We also employ in-house translational medicine research to discover and validate biomarkers, direct patient selection, monitor treatment responses in clinical trials, and analyze clinical data to guide the design and execution of preclinical studies. More importantly, our clinical development team discovers and explores often unanticipated clinical opportunities. For instance, telitacicept's application in NMO/D and disitamab vedotin's application in UC (among other HER2-expressing indications) were discovered and explored during the products' respective early-stage clinical development and now indicates substantial potential to address unmet medical needs.

To support the global clinical development strategy for our rich product pipeline, we have built a seasoned team of regulatory affairs specialists with rich experience in communicating and cooperating with global drug regulatory agencies. Leveraging Dr. He's unique experience working for nearly 20 years in leadership positions with the FDA in the U.S. and the NMPA in China, we have accumulated substantial expertise at and familiarity with regulatory review

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requirements and processes both in China and abroad, including the approval and conduct of registrational trials in the U.S. and Europe. Since our inception, we have submitted ten IND applications for five drug candidates and have obtained approvals for all applications, including two IND applications which received clearance from the FDA in the U.S. for telitacept and disitamab vedotin. With efficient communication with the FDA, we were able to convince the FDA to skip early phase studies for telitacept and disitamab vedotin in the U.S. and clear our IND application for a Phase III trial for telitacept and potential registrational trial for disitamab vedotin. In addition, the NMPA has accepted our NDA in China for our telitacept in November 2019 and granted it priority review in the following month.

Our industry-leading manufacturing capabilities boast global GMP-compliant and world-class manufacturing facilities with six 2,000L disposable bag bioreactors for a total capacity of 12,000L for large-scale recombinant protein production. Our existing GMP facility for commercial manufacturing is capable of an annual output of up to 2.3 million vials of antibodies and up to 1.5 million vials of ADCs. With these capabilities and experiences, we have established a successful track record of manufacturing five drug candidates in-house.

To prepare for the anticipated commercialization of telitacept, we are building a strong sales and marketing team that is expected to consist of around 100 members with rich sales experience in the autoimmune areas. The team is expected to further expand to 200 members in the second 12-month period after we commence market launch of telitacept. We will also build a separate team for oncology and we expect the team to be well positioned to target the right markets with high operational efficiency. In addition, we benefit significantly from our management team’s successful experience with founding and operating RC Pharma, our strategic partner and a leading pharmaceutical company in China. Among other invaluable assets, our management team brings us nearly three decades of substantial operational, managerial and commercialization experience, resources and expertise, especially market access and distribution resources that are often valuable and can be leveraged to accelerate the build-out of our own commercialization infrastructure.

We have built our fully-integrated platform with a global vision for our business operations and drug products. Encouraged by the promising clinical results and substantial addressable markets for our lead products including telitacept and disitamab vedotin, our clinical development team is currently implementing global clinical development programs for them. In the meantime, our regulatory affairs and commercialization teams have invested significant resources in seeking regulatory filings, marketing approvals and eventually successful commercial launches for these products in major markets both in and outside of China. Finally, our management team has been actively seeking strategic partnership opportunities with global leading pharmaceutical companies to maximize the clinical and commercial value of these potential first-in-class and/or best-in-class drug products.

A visionary management team with rich industry experience and scientific expertise and backed by leading healthcare investors

We are led by our visionary management team with an average of more than 20 years of industry experience and proven track records of innovative drug R&D, clinical development and commercialization.

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Dr. Jianmin Fang, our Co-Founder, CEO and CSO, has over 20 years of fruitful experience in biopharma R&D and over 40 drug invention patents. Dr. Fang obtained a Ph.D. in biology from Dalhousie University, Canada, and received post-doctoral training in Harvard Medical School. Among his many roles, he is a member of scientific expert committee of the National Scientific and Technological Major Project for “Major Drug Innovation” (“重大新藥創制”國家科技重大專項) of China. He is the inventor for our core products including telitacicept, disitamab vedotin and RC28, as well as conbercept, which was the first domestically-developed wet AMD biologic drug in China. Having received approvals for wet AMD in 2013 and pathological myopia choroidal neovascularization (pmCNV) in 2017, conbercept has an over 40% market share of anti-VEGF therapeutics in China in 2019. Dr. Fang is one of the few founders in China’s biopharmaceutical industry with successful track record of progressing novel drug from discovery through commercialization.

Mr. Weidong Wang, our Co-Founder and Chairman, brings us 25 years of entrepreneurial, operational and managerial experience in the pharmaceutical sector. Mr. Wang founded and managed RC Pharma, a top Chinese pharmaceutical company for the development, production, marketing and sales of traditional Chinese medicine. Mr. Wang has been dedicated to the Company’s entry into innovative biologics development since 1997. Mr. Wang was recognized as the Entrepreneurs with Outstanding Contribution in Shandong Province, China, and he was elected a Representative of China’s 13th National People’s Congress.

Dr. Daotian Fu, our President, was previously the vice president and executive director of Livzon Pharmaceutical Group and also the general manager of Livzon MABPharm, Inc., a biologics development company. At Livzon, he led the biologics development efforts with one successful NDA submission and multiple programs in clinical development. Dr. Fu returned to China after spending 28 years working in the biopharmaceutical industry in the U.S. Between 1998 and 2012, he served as the vice president of R&D at Genzyme Corp., one of the top five global biotech companies (later acquired by Sanofi). During this period, Dr. Fu was responsible for CMC development of clinical stage programs, and was directly involved in global launching of five major biologics and clinical development of multiple R&D programs. Dr. Fu received his B.S. from Shandong University in China, and his Ph.D. from Iowa State University.

Dr. Ruyi He, our Chief Medical Officer, is one of the most authoritative experts in China in the areas of clinical development and global regulatory regimes for medical products. He brings us nearly 20 years of experience working at the FDA in the U.S. and the NMPA in China. In the more than 17 years with the FDA, he held a number of strategic leadership positions and chaired several working groups that were tasked with drafting and finalizing guidelines for the pharmaceutical industry. He was also involved in FDA guidance development in multiple therapeutic areas. In China, Dr. He was Chief Scientist at the Center for Drug Evaluation (CDE) of the NMPA where he led multiple important policy initiatives. In addition to his policy-making roles with both the FDA and the NMPA, Dr. He also gained first-hand experience reviewing and approving numerous applications for INDs and NDAs in both the U.S. and China. A prolific author, Dr. He has also published more than 20 research papers and abstracts in the fields of drug regulatory science and internal medicine. Dr. He received his medical degree from China Medical University. He completed his intern and residency training in Internal Medicine at Howard University Hospital in Washington, D.C. He received his clinical research training at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH) in Bethesda, Maryland. Dr. He is a licensed, board-certified physician in internal medicine in the U.S.

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We have also established our Scientific Advisory Board which currently comprises five renowned professors and key opinion leaders in the areas of our research and development, including Dr. Gang Pei, Dr. Jianmin Fang, Dr. Ruyi He, Dr. Marsha A. Moses and Dr. Lorne Babiuk. Members of our Scientific Advisory Board routinely meet or communicate with us and provide us with advisory services including advice in respect of our business strategies and objectives, academic updates and technical insights relevant to our research and development plans, recommendations relating to innovative drug targets, mechanisms and modalities, and advice on new drug discovery projects, as well as biopharmaceutical market data and intelligence.

Dr. Pei, a world-leading expert in the area of GPCR research, is an academician of the Chinese Academy of Sciences, and the former president of Tongji University and Shanghai Institute of Biological Sciences of Chinese Academy of Sciences. With more than 150 research publications on international academic research journals, Dr. Pei serves for many professional societies in China and around the world, such as Chinese Society of Cell Biology, the World Academy of Sciences, the Consortium for Globalization of Chinese Medicine, and the Editor-in-Chief of the renowned scientific journal “*Cell Research*.”

Dr. Moses is the Julia Dyckman Andrus Professor at Harvard Medical School and the Director of the Vascular Biology Program at Boston Children’s Hospital. Dr. Moses has published work in *Science*, *The New England Journal of Medicine*, *Cell*, *PNAS* and *Nature Communications*, among other journals, and has made significant contributions to our understanding of the biochemical and molecular mechanisms that underlie the regulation of tumor development and progression. Dr. Moses has been named a pioneer in the field of Biomarker Medicine by the *Journal of the National Cancer Institute* and has been elected to the Institute of Medicine (National Academy of Medicine) of the National Academies of the United States.

Dr. Babiuk is a Canadian scientist and a global authority in immunology, pathogenesis, virology, molecular virology, and vaccinology. He was the former Vice-President of Research at the University of Alberta and the former Director of the Vaccine and Infectious Disease Organization at the University of Saskatchewan. Dr. Babiuk has published over 500 manuscripts and has trained over 100 Ph.D.s and post-doctoral fellows. Dr. Babiuk has been awarded or made a Fellow of the Royal Society of Canada, the Saskatchewan Order of Merit, an Officer of the Order of Canada, and the Gairdner Foundation Wightman Award, among many other honors and awards.

Our shareholders consist of leading healthcare investors, including renowned global institutional investors, such as Lilly Asia Ventures and Lake Bleu Capital, and reputable domestic investors, providing us with industry expertise and vital connections to the pharmaceutical sector in China and worldwide.

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OUR STRATEGY

Our mission is to discover, develop, manufacture and commercialize innovative biologic drugs to address unmet medical needs in the major therapeutic areas of autoimmune diseases, oncology and ophthalmology for patients worldwide. Our vision is to become a leading player in the global biopharmaceutical industry. To achieve our mission and vision, we intend to execute the following strategies.

Rapidly advance the development and commercialization of our existing pipeline products, primarily focusing on obtaining marketing approvals and launching commercial sales of our core products

Obtain marketing approval and launch telitacicept (RC18) for the treatment of SLE in China in fourth quarter of 2020.

Telitacicept is a first-in-class and potential best-in-class drug candidate targeting various B cell-mediated autoimmune diseases. Our NDA for telitacicept for the treatment of SLE was accepted by the CDE of the NMPA in November 2019 and was granted priority review the following month. We expect to obtain conditional marketing approval and commence commercial sales of telitacicept in the fourth quarter of 2020. We have started preparing for the commercial launch of this product. We have assembled our sales and marketing leadership team, and expect to build a sales and marketing team consisting of around 100 members with extensive expertise in the field of autoimmune diseases by 2020.

In the meantime, we will continue to advance telitacicept in clinical trials for other indications, including NMOSD (a rare disease), RA, IgAN, SS, MG (a rare disease) and MS (a rare disease). We strive to obtain marketing approvals for these indications as early as possible, which will allow us to establish comprehensive competitive advantages in China’s autoimmune disease market.

Advance the clinical development of disitamab vedotin (RC48) towards commercialization across a variety of solid tumor types.

Disitamab vedotin is a potential best-in-class HER2 ADC. We are finalizing a registrational clinical study for GC in China and plan to submit an NDA to the CDE of the NMPA for conditional approval in the third quarter of 2020. With respect to the registrational clinical study in UC, we expect to complete patient enrollment in the second half of 2020 and plan to submit an NDA in the first half of 2021. Furthermore, we will also advance the Phase III clinical studies for HER2 low-expressing BC and clinical trials for other solid tumors as planned. We are currently building a specialized oncology marketing team based on the progress of clinical trials and regulatory reviews.

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Advance clinical development of RC28 in various ophthalmic diseases.

RC28 is a next-generation dual inhibitor of VEGF and FGF designed by our Co-Founder, CEO and CSO and conbercept’s original inventor, Dr. Jianmin Fang. It is developed for the treatment of wet AMD, DME, DR and other potential indications. The product is the first VEGF/FGF dual-targeting drug candidate worldwide to be in clinical trials and has the potential to become best-in-class. We are currently conducting a Phase Ib clinical trial for wet AMD and plan to initiate Phase II clinical trials for DME and DR in the second half of 2020 and 2021, respectively, in China.

Continuously advance clinical trials of other products by leveraging our outstanding in-house clinical research and development capabilities.

We have a clinical development team of approximately 200 members with rich experience and abundant resources as of the Latest Practicable Date. In addition to developing our core products, we are also carrying out clinical trials to evaluate RC88 (an innovative anti-mesothelin ADC) and RC98 (an innovative PD-L1 monoclonal antibody) and may conduct clinical trial to evaluate their combination therapies, in order to realize their substantial clinical value and potential.

Leveraging our advanced and reliable proprietary technology platforms, we have been able to continuously enrich our drug pipeline. Over the years, we established technology platforms for antibody and fusion protein, ADC and bifunctional antibody (HiBody), and have developed the above-mentioned core products and other products in the pipeline. We will continue to leverage these technology platforms to design and create new molecules with innovative mechanisms and novel targets. That would allow us to enrich our product pipeline, and we expect to submit IND applications for one to two drug candidates each year to ensure our sustained growth.

Execute our well-planned and organized global strategy

It is our vision to become a leading player in the global biopharmaceutical industry. In order to achieve this strategic goal, we are committed to accomplishing the following.

Actively carry out global multi-center clinical trials for our core products.

With the global planning for our products and an overall global strategy, we are determined to initiate global multi-center clinical trials for our products.

- **Telitacept:** In January 2020, the FDA held a meeting with us, where we were allowed to conduct the global Phase III clinical trial of SLE in the U.S. based on the clinical trial data used in our NDA for SLE in China. On April 15, 2020, the FDA granted Fast Track designation for telitacept. We have also communicated with the EMA and submitted our application for a Phase III clinical trial in SLE in Europe. We expect to initiate global multi-center Phase III clinical trials in multiple

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jurisdictions including the U.S., Europe and other countries in the first half of 2021. Meanwhile, we will also conduct global multi-center Phase II/III clinical trials for other indications as we have planned, and we seek to obtain marketing approvals as soon as possible.

- **Disitamab vedotin:** This product has been granted orphan drug designation for GC by the FDA in July 2018. For UC, we held a pre-IND meeting with the FDA in December 2019 and obtained the FDA's clearance to proceed with a Phase II clinical trial in April 2020. Therefore, we expect to initiate the global clinical trial for HER2-expressing UC in the first quarter of 2021. In the meantime, we plan to initiate a bridging study for disitamab vedotin for GC in the U.S. in 2021 to seek expedited approval. In addition, we are also considering and planning global multi-center clinical trials of HER2 low-expressing BC and other indications.
- For our RC28 and other innovative drug candidates in our pipeline, we are also designing their clinical trial development plans with the considerations with going global in the near future. Depending on the development status of our candidates in the future, we also plan to submit IND applications for our drug candidates at appropriate times for global multi-center clinical trials to explore their clinical value and implement our global strategy.
- We are building out a strong clinical operation team that is led by our Chief Medical Officer (CMO), Dr. Ruyi He, and possesses rich experience in carrying out global multi-center clinical trials. This team will be responsible for planning and high-quality execution of clinical trials by closely working with multinational collaboration partners, CRO companies and principal investigators.

Implement a global registration strategy to achieve commercialization of our products globally.

Advancing the global registration plan for our pipeline products is a critical aspect in the implementation of our global strategy. Therefore, we are building a regulatory affairs team led by Dr. Ruyi He to cover China and overseas markets. This team will formulate a global registration strategy and detailed working plan for all the products in our pipeline according to their different stages of development. This team will also coordinate and systematically push forward the regulatory review processes in and outside of China, and will oversee the submission of IND applications and NDAs/BLAs in a timely manner to facilitate our drug candidates' accelerated entry into clinical trials and ensure a smooth path to commercialization. Meanwhile, we intend to also strengthen the protection of our intellectual property rights by prosecuting patent applications and enhancing patent protection for our pipeline assets in major overseas markets as planned.

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Actively seek commercial partnerships with global pharmaceutical companies to maximize the clinical and commercial value of our pipeline products.

Two of our core products, telitacicept and disitamab vedotin, are both potential first-in-class/best-in-class drug candidates with great clinical value and commercial potential. We are actively communicating with the world’s leading multinational pharmaceutical companies that could bring significant strategic synergy with us in the pursuit of potential opportunities for strategic collaboration, in order to gain reasonable commercial returns and expedite the clinical use of our products globally. We are assembling a seasoned international commercialization team with extensive industry experience. In addition to our ongoing business discussions with respect to the two core products, we will also introduce other assets in our pipeline to the global market, explore licensing or acquisition of valuable assets in our interested fields and carry out collaborations with domestic players.

Expand our global footprint and enhance our all-around drug discovery and development capabilities.

Our core competencies lie in our capabilities to design and discover new molecules with novel targets and novel mechanisms of action and develop them into drugs, and we have made remarkable achievements so far. In the future, we will continue to strengthen these capabilities. We plan to establish an R&D center in California, the U.S. in order to take advantages of the abundant resources of talents, technology, information and supply chain in the U.S. This R&D center will focus on drug discovery activities to help feed and sustain the continued growth of our drug pipeline and will be tasked with developing blockbuster drugs with competitive advantages at the global level. At the same time, we aim to enhance the synergy among our Yantai headquarters, Shanghai R&D center and the U.S. R&D center. We will design an R&D roadmap and reasonably allocate the resources among our R&D centers to achieve efficiency and significantly enhance our drug discovery capabilities.

Scale up manufacturing capacity to meet the needs of global clinical studies and commercial sales

With the support of the local government to the biopharmaceutical industry, an investment-friendly environment, and sufficient and cost-effective supply of land and manpower in Yantai, Shandong, we believe that we are in an ideal location for the production of large molecule biologics. We plan to establish our global GMP-compliant manufacturing and supply base for the domestic market and global trials in our headquarters in Yantai. We intended to increase our antibody manufacturing capacity to 36,000L by 2021 and to 80,000L by 2025. In the first quarter 2020, we purchased the use right to land with an aggregate area of 81,038 m², and we have started construction of new manufacturing facilities. According to the schedule of our construction project, we plan to complete the construction of the first stage of new manufacturing facilities by 2022 and use those new facilities to manufacture drug products for telitacicept’s global multi-center clinical trial, and we expect to complete the entire construction project by 2025. Upon the completion of new facilities together with our existing manufacturing facilities, we plan to increase our total antibody manufacturing capacity to an annual output of up to 9.3 million vials for antibodies and an annual output of up to 7.5 million vials for ADCs. We will reasonably manage the schedule of these new construction projects according to the development status and commercialization plan of our pipeline products.

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OUR DRUG CANDIDATES

We strategically focus on the discovery, research and development (R&D) and commercialization of innovative biologics mainly in the therapeutic areas of autoimmune diseases, oncology and ophthalmology. Leveraging our strong capabilities in drug discovery, research and development, we have built a robust pipeline of more than 10 drug candidates. Among our drug candidates, five have entered into clinical trials targeting 17 indications. Two of our five clinical-stage drug candidates, telitacept, a novel TACI-Fc fusion protein, and disitamab vedotin, a novel anti-HER2 antibody-drug conjugate (ADC), are currently being evaluated in a total of six registrational clinical trials for various indications, and both drug candidates have demonstrated the potential to become first-in-class and/or best-in-class therapies. For telitacept, we have submitted an NDA in China for the first indication (SLE), and the NMPA has accepted the NDA in November 2019 and granted us priority review in the following month.

With technologies and industry know-how accumulated over ten years, we have established a world-class biopharmaceutical discovery and R&D platform which serves as the foundation of our continuous innovations. Our discovery and R&D platform consists of three proprietary specialized platforms, including an antibody and fusion protein platform, an ADC platform and a bifunctional antibody (HiBody) platform. Leveraging these platforms, we have developed a robust pipeline of drug candidates. The following chart illustrates our pipeline and summarizes the development status of clinical-stage drug candidates and selected IND-enabling stage candidates as of the Latest Practicable Date:

Drug Candidates	Target (Modality)	Indication	Status (Clinical Sites Indicated on Status Bar)					NDA/BLA submission date	Commercial Rights			
			Pre-clinic.	IND	Ph I	Ph II	Pivotal/Ph III					
Autoimmune Diseases	Telitacept (RC18)*	Systemic Lupus Erythematosus	China				NDA Filed	October 2019	Global			
		Systemic Lupus Erythematosus	US									
		Neuromyelitis Optica Spectrum Disorder	China									
		Rheumatoid Arthritis	China					In registrational trial ¹⁰				
		IgA Nephritis	China									
		Sjogren's Syndrome	China									
		Multiple Sclerosis	China					In registrational trial ¹⁰				
Oncology	Disitamab Vedotin (RC48)*	HER2-Expressing ² Gastric Cancer	China					3	Q3 of 2020	Global		
		HER2-Expressing Urothelial Cancer	China					4	1H of 2021			
		HER2-Expressing Urothelial Cancer	US									
		HER2-Expressing Gastric Cancer	US									
		HER2 Low-Expressing ² Breast Cancer	China						In registrational trial ¹⁰			
		HER2 Low- to Non-Expressing ² Urothelial Cancer	China									
		HER2-Expressing Biliary Tract Carcinoma	China									
		HER2-Expressing Non-Small-Cell Lung Cancer	China									
		RC88	Mesothelin (ADC)	Multiple Solid Tumors	China							Global
		RC98	PD-L1 (mAb)	Multiple Solid Tumors	China							Global
RC108	e-MET (ADC)	Multiple Solid Tumors	China						Global			
RC118	Confidential (ADC)	Multiple Solid Tumors							Global			
RC138	Confidential (HiBody)	Multiple Solid Tumors							Global			
RC148	Confidential (HiBody)	Multiple Solid Tumors							Global			
RC158	Confidential (HiBody)	Multiple Solid Tumors							Global			
Ophthalmology	RC28*	Wet Age-Related Macular Degeneration	China					7		Global		
		Diabetic Macular Edema	China					8				
		Diabetic Retinopathy	China					9				

* Denotes our core drug candidates.

Abbreviations: 1H = first half; ADC = antibody drug conjugate; HiBody = a novel bifunctional antibody; mAb = monoclonal antibody; Q3 = third quarter

Notes:

- (1) The FDA has provided clearance for us to proceed with the Phase III clinical trial of telitacept for SLE in the U.S in January 2020 and granted telitacept Fast Track designation in April 2020.
- (2) HER2-expressing refers to a HER2 status of tumor cells identified with a test score of IHC 1+ or above. HER2 low-expressing refers to a HER2 status of tumor cells identified with a test score of IHC 1+ or IHC 2+/FISH-. HER2 non-expressing refers to HER2 status of tumor cells identified with a test score of IHC 0.
- (3) In China, we are (i) finalizing a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) gastric cancer (GC), and (ii) conducting a Phase I clinical trial to evaluate distamab vedotin in combination with PD-1 inhibitor for the treatment of HER2 over-expressing GC.

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- (4) In China, we are conducting (i) a Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) urothelial cancer (UC), and (ii) a Phase Ib/II trial to evaluate disitamab vedotin in combination with PD-1 inhibitor for the treatment of UC.
- (5) The FDA has provided clearance for us to proceed with the Phase II clinical trial of disitamab vedotin in the U.S in April 2020.
- (6) We have initiated pre-IND discussion with the FDA to obtain their consents for disitamab vedotin’s Phase II clinical trial in GC in the U.S.
- (7) We have completed a Phase I trial of RC28 in wet age-related macular degeneration (wet AMD) in August 2019 in China, of which the primary endpoint of safety was met. In July 2018, we obtained the NMPA’s approval for us to conduct Phase I, II and III trials of RC28 according to our clinical development plan and progress, and the NMPA has not raised any objections towards our clinical trials of RC28 since then. We are currently conducting a Phase Ib trial of RC28 to further evaluate its efficacy and safety for the treatment of wet AMD.
- (8) We plan to initiate a Phase II trial for RC28 in diabetic macular edema in the second half of 2020 in China.
- (9) We plan to initiate a Phase II trial for RC28 in diabetic retinopathy in the second half of 2020 in China.
- (10) Registrational trial, or pivotal trial, means the clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval.

Our Core Drug Candidates

Telitacicept (RC18)

Telitacicept is a proprietary novel fusion protein of us to treat autoimmune diseases. It is constructed with the extracellular domain of the human transmembrane activator and calcium modulator and cyclophilin ligand interactor (TACI) receptor and the fragment crystallizable (Fc) domain of human immunoglobulin G (IgG). Telitacicept targets two cell-signaling molecules critical for B-lymphocyte development: B-cell lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL), which allows it to effectively reduce B-cell mediated autoimmune responses that are implicated in several autoimmune diseases.

We are currently evaluating telitacicept in late-stage clinical trials in order to explore its potential to address seven autoimmune diseases, in an attempt to address the significant unmet or underserved medical needs in this therapeutic area. The chart below shows the indications for which we are currently evaluating telitacicept in clinical trials:

Indication ⁽¹⁾	Status					
	IND (Accepted)	Phase I		Phase II	Pivotal/ Phase III	NDA/BLA (Filed)
		Ia	Ib			
China						
SLE ⁽²⁾	●	●		● (pivotal) ⦿ (post-launch confirmatory)		●
NMOSD	●				⦿	
RA ⁽²⁾	●	●	●	●	⦿	
SS	●			⦿		
IgAN	●			⦿		
MS	●			⦿		
MG	●			⦿		
U.S.						
SLE	●				⦿	

Abbreviations: IgAN = IgA nephropathy; MG = myasthenia gravis; MS = multiple sclerosis; MTX = methotrexate; NMOSD = neuromyelitis optica spectrum disorder; RA = rheumatoid arthritis; SLE = systemic lupus erythematosus; SS = Sjögren’s syndrome.

Symbols: ● = complete; ⦿ = in progress (a clinical trial is deemed to have been initiated when we submit trial design and protocol to apply for ethical approval); ◐ = to be initiated

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Notes:

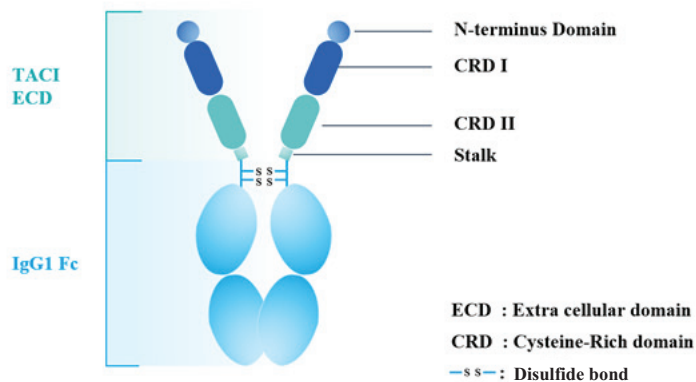
- (1) Some indications may not require every phase of the clinical trials indicated on this chart to be completed prior to the filing of an NDA/BLA. Based on the encouraging safety data from our clinical trials in SLE and RA, we advanced the clinical studies of telitacept for SS, IgAN, MS and MG to Phase II stage. In addition, as NMOSD is a rare disease with highly unmet medical needs and based on our communication with the NMPA, we skipped the early clinical studies and initiated a Phase III trials in NMOSD.
- (2) These trials evaluate telitacept in patients with moderate to severe SLE who have an inadequate response to standard of care (SOC), and patients receive telitacept plus SOC in the experimental group of these trials.
- (3) These trials evaluate telitacept in patients with moderate to severe RA who have an inadequate response to methotrexate (MTX) therapy, and patients receive telitacept plus MTX in the experimental group of these trials.

Telitacept demonstrated encouraging efficacy and safety results in SLE patients from our recently completed Phase IIb registrational trial in China. The NMPA accepted our NDA for telitacept for the treatment of SLE in November 2019 and granted us priority review in December 2019 and we expect to receive conditional approval to market telitacept for the treatment of SLE in the fourth quarter of 2020. The approval will be conditional on a commitment to complete a confirmatory Phase III trial in SLE post the commercial launch, and we are currently in the process of enrolling patients in this Phase III trial.

In parallel with the clinical development and regulatory process in China, we plan to also carry out a global clinical development plan for telitacept in order to maximize its therapeutic and commercial value. We expect to initiate global Phase III clinical trials in the first half of 2021 to cover multiple jurisdictions, including the United States, Europe and other countries. On April 15, 2020, the FDA granted Fast Track designation to telitacept, which could expedite the review and potential approval process with the FDA. With Fast Track designation, the frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

Mechanism of Action

As illustrated by the diagram below, telitacept is a novel recombinant fusion protein designed to simultaneously target two important cell-signaling molecules, B-cell lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL).



Source: Company data

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BLyS (also known as B-cell activating factor, or BAFF) and APRIL are both involved in the development of B cells from pre-B lymphocytes to mature B cells, and ultimately to plasma cells, the professional cells producing antibodies, as well as in the co-stimulation of T-cell proliferation under certain conditions. Aberrant B cell activities and antibody production are known to be implicated in a number of autoimmune diseases. BLyS and APRIL function through the following mechanisms:

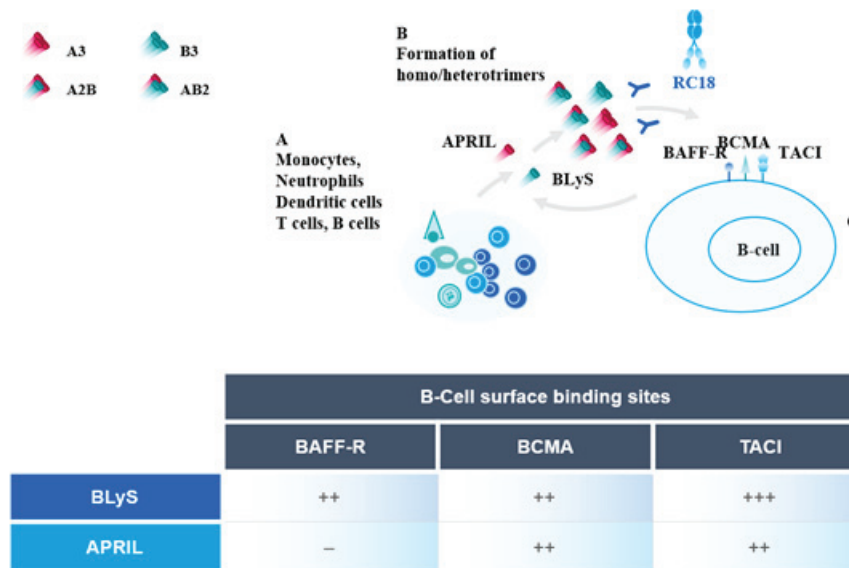
- BLyS binds to three types of membrane receptors expressed on B-cells, i.e., (1) TACI, (2) B-cell maturation antigen (BCMA) and (3) B-cell activating factor receptor (BAFF-R), to inhibit cell death and stimulate differentiation of B cells into antibody-producing plasma cells. The interaction between BLyS and TACI induces a T-cell independent B-cell activation, immunoglobulin class-switching and B-cell homeostasis, while BLyS' interaction with BCMA is important for the differentiation and survival of plasma cells.
- Unlike BLyS, APRIL only binds to TACI and BCMA (but not BAFF-R) to modulate the function and survival of B cells and promotes their differentiation into plasma cells.
- In sum, whereas BCMA binds to BLyS weakly and BAFF-R does not bind to APRIL, TACI binds to BLyS and APRIL with equal affinity and can also bind to heteromeric forms of BLyS and APRIL.
- BLyS and APRIL also play a role in the co-stimulation of T cells as B cells and T cells cross-talk. For instance, since BAFF-R is a potent T cell co-stimulator, the signalling of BLyS to BAFF-R could promote aberrant T cell maturation, which is known to be implicated in certain autoimmune diseases.

Consistent with their known functionalities, increased BLyS and APRIL expression has been observed in various B cell-mediated autoimmune diseases, such as SLE, NMOSD and RA. Studies have shown that direct inhibition of BLyS and APRIL has the potential to prevent the engagement of their receptors, BAFF-R, TACI and BCMA, and thus to prevent the subsequent activation of B cell-driven mechanisms, such as autoantibody production that contributes to the pathology of autoimmune diseases. BLyS and APRIL have therefore emerged as important targets for autoimmune therapeutics, although most of the clinical-stage drug candidates targeting this signaling pathway have been designed to neutralize either BLyS or APRIL, but not both.

As illustrated in the diagram below, telitacept blocks BLyS and APRIL from binding to BAFF-R, BCMA and TACI receptors expressed on B-cell surface, suppressing the BLyS and APRIL signaling, and inhibiting the development and survival of mature B cells and plasma cells.

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Mechanism of Action for Telitacicept



Abbreviation: A3 = APRIL homotrimers; B3 = BlyS homotrimers; A2B = heterotrimers of two APRIL and one BlyS molecules; AB2 = heterotrimers of one APRIL and two BlyS molecules

Source: Company data

Market Opportunities and Competition

- SLE

We have completed Phase IIb registrational trial of telitacicept for the treatment of moderate to severe systemic lupus erythematosus (SLE). SLE is an autoimmune disease in which the body’s immune system mistakenly attacks healthy body tissues, often leading to long-term damage to patient health. Clinical manifestations of SLE range from joint pains and skin rashes to severe organ damage and complications at later stages, such as kidney failure, heart and lung inflammation and central nervous system abnormalities. The disease places a substantial economic burden on the patients due to high healthcare costs and loss of ability to work, and it also imposes considerable negative impact on patients’ social functions and quality of life. SLE has one of the highest mortality and disability rates among autoimmune rheumatic diseases.

According to Frost & Sullivan, the global SLE prevalence was approximately 7.7 million in 2019, and it is estimated to reach 8.6 million by 2030. In China, there were approximately 1.0 million SLE patients in 2019, which is estimated to grow to approximately 1.1 million by 2030. Studies also show a tenfold higher prevalence of SLE in women compared to men – predominantly young and middle-aged women (typically within the age band of 15 to 45). According to the Frost & Sullivan, the market size of global SLE biological therapeutics is estimated to grow at a CAGR of 26.8% from US\$0.8 billion in 2019 to US\$10.8 billion by 2030.

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While a large population of SLE patients in China and the world have an urgent need for effective medical treatment, there is no effective cure for SLE and currently available treatments are either limited in efficacy or poorly tolerated in a sizeable group of patients. The medications most commonly used to control SLE symptoms include corticosteroids, anti-malarial agents, non-steroidal anti-inflammatory drugs, immunosuppressants and biologics. Among these medications, although high doses of corticosteroids and immunosuppressants can be helpful in severe cases of SLE, the patients tend to progress and relapse over time and face a high risk of serious side effects, including weight gain, easy bruising, thinning bones (osteoporosis), high blood pressure, diabetes and increased risk of infections. In addition, treatment with immunosuppressants may result in an increased risk of serious infections and certain types of cancer.

As of the Latest Practicable Date, GlaxoSmithKline’s Benlysta (belimumab), a BLYS single-targeted therapy and immunosuppressant biologic, is the only FDA-approved biologic therapy for SLE, and the only FDA-approved novel drug for SLE in the last nearly 60 years. GlaxoSmithKline acquired Benlysta along with its developer Human Genome Sciences in 2012 for approximately US\$3.6 billion, and reported US\$782.8 million in worldwide sales of Benlysta in 2019, including US\$683.2 million in the U.S. Benlysta was approved in Europe also in 2011, but has not yet been covered by mainstream medical insurance in Europe. In July 2019, Benlysta was approved by the NMPA to treat SLE in China, and its estimated annual treatment cost in China was around RMB79,040 in 2019 under patient assistance program.

There remains significant unmet needs for new therapeutics for SLE that effectively control disease activity, have a favorable safety profile and improve the patients’ quality of life. Despite substantial investments by biopharmaceutical companies in the development of SLE therapies over the years, many drug candidates have failed to show clinical efficacy (especially the late-stage clinical trial results). The table below summarizes the development status of telitacept and its major global competitors for SLE that are marketed or in Phase III clinical trials as of the Latest Practicable Date.

Molecule	Target	Company	Indication	Status	Initiation Date ¹
China					
belimumab	BLYS	GlaxoSmithKline	SLE	Marketed	N.A.
telitacept	BLYS/APRIL	RemeGen	SLE	NDA	N.A.
Global (Outside of China)					
belimumab	BLYS	GlaxoSmithKline	SLE	Marketed	/
anifrolumab	IFNAR1	AstraZeneca	SLE	Phase III	2015-05
dapirolizumab pegol	CD40L	UCB	SLE	Phase III	2020-03

Note:

1. denotes the first public announcement date of the trial.

Source: Frost & Sullivan Report

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- NMOSD:

We are also evaluating telitacicept in a Phase III clinical trial in China for the treatment of neuromyelitis optica spectrum disorder (NMOSD). NMOSD is a central nervous system disorder that occurs when the body’s immune system mistakenly attacks against its own cells in the central nervous system, mainly in the optic nerves and spinal cord, but sometimes in the brain as well. These attacks often lead to severe visual loss, and cause limb weakness, sensory loss, and bladder dysfunction. Most NMOSD patients experience relapses in one to three years. With each relapse, the disability can be worsen.

According to Frost & Sullivan, the global prevalence of NMOSD reached 169,300 in 2019 and is estimated to reach 187,600 by 2030, while in China there were 48,300 NMOSD patients in 2019 and that figure is estimated to increase to 52,600 by 2030.

The current standard of care for NMOSD includes corticosteroids. High-dose or long-term use of corticosteroids carries a significant risk of side effects. As of the Latest Practicable Date, Alexion’s Soliris (eculizumab) and Viela’s Uplizna (inedilizumab) are the two biologic therapies that have been approved by the FDA for the treatment of NMOSD. So far, no biologic therapy has received marketing approval for NMOSD in China.

The table below summarizes the development status of telitacicept and its major global competitors for NMOSD that are marketed or in late-stage clinical trials as of the Latest Practicable Date.

Molecule	Target	Company	Indication	Status	Initiation Date ¹
China					
telitacicept	BLYS/APRIL	RemeGen	NMOSD	Phase III	2017-10
Global (Outside of China)					
Soliris (eculizumab)	C5	Alexion	NMOSD	Marketed	N.A.
inedilizumab	CD19	Viela	NMOSD	Marketed	N.A.
satralizumab	IL-6	Roche	NMOSD	BLA	N.A.
ravulizumab	C5	Alexion	NMOSD	Phase III	2019-12

Note:

1. denotes the first public announcement date of the trial.

Source: Frost & Sullivan Report

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- RA:

We are evaluating telitacept for the treatment of moderate to severe rheumatoid arthritis (RA) in a Phase III clinical trial in China. Similar to SLE, RA is an autoimmune disorder that occurs when the body’s immune system mistakenly attacks its healthy tissues, affecting twice as many women as men with a mean age of 40-60 years. As a chronic inflammatory disorder, RA can affect the joints and, in some cases, damage a wide range of human body organs, including the skin, eyes, lungs, heart and blood vessels.

RA is the third largest therapeutic area globally in terms of market size, following oncology and diabetes. According to Frost & Sullivan, there were 39.3 million RA patients globally in 2019 and this figure is estimated to increase to 45.0 million by 2030, while RA prevalence in China reached 5.9 million in 2019 and is estimated to reach 6.4 million by 2030.

The current standard of care for RA includes non-steroidal anti-inflammatory drugs, corticosteroids, disease-modifying anti-rheumatic drugs, and subcutaneous biologics. Except for a few targeted therapeutics, the existing medications either lack effectiveness in controlling the diseases or are associated with high risks of serious side effects. The most commonly used biologic therapy in RA patients is AbbVie’s Humira (adalimumab), a TNF- α inhibitor, whose efficacy and safety both can be further improved. In 2018, Humira (adalimumab) recorded global sales of US\$20.5 billion. Currently, the penetration rate of biologic therapies in China’s RA market is extremely low, indicating a significantly unmet medical need and the commercial potential for new RA biologic therapies in China.

As of the Latest Practicable Date, there were ten innovator biologics approved for RA in the U.S. and seven in China. Our telitacept has entered Phase III clinical trials. For further details, please refer to the paragraph headed “Industry Overview—2. Autoimmune Disease Drug Market—2.4 Rheumatoid Arthritis—2.4.3 Competitive Landscape of Biologics Treatment of RA in the U.S. and in China”.

- Sjögren’s syndrome:

We are evaluating telitacept for the treatment of Sjögren’s syndrome (SS) in a Phase II clinical trial in China. SS is a female-dominated, autoimmune disorder characterized by autoimmune destruction of moisture-producing glands. It is identified by two most common symptoms, i.e., dry eyes and dry mouth. The condition of SS often accompanies other immune system disorders, such as RA and lupus. The condition is much more common in women, who are affected at a 9:1 ratio in comparison to men, and most patients are older than 40 at the time of diagnosis.

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According to the Frost & Sullivan, the prevalence of SS in China was 628,600 in 2019 and is expected to reach 644,900 in 2030, while the prevalence of SS in the U.S. was 198,800 in 2019 and is expected to reach 215,600 in 2030. Though there is no cure for SS, medical treatments, from over-the-counter eyedrops, sipping water, prescription drugs to minor surgical procedures, can help manage the symptoms depending on the parts of body affected.

Currently, no biologics anywhere in the world have been approved for the treatment of SS. As of the Latest Practicable Date, our telitacept is the only biologic to have entered clinical trials in China in SS. For further details, please refer to the paragraph headed “Industry Overview—2. Autoimmune Disease Drug Market—2.5 Sjögren’s Syndrome—2.5.3 Competitive Landscape of Biologics Treatment of SS in the U.S. and in China”.

- IgA Nephropathy:

We are evaluating telitacept for the treatment of IgA nephropathy (IgAN) in a Phase II clinical trial in China. IgAN is an autoimmune disease affecting kidney that occurs when an antibody called immunoglobulin A (IgA) builds up in the kidneys, resulting in local inflammation and damage that, over time, results in a decline in the kidneys’ function and ability to filter waste from the blood. IgAN usually progresses slowly over years, but the course of the disease varies from person to person. In some patients, IgAN can eventually lead to end-stage kidney failure.

China has a high prevalence of IgAN, with 2.2 million patients in 2019, and this patient population is estimated to reach 2.4 million by 2030, according to the Frost & Sullivan. There is currently no cure for IgAN, but certain medications can slow its course and control its symptoms, such as blood pressure medicines, corticosteroids, prescription strength fish oil and cholesterol-lowering medicines. This disease most frequently occurs in teenagers and young adults. For these young patients, treatment with corticosteroids generally creates a higher risk of adverse events and negative psychological effects.

Currently, no biologics anywhere in the world have been approved for the treatment of IgAN. As of the Latest Practicable Date, our telitacept is the only one biologics to have entered clinical trials in China for IgAN. For further details, please refer to the paragraph headed “Industry Overview—2. Autoimmune Disease Drug Market—2.6 Immunoglobulin A Nephropathy—2.6.3 Competitive Landscape of Biologics Treatment of IgAN in the U.S. and in China”.

In addition to the above, we are also developing telitacept for other B-cell mediated autoimmune diseases for which there is a significantly unmet medical need, including multiple sclerosis (MS) and myasthenia gravis (MG). For further details of market opportunities and competition for MS and MG, please refer to the paragraph headed “Industry Overview—2. Autoimmune Disease Drug Market—2.7 Myasthenia Gravis” and “Industry Overview—2. Autoimmune Disease Drug Market—2.8 Multiple Sclerosis” in this document.

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Competitive Advantages of Telitacicept

With its significant efficacy and favorable safety profile observed in SLE patients in the China trials, telitacicept has demonstrated the potential to become a global first-in-class and best-in-class biological therapy for SLE. We believe that telitacicept has the following major competitive advantages:

Optimized structure design leads to improved biological activities and productivity

Benefiting from our expertise in structural biology and advanced protein engineering capabilities, telitacicept incorporates almost the full extracellular BLyS/APRIL-binding domain of human TACI. The structural design allows telitacicept to target and neutralize activities of two important B cell-signaling molecules, i.e., BLyS and APRIL. As both BLyS and APRIL are over-expressed in patients suffering from SLE as well as certain other B cell-mediated autoimmune diseases, dual blockade of BLyS/APRIL pathway can be more potent in the treatment of SLE and other B cell-mediated autoimmune diseases than blocking either BLyS or APRIL alone and can have the benefit of inhibiting B cell maturation as well as T cell maturation.

Moreover, employing neural network-based bioinformatics, we have constructed telitacicept in a way that allows it to retain most of the N-terminal and C-terminal domains of the TACI molecule. The bioinformatics-optimized TACI fragment retains human TACI's high binding affinity for BLyS, APRIL and BLyS/APRIL homo/heterotrimers and to preserve its *in vivo* biological functions.

In animal models of SLE, telitacicept's innovative dual-targeting mechanism appears to have generated more pronounced pharmacodynamics effects than a BLyS single-targeting mechanism, suggesting a stronger efficacy profile. In one of our studies, telitacicept led to meaningful reduction in IgM and IgG levels in cynomolgus monkeys, while according to published data, belimumab, a BLyS single-targeting monoclonal antibody, demonstrated less reduction on the same measurements in the monkeys. Our study also found that treatment with telitacicept resulted in a linear, dose-dependent reduction in both IgG and IgM across a dosing range from 6mg/kg up to 60mg/kg, suggesting a wide dosing range that would be available for controllable modulation of B-cell immune activity. Although these were not head-to-head studies, we believe that valuable insight can nonetheless be drawn from the comparisons.

In addition, leveraging our antibody and fusion protein engineering platform, we have combined the TACI fragment of telitacicept with the Fc region of human IgG. Human immunoglobulins of the IgG isotypes are known to have remarkable serum stability and long half-lives, and also to help increase the stability and half-lives of fusion proteins when they are integrated as a component. These optimized structural features of telitacicept promote its molecular stability and facilitate our remarkable productivity of the fusion protein.

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Full human amino acid sequence to minimize potential immunogenicity

Therapeutic proteins may be seen as foreign antigens by the immune system of human bodies and as a result elicit unwanted immune responses against themselves called immunogenicity, thereby limiting therapeutic effects and even causing life-threatening complications. In order to minimize the immunological risks, telitacept is designed and genetically engineered to be composed of TACI and Fc portions derived from human TACI receptor and human IgG, respectively.

Leveraging our advanced fusion protein engineering technology, we successfully produced the fusion protein with TACI fragment preserving almost the full amino acid sequence of human TACI to the maximum extent. The optimal truncation sites of human TACI domain were determined through our analysis using neural network bioinformatics. As a result, the structure of telitacept incorporates most of the N-terminal and C-terminal of human TACI molecule in order to preserve the biological functions while reducing immunogenicity. Furthermore, we have the TACI fragment fused to the Fc portion of human IgG. Immunoglobulins, especially IgG subclasses, are known to be tolerogenic, or capable of producing immunological tolerance. Therefore, we engineered TACI fragment in frame with an IgG heavy chain to improve immunological tolerance and, with the design-based advantages, we have not observed signs of immunogenicity in our clinical trials of telitacept.

Superior clinical efficacy profile

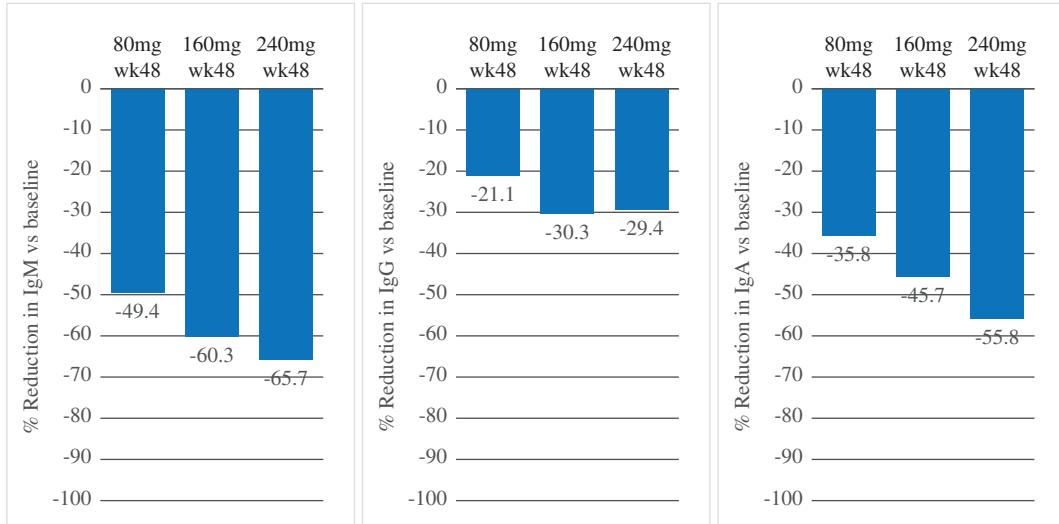
Our telitacept’s innovative BLYS/APRIL dual-targeting mechanism and bioinformatics-optimized molecular structure and biochemical properties, including its enhanced binding affinity for the targeted signaling factors, have enabled it to demonstrate more robust clinical benefit than its competitors.

While there is no head-to-head clinical trial comparison, our telitacept and GlaxoSmithKline’s Benlysta (belimumab) have both completed registrational trials in SLE patients, and telitacept has demonstrated potential superior clinical efficacy to that of belimumab in SLE patient population based on the published data. In the clinical trials, our telitacept demonstrated a dose-dependent modulation of B-cell immune response in SLE patients and resulted in large reductions in IgM, IgG and IgA levels. As shown in the figures below, telitacept generally achieved a dose-dependent linear and robust effect on IgM, IgG and IgA reduction within a wide dosing range from 80 mg to 240 mg, while subcutaneous administration of 200 mg belimumab resulted in modest reduction in IgM, IgG and IgA compared to baseline.

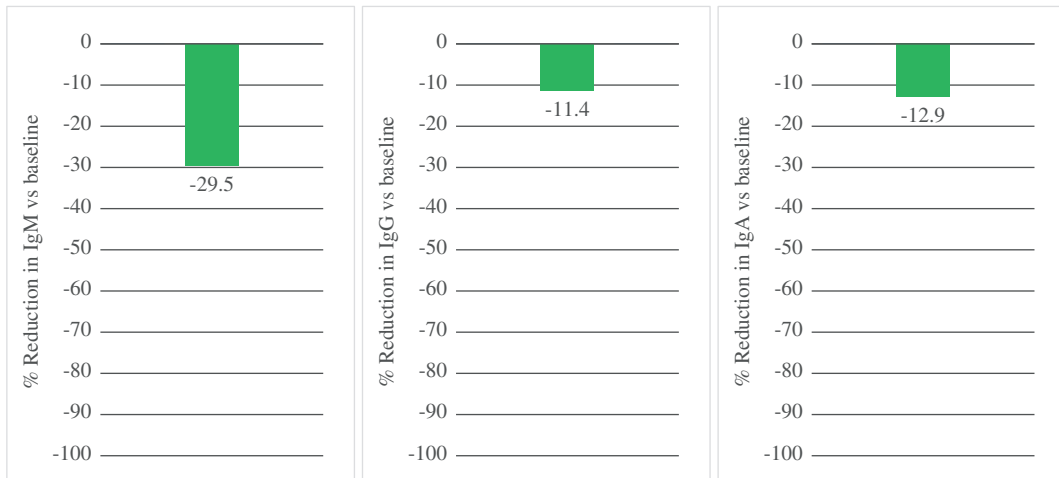
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Comparison of Median Percentage Reduction in IgM, IgG and IgA from Baseline in SLE Patients

Telitacicept (QW x 48 SC, 80-240 mg)



Belimumab (QW x 52 SC, 200 mg)



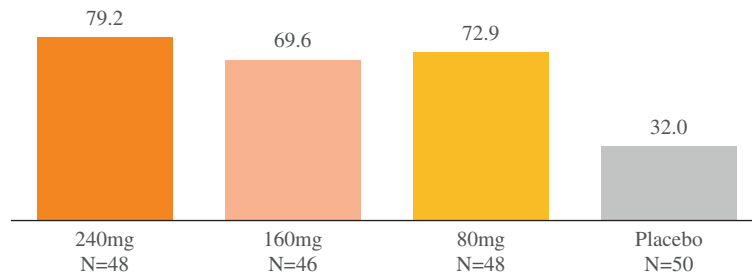
Source: (1) Belimumab: European Medicines Agency: EMA/CHMP/346577/2017, 2017; (2) Telitacicept: Company data

In November 2019, we orally presented the results of our Phase IIb registrational trial of telitacicept for the treatment of SLE in China at the 2019 American College of Rheumatology (ACR)/Association of Rheumatology Professionals (ARP) Annual Meeting held in Atlanta, Georgia, United States. As observed in this Phase IIb trial, telitacicept showed a superior clinical efficacy and good safety profile that suggests best-in-class potential in SLE. The primary endpoint of this trial was the proportion of patients achieving SLE responder index-4 (SRI-4) response at week 48, which is a composite measurement for disease activity and response in SLE. In each of three treatment arms receiving subcutaneous telitacicept at multiple dose levels throughout the

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duration of the trial, a significant larger portion of patients achieved SRI-4 response than the patients in the placebo arm, which indicates significant reduction in SLE disease activity in the telitacept treatment arms. The high-dose arm (240 mg) in this trial achieved SRI-4 response rate as high as 79%, as compared to 32% in the placebo arm, in per protocol set (PPS) analysis with 192 randomised patients. The chart below shows the SRI-4 response rates of telitacept at different dose levels in the PPS analysis. Additionally, given good efficacy was seen in all groups of different doses, lower doses are planned to be investigated in future studies to potentially further enhance the safety profile of telitacept.

Telitacept: SRI-4 Response Rate (PPS)



Source: Company data

Favorable safety profile

As of the Latest Practicable Date, telitacept demonstrated a good safety profile and tolerability in eight clinical trials that we have completed to evaluate telitacept in various autoimmune diseases. Although patients treated with telitacept were slightly more prone to experience adverse events (AEs) as compared to placebo-treated patients, most of the AEs were rated mild or moderate on the mild-moderate-severe scale and were resolved without leading to withdrawal from the studies.

The table below summarizes the safety results of telitacept in our Phase IIb registrational trial in SLE in China per full analysis (FAS) with 249 patients.

	240mg (N=62), n (%)	160mg (N=63), n (%)	80mg (N=62), n (%)	Placebo (N=62), n (%)
AEs	58(93.5)	58(92.1)	56(90.3)	51(82.3)
SAEs	8(12.9)	10(15.9)	8(12.9)	10(16.1)
SARs	3(4.8)	2(3.2)	3(4.8)	2(3.2)
AEs leading to permanent discontinuation	7(11.3)	8(12.7)	7(11.3)	8(12.9)
ARs leading to permanent discontinuation	2(3.2)	3(4.8)	2(3.2)	6(9.7)

Abbreviation: AE=adverse event; AR=adverse reaction; SAE=serious adverse event; SAR=serious adverse reaction

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In general, telitacicept was well tolerated by patients in the Phase IIb registrational study. The SAE rate was 13% – 16% in the treatment groups for dose levels ranging from 80mg to 240mg, which was lower or in line with the placebo group which had an SAE rate of 16%. The overall incidence of adverse events (AEs) was 92.0% across the treatment arms, compared to 82.3% in the placebo arm. There was no statistically significant difference in the incidence of AEs between treatment and placebo arms. The most frequent AEs noted in this study were infections and infestations (72.7%). The majority of AEs with telitacicept were mild or moderate. The percentage of patients who discontinued the treatment due to AEs or ARs in the treatment groups was lower or in line with that in the placebo group. The one and only fatality reported in the telitacicept 240 mg treatment arm was considered not to be drug-related.

Summary of Clinical Trial Results

As of the Latest Practicable Date, we had evaluated the safety and efficacy profiles of telitacicept in eight completed clinical trials and seven ongoing clinical trials covering a wide variety of indications, including SLE, NMOSD, RA, SS, IgAN, multiple sclerosis and myasthenia gravis. We have completed the Phase IIb registrational trial of telitacicept in SLE patients in China, and we have two other registrational trials of telitacicept respectively in RA and NMOSD patients ongoing.

Clinical Trials in SLE

We have completed Phase I, IIa and IIb trials in China to assess the safety, efficacy, pharmacokinetics (PK) and pharmacodynamics (PD) of telitacicept either as a monotherapy or in combination with standard therapy in SLE patients.

We completed two Phase I trials of telitacicept to evaluate the safety and PK/PD profile of telitacicept in October 2012 and December 2019, respectively. In the first Phase I trial, 12 patients were randomized into two groups at the ratio of 3:1, and received telitacicept at 180 mg or placebo, in each case plus standard of care. In the second Phase I trial, 36 healthy volunteers were randomized into three groups at the ratio of 1:1:1, and received telitacicept at the dosage of 80 mg, 160 mg and 240 mg, respectively. In these two trials, telitacicept demonstrated that it was well tolerated in SLE patients and had a linear PK profile, and in the first Phase I trial, we also obtained preliminary evidence of its promising efficacy in SLE. We also conducted Phase Ia and Ib trials in RA patients to assess the safety, PK and PD of telitacicept prior to initiation of our Phase II trials in SLE patients. In January 2016, we completed a multi-center, randomized, double-blinded and placebo-controlled Phase IIa trial to explore recommended dose and dosing frequency for late-stage clinical trials. 138 patients with moderate to severe SLE were randomized at the ratio of 1:1:1:1 to receive telitacicept at low-dosages (40 mg, 80 mg or 120 mg) or placebo, in each case plus standard of care, for a total of 14 doses across 48 weeks (once every two weeks for the first three doses and once every four weeks thereafter). In this trial, no significant difference in the incidence of AEs, ARs or SAEs were observed

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between treatment and placebo groups, which showed a favorable safety profile of telitacept. However, the treatment groups did not show statistically significant improvement on disease conditions, comparing to the placebo group, at these dose levels. Considering the results of this study, we determined that the dosing level and schedule used in this study was insufficient to achieve sustained therapeutic benefits of telitacept, and then largely increased the dose and frequency in designing the subsequent Phase IIb registrational trial in which the patients received 80, 160 or 240 mg telitacept once every week. In the completed Phase IIb registrational trial, telitacept demonstrated its high efficacy and excellent safety for SLE patients at all doses. Based on the data from this clinical trial, we submitted our NDA for conditional approval of telitacept for the treatment of SLE, which was accepted and granted with priority review status by the NMPA. We are currently enrolling patients in a confirmatory Phase III trial in China to evaluate telitacept in combination with standard therapy in SLE patients.

Registrational Phase IIb trial in patients with moderate to severe SLE in China

Trial Design: This is a multi-center, randomized, double-blind and placebo-controlled Phase IIb clinical trial conducted in China. A total of 249 patients with moderate or severe SLE were enrolled in this trial. The duration of this trial was 48 weeks. Patients were equally divided into four groups to receive subcutaneous telitacept (at dose levels of 80 mg, 160 mg or 240 mg) or placebo once a week, in each case in combination with standard of care. For purposes of this trial, standard therapy comprises any of the following (alone or in combination): corticosteroids, antimalarials, non-steroidal anti-inflammatory drugs (NSAIDs), and immunosuppressive and immunomodulator therapy (i.e., azathioprine, mycophenolate, cyclophosphamide, methotrexate, tacrolimus or ciclosporin).

The primary endpoint of the trial is the proportion of patients achieving the SLE Responder Index 4 (SRI-4) response at week 48. SRI-4 response is a composite endpoint used in SLE clinical trials that assesses disease activity and response to treatment. Clinically meaningful disease activity improvement is achieved if a greater than four point reduction in SRI occurred. SRI-4 includes criteria from three internationally validated indices, including SELENA-SLE Disease Activity Index (SELENA-SLEDAI), British Isles Lupus Assessment Group (BILAG) and Physician's Global Assessment (PGA).

The secondary endpoints are (i) proportion of patients with a four points or more decrease in SELENA-SLEDAI scores after treatment, (ii) change in the overall evaluation by physicians versus baseline, (iii) proportion of patients with prednisone doses of ≤ 7.5 mg/d or $\geq 25\%$ reduction from baseline after 44 to 48 weeks of treatment, and (iv) changes from the baseline values in serological tests of IgG, IgA, IgM, B-cell (CD19⁺), anti-ds-DNA antibodies, antinuclear antibodies (ANA) and complement (C3 and C4).

Trial Status: This trial was completed in June 2019 and we finalized the analysis in October 2019.

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Efficacy Data: Telitacept achieved statistically significant results and reached both the primary and secondary endpoints of this trial.

In all three groups receiving telitacept (80 mg, 160 mg and 240 mg) in this trial, the proportion of patients achieving clinically meaningful disease activity improvement were significantly higher than that of the placebo group in both the full analysis set (FAS) which includes all 249 patients randomly assigned to a treatment group having at least one efficacy assessment after randomization and the per protocol set (PPS) which includes 192 randomised patients who had received at least 12 doses of telitacept and completed the SRI-4 assessment. In the FAS analysis, disease activity was significantly reduced among 75.8% patients treated with telitacept at 240 mg, as compared to a 33.9% in the placebo group. Significant reduction of disease activity was also observed in a large proportion of patients treated at lower doses: 68.3% at 160 mg and 71.0% at 80 mg in the FAS analysis. The following figures show the SRI-4 response rates of telitacept in both FAS and PPS analyses.

Telitacept (RC18): SRI-4 Response Rate (FAS)

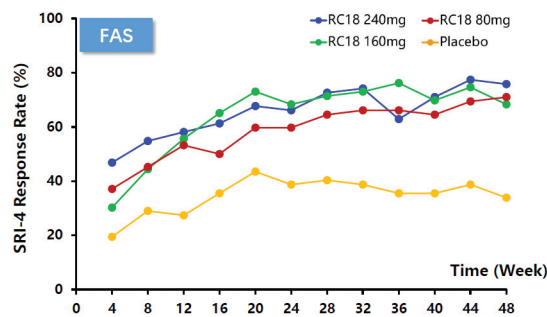


Figure 1. Diachronic changes of the SRI-4 Response Rate from Week 0 to Week 48 (FAS)

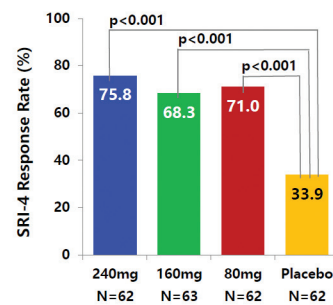


Figure 2. The SRI-4 Response Rate at Week 48 (FAS)

Telitacept: SRI-4 Response (PPS)

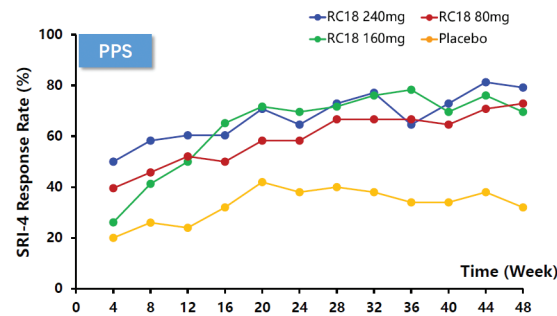


Figure 3. Diachronic changes of the SRI-4 Response Rate from Week 0 to Week 48 (PPS)

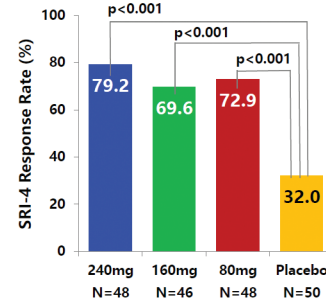


Figure 4. The SRI-4 Response Rate at Week 48 (PPS)

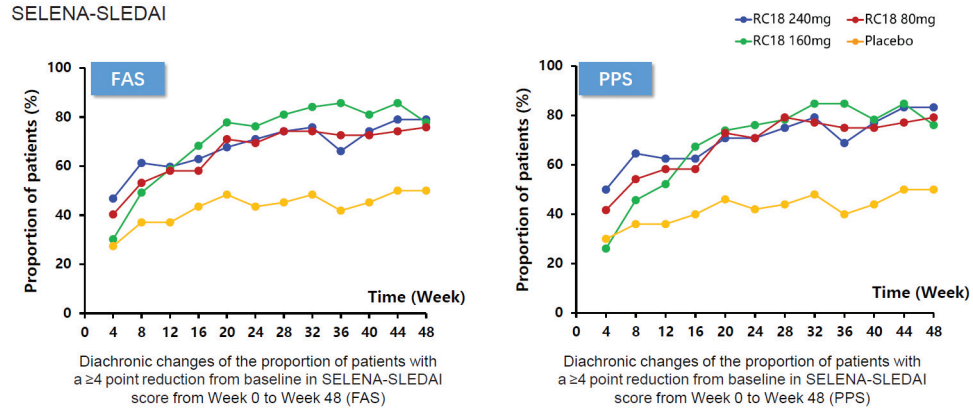
Source: Company data

The proportion of patients with a four points or more decrease in SELENA-SLEDAI scores also increased significantly after four weeks of treatment with telitacept and continued to grow in the remainder of the 48-week treatment period. At Week 48, this proportion in the treatment groups reached around 79.0% at 240

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mg, 77.8% at 160 mg and 75.8% at 80 mg in the FAS analysis, as compared to 50.0% in the placebo group, whereas this proportion in the treatment groups reached around 83.3% at 240 mg, 76.1% at 160 mg and 79.2% at 80 mg in the PPS analysis, as compared to 50.0% in the placebo group. The following figures show the proportion of patients with a four points or more decrease in SELENA-SLEDAI scores in both FAS and PPS analyses.

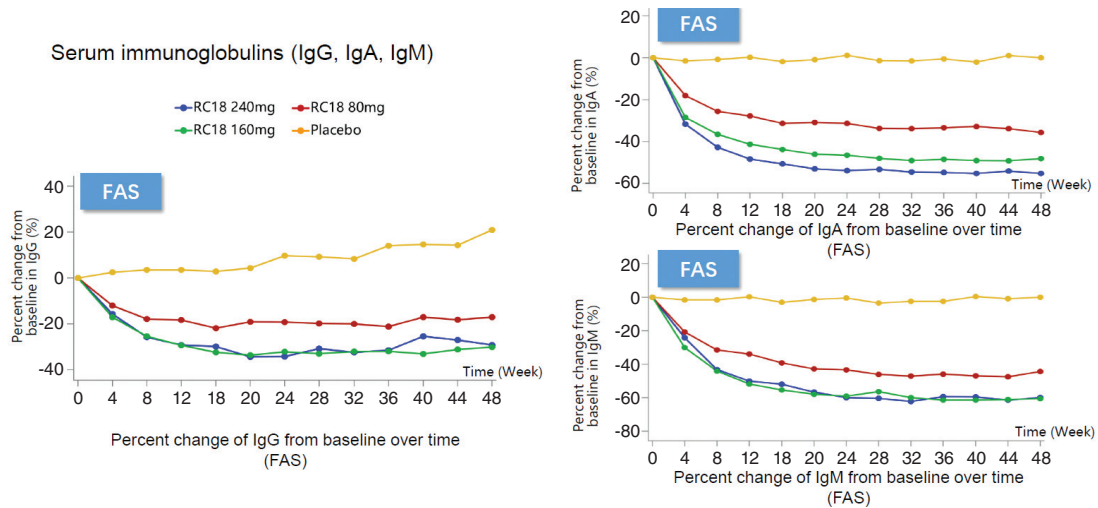
Telitacicept: SELENA-SLEDAI Results



Source: Company data

As compared to the placebo group, significant reductions of serum immunoglobulins (IgG, IgA, IgM) in the three treatment groups receiving telitacicept were observed at Week 4 and were sustained throughout the remainder of the 48-week treatment period. The following figures show the percentage changes from the baseline values in serological tests of IgG, IgA and IgM.

Telitacicept: Percentage Changes of Serum Immunoglobulins

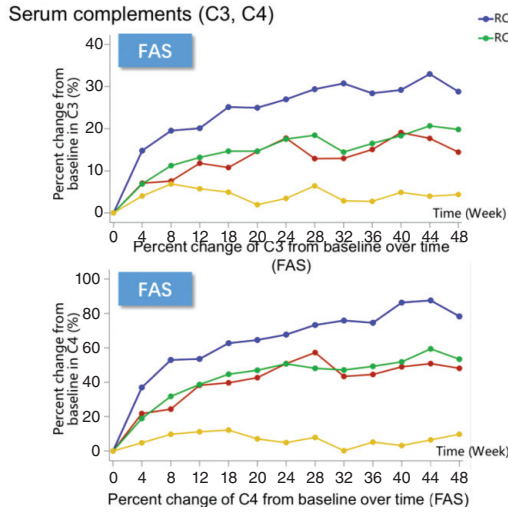


Source: Company data

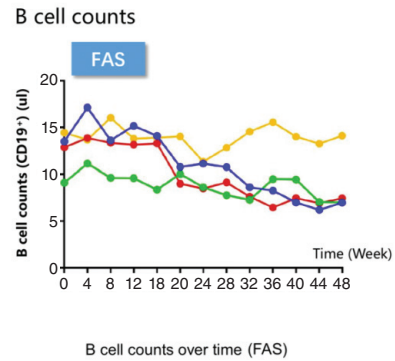
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In addition, significant increases in serum complements (C3 and C4) and decreases in B cell counts were observed in telitacept treatment groups compared to the placebo group over the treatment period. The following figures show the percentage changes of C3 and C4 from the baseline and the changes in B cell counts.

Telitacept: Percentage Change of Serum Complements



Telitacept: B Cell Counts



31

Source: Company data

Safety Data: In this trial, telitacept demonstrated a favorable safety profile and tolerability in SLE patients. Serious adverse events (SAEs) were observed with 8 patients (12.9%), 10 patients (15.9%) and 8 patients (12.9%) in treatment groups with telitacept of 240 mg, 160 mg and 80 mg, respectively, as compared to 10 patients (16.1%) experiencing SAEs in the placebo group. The adverse events observed in this trial are summarized in the table below.

	240mg (N=62), n (%)	160mg (N=63), n (%)	80mg (N=62), n (%)	Placebo (N=62), n (%)
AEs	58(93.5)	58(92.1)	56(90.3)	51(82.3)
SAEs	8(12.9)	10(15.9)	8(12.9)	10(16.1)
SARs	3(4.8)	2(3.2)	3(4.8)	2(3.2)
AEs leading to dose reduction or suspension of treatment	39(62.9)	24(38.1)	25(40.3)	27(43.5)
ARs leading to dose reduction or suspension of treatment	30(48.4)	21(33.3)	20(32.3)	22(35.5)
AEs leading to permanent discontinuation	7(11.3)	8(12.7)	7(11.3)	8(12.9)
ARs leading to permanent discontinuation	2(3.2)	3(4.8)	2(3.2)	6(9.7)
AEs leading to death	1(1.6)	0(0)	0(0)	0(0)
ARs leading to death	0(0)	0(0)	0(0)	0(0)
AEs at injection site	6(9.7)	12(19.0)	7(11.3)	4(6.5)
ARs at injection site	6(9.7)	11(17.5)	7(11.3)	4(6.5)

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In general, telitacicept has been well tolerated by patients in the study, although more mild to moderate infections were reported in patients receiving telitacicept than patients receiving placebo. Among all patients, the most common ($\geq 10\%$) treatment-related AEs were upper respiratory tract infection (telitacicept vs. placebo: 35.5%-43.5% vs. 46.8%), urinary tract infection (telitacicept vs. placebo: 8.1%-12.9% vs. 4.8%) and injection site reaction (telitacicept vs. placebo: 8.1%-12.7% vs. 4.8%). The percentage of patients who discontinued the treatment due to AEs or ARs in the treatment groups was lower or in line with that in the placebo group. One death was reported in the telitacicept 240 mg group but it was considered not to be drug-related.

SLE predominantly occurs in young women at childbearing ages. Pregnancy in a woman with SLE carries a higher risk of maternal and fetal mortality and morbidity as compared to pregnancy in healthy women. In this Phase IIb trial, 11 patients' health conditions were so improved under the treatment with telitacicept that they were able to get pregnant during the trial and withdrew from the trial according to the protocol. Among these pregnant patients, one patient gave birth to a fetus while ten others chose active termination of pregnancy. The status of pregnant patients in this trial are summarized in the table below.

		240mg (N=62)	160mg (N=63)	80mg (N=62)	Placebo (N=62)
Number of Pregnant Recipients		4	3	4	0
Pregnancies					
Active termination of pregnancy	n(%)	4(100.0)	3(100.0)	3(75.0)	0
Birth of Fetus	n(%)	0(0)	0(0)	1(25.0)	0

Conclusion: Based on the data from this clinical trial, telitacicept in combination with standard therapy has demonstrated a strong profile in terms of both efficacy and safety in patients with moderate to severe SLE. Based on the trial results, our NDA for conditional approval of telitacicept for the treatment of SLE was accepted by the NMPA in November 2019, which was granted priority review in December 2019. Based on our communication with the NMPA, we have also initiated a Phase III confirmatory clinical trial in China in 2019.

Clinical Trials in RA

We have completed Phase Ia, Ib, IIa and IIb trials in China to assess safety, efficacy, PK and PD of telitacicept in RA patients. In these trials, telitacicept was well tolerated over a wide dose range.

In the Phase Ia study and the Phase Ib study, telitacicept demonstrated that it was safe and well tolerated in RA patients at dose levels of up to 360 mg once a week for 5 weeks. We also obtained preliminary evidence of its promising efficacy in RA. We

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completed the Phase Ia study in February 2012 in a total of 28 RA patients. No serious adverse events occurred in RA patients receiving a single subcutaneous injection of telitacept at doses levels of 1.2mg to 540mg. In the Phase Ib study completed in October 2012, a total of 21 RA patients were enrolled and treated with subcutaneous injections of 180mg once a week (QW) for 3 weeks, 180mg twice weekly (BIW) for 4 weeks or 360mg once a week (QW) for 5 weeks. 16 patients showed clinically meaningful disease activity improvement. For purposes of this trial, clinically meaningful disease activity improvement is achieved if a greater than 3.2 point disease activity score-28 (DAS28) score above baseline is recorded. The DAS28 is a measure of disease activity in RA and examines 28 joints in the assessment. No serious adverse events occurred in the patients in this trial. Compared with the placebo arm, the treatment arm was more likely to have various mild to moderate infections and skin reactions at the injection site.

In the multi-center, randomized, double-blinded and placebo-controlled Phase IIa trial, a total of 74 patients were enrolled and randomized into a treatment arm and a placebo arm. We have completed the Phase IIa trial in September 2014. The patients received 160mg telitacept or placebo, as applicable, in each case in combination with methotrexate once a week (QW) for the first four weeks and every two weeks (Q2W) for the next 20 weeks. In the FAS analysis, 58.3% of 36 patients treated with telitacept achieved ACR20 responses at Week 24, as compared to 39.5% of 38 patients in the placebo arm. 43.8% of 32 patients treated with telitacept achieved ACR50 responses at Week 24, as compared to 14.3% of 28 patients in the placebo arm. ACR20 and ACR50 are measurements of disease activity improvement for RA. The incidence rate of adverse events was 47.2% in the treatment arm, compared to 39.5% in the placebo arm. There were no SAEs or premature study discontinuations due to AEs in this trial.

In the multi-center, randomized, double-blinded and placebo-controlled Phase IIb trial, 182 patients were enrolled and randomized to three groups receiving 160 mg and 240 mg of telitacept and placebo, respectively, in each case in combination with methotrexate. We have completed the Phase IIb trial in April 2016. The patients received telitacept or placebo, as applicable, QW for the first 13 weeks and every two weeks (Q2W) for the next 12 weeks. In the per protocol set (PPS), 69.8% of 43 patients in the 240mg dosage-level treatment arm and 68.3% of the 41 patients in 160 mg dosage-level treatment arm respectively achieved ACR20 responses at Week 24, as compared to 45.0% of 40 patients in the placebo group. We also measured other markers including the erythrocyte sedimentation rate, rheumatoid factor, total number of B cells, IgM, IgA, and IgG levels of patients in treatment and placebo arms. In the telitacept treatment arms, these markers of patients gradually decreased and remained relatively low, as compared with those in the placebo arm. The incidence rate of adverse events was 52.5% and 63.3% in the 160 mg and 240 mg treatment arms, respectively, compared to 41.0% in the placebo arm. The incidence rate of SAE was 1.6% and 3.3% in the 160 mg and 240 mg treatment arms, respectively, compared to 1.6% in the placebo arm. The safety results further confirmed that telitacept was safe and well tolerated in RA patients at dose levels of up to 160 mg QW.

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In April 2017, we enrolled the first patient in a randomized, double-blind and placebo-controlled Phase III clinical trial to evaluate the efficacy and safety of telitacept at varied dosage levels in combination with methotrexate for the treatment of RA in China. We plan to enroll a total of 480 patients. The primary endpoint of this trial is the proportion of patients achieving the ACR20 response at week 24. As of June 22, 2020, a total of 233 RA patients were enrolled.

Clinical Development Plan

We are implementing an advanced and comprehensive strategy for the research and development of telitacept globally. We have been building a foundation for the strategy by developing telitacept in China for the treatment of patients with a variety of B-cell mediated autoimmune diseases, with our leading indications in SLE, NMOSD and RA. We have generated abundant and encouraging efficacy and safety data of telitacept in SLE patients from clinical trials in China. We believe that these SLE data and the additional data from our China trials for other indications will allow us to pursue and achieve global registration and commercialization of telitacept. Among all indications for which we are currently developing telitacept, SLE is our highest priority on the product’s global development agenda, and it is closely followed by other autoimmune diseases.

The table below sets forth the details of our global clinical development plan for telitacept:

Indication	Clinical trial stage	(Expected) first patient in date	(Expected) NDA submission date	Location and competent authority
SLE	Phase III (confirmatory)	October 2019	October 2019 ⁽¹⁾	China/NMPA
	Phase III	1H 2021	–	U.S./FDA
NMOSD	Phase III	January 2018	–	China/NMPA
RA	Phase III	April 2017	–	China/NMPA
SS	Phase II	November 2019	–	China/NMPA
IgAN	Phase II	May 2020	–	China/NMPA
MS	Phase II	Q3 2020	–	China/NMPA
MG	Phase II	Q3 2020	–	China/NMPA

Note:

- (1) The NDA submission for conditional approval was based on the data from our Phase IIb registrational trial.

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- SLE:

We have completed a Phase IIb registrational trial in China for SLE, in which telitacept met the primary endpoint with statistically significant difference between treatment and placebo groups. In October 2019, we submitted our first NDA to the NMPA for the conditional approval of telitacept in China for the treatment of SLE. The NMPA accepted our NDA in November 2019, and granted us priority review in December 2019, based on the urgent unmet medical needs in the treatment of SLE. Based on our communication with the NMPA, we initiated a Phase III confirmatory clinical trial in China in July 2019 and patient enrollment started in October 2019. We have enrolled 158 patients in this trial as of June 22, 2020 and plan to enroll a total of 318 patients in this trial. The primary endpoint of this trial is the proportion of patients achieving SLE responder index-4 (SRI-4) at Week 52. We expect to complete patient enrollment in the first half of 2021.

We plan to conduct global Phase III clinical trials of telitacept for SLE covering multiple jurisdictions and regions, including the U.S., Europe, South America and Asia. If the global trials meet their primary endpoints, we will use the data to apply for marketing approvals of telitacept in the U.S. and Europe, and at a later stage in other jurisdictions included in this study.

The FDA has cleared our Phase II IND application for telitacept in August 2019. We held an end-of-Phase II meeting with the FDA in January 2020 when the FDA reviewed the drug candidate's positive data from our trials in China and discussed the design for the Phase III clinical trials. Based on this meeting, the FDA allowed us to conduct the Phase III studies of telitacept for the treatment of SLE in the U.S. On April 15, 2020, the FDA granted Fast Track designation to telitacept, which could expedite the review and potential approval process with the FDA. We expect to initiate this global study with patient cohorts in the U.S. in the first half of 2021.

In addition to the U.S., we plan to initiate Phase III trials with extension cohorts in Europe and Asia in the first half of 2021, as part of the global Phase III trials. We have communicated with the EMA for the global Phase III clinical trials for SLE.

Dr. Joan Merrill is the coordinating investigator for the upcoming global study of telitacept in SLE and has been advising on the development of our protocol for this global study since 2018. Dr. Merrill is a member of the Oklahoma Medical Research Foundation (OMRF) and OMRF Professor of Medicine at the University of Oklahoma Health Sciences Center. She is also an Adjunct Professor of Medicine at New York University and Chief Advisor for Clinical Development for the Lupus Foundation of America. Dr. Merrill is the director of the Oklahoma Lupus Cohort which includes more than 650 lupus patient volunteers, and has been involved in the design and execution of many clinical trials of immune modulating treatments for SLE for over 20 years. She has helped to pioneer innovative protocols aimed at ensuring interpretable outcomes in SLE trials by combining novel approaches for safely reducing polypharmacy with biomarker-based adaptive designs. She received the 2016 Research & Hope Award for Excellence in Academic/Government Research from the Pharmaceutical Research and Manufacturers of America (PhRMA).

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To ensure the success of global registration and commercial launch of telitacicept, we are also actively pursuing potential partnership opportunities with global leading pharmaceutical companies.

- NMOSD:

As NMOSD is a rare disease with highly unmet medical needs, we have consulted with the NMPA and, after reviewing the clinical data of telitacicept in SLE and RA and the overall design of the Phase III trial, CDE confirmed that it has no objection to the entry into a Phase III trial of telitacicept for the treatment of NMOSD.

We are conducting a randomized, double-blind and placebo-controlled Phase III clinical trial to evaluate the efficacy and safety of telitacicept for the treatment of NMOSD in China. We initiated the Phase III clinical trials in September 2017 and enrolled the first patient in January 2018. We have enrolled 107 patients in this trial as of June 22, 2020 and plan to enroll a total of 118 patients in this trial. The primary endpoint of this trial is the time to first relapse after randomization.

- RA:

We are conducting a multi-center, double-blinded and placebo-controlled Phase III trial in China to evaluate the efficacy and safety of telitacicept in patients with moderate to severe RA who have an inadequate response to methotrexate (MTX), an antimetabolite and antifolate drug and the standard of care for RA. We have enrolled 233 patients in this trial as of June 22, 2020 and plan to enroll a total of 480 patients in this trial. Patients in the treatment group receive telitacicept at 160mg dose level plus MTX through weekly subcutaneous administration for 24 weeks. Patients in the control group receive standard of care plus MTX weekly for 24 weeks.

The primary endpoint of this trial is the proportion of patients in each group achieving an ACR20 response at Week 24. An ACR20 response is defined as at least 20% improvement in both the tender joint count and the swollen joint count and at least 20% improvement in three of five other core set measures, including patient global assessment, physician global assessment, Health Assessment Questionnaire (HAQ), visual analog pain scale (VAS), and acute phase reactants (erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP)).

- SS:

We are conducting a randomized, double-blind and placebo-controlled Phase II clinical trial to evaluate the efficacy and safety of telitacicept for the treatment of SS in China. We have enrolled 17 patients in this trial as of June 22, 2020 and plan to enroll a total of 30 patients in this trial. The primary endpoint of this trial is the change in ESSDAI scores from baseline at Week 24.

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- IgAN:

We are conducting a randomized, double-blind and placebo-controlled Phase II clinical trial in China to evaluate the efficacy and safety of telitacicept in IgAN patients. We have enrolled four patients in this trial as of June 22, 2020 and plan to enroll a total of 30 patients in this trial. The primary endpoint of this trial is the change in urinary protein within 24 hours from the baseline at Week 24.

- Other indications:

In addition to the indications described above, we are also evaluating telitacicept for two other hard-to-treat autoimmune diseases, namely MS and MG. For MS, we have initiated an open-label, randomized Phase II clinical trial in China. We plan to enroll a total of 18 patients and expect to enroll the first patient in the third quarter of 2020. The primary endpoint of this trial is the number of gadolinium-enhanced T1 lesions in brain at Weeks 12, 24, 36 and 48 compared to baseline. For MG, we have initiated an open-label, randomized Phase II clinical trial in China. We plan to enroll a total of 20 patients and expect to enroll the first patient in the third quarter of 2020. The primary endpoint of this trial is the weekly average change in QMG score from the baseline at Week 24.

Leveraging our experience in developing telitacicept for SLE globally, we will continue to explore the global path of approval and commercialization for the treatment of other autoimmune diseases. We intend to prioritize indications with high unmet medical need and a sizeable addressable patient population in the global market, such as IgAN and primary Sjögren’s syndrome, or indications for which telitacicept has the potential to be the first biologic therapy, such as NMOSD.

Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize this drug candidate.

Material Communications

We have not received any relevant regulatory agency’s concerns or objections to our clinical development plans as of the Latest Practicable Date. As of the Latest Practicable Date, no material unexpected or adverse changes have occurred since the date of issue of relevant regulatory for telitacicept.

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Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET TELITACICEPT SUCCESSFULLY.

Disitamab vedotin (RC48)

Antibody-drug conjugate (ADC) has been one of the focuses of our research and development efforts since our inception. Over the past eight years, we have established an end-to-end ADC platform with industry-leading technologies covering the discovery/optimization, process/analytical development and production of novel ADC therapeutics. Leveraging this platform, we are developing four ADC drug candidates, including two in clinical development (disitamab vedotin and RC88) and two in IND filing preparations (RC108 and RC118).

Disitamab vedotin is our leading ADC product candidate and is the first ADC in China to have received IND approval for clinical trials. Disitamab vedotin is a novel ADC independently developed by us to treat human epidermal growth factor receptor 2 (HER2) expressing (including low-expressing) solid tumors. Disitamab vedotin is currently being studied in multiple late-stage clinical trials in China across a variety of solid tumor types. In two Phase II clinical trials in China, disitamab vedotin has demonstrated promising efficacy in patients with HER2-expressing advanced or metastatic gastric cancer (GC) and urothelial cancer (UC), and has also proved its potential as treatment for HER2-expressing (including low-expressing) breast cancer (BC) in a Phase Ib clinical trial.

In the U.S., the FDA provided clearance for us to proceed with a Phase II study for disitamab vedotin in UC in April 2020. We plan to initiate trials of disitamab vedotin for the treatment of HER2-expressing locally advanced or metastatic UC in the U.S. in the first quarter of 2021. In addition, the FDA has also granted orphan drug designation to disitamab vedotin for GC in July 2018. With orphan drug designation, we are entitled to a seven-year exclusive marketing period in the U.S. for disitamab vedotin for this indication, and among the other benefits of orphan drug designation, we may enjoy tax credits for certain research and a waiver of the BLA application user fee.

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The chart below shows the indications for which we are currently evaluating disitamab vedotin in clinical trials and indicates the status for each of these clinical trials:

Indication	HER2 Status ³	Mono- /Combo- Therapy	Status ⁴					
			IND (Accepted)	Phase I Ia Ib		Phase II	Pivotal/ Phase III	NDA/BLA (Filed)
China								
HER2-expressing GC:								
HER2 over-expressing locally advanced or metastatic GC	IHC 2+ or IHC 3+	Mono	●			● (pivotal Phase II)		● (Q3 2020)
HER2-expressing advanced solid tumors ⁵	IHC 1+, IHC 2+, or IHC 3+	Combo (PD-1)	●	●				
HER2-expressing UC:								
HER2 over-expressing advanced or metastatic UC	IHC 2+ or IHC 3+	Mono	●			● (initial Phase II) ● (pivotal Phase II)		● (1H 2021)
HER2 low- to non-expressing locally advanced UC	IHC 1+ or IHC 0	Mono	●			●		
Locally advanced or metastatic UC	All	Combo (PD-1)	●			● (Ib/II)		
HER2 low-expressing advanced BC	IHC 2+ and FISH-	Mono	●				●	
HER2 over-expressing or HER2 mutated advanced NSCLC	IHC 2+ or IHC 3+ or HER2 mutated	Mono	●		●			
HER2 over-expressing metastatic BTC	IHC 2+ or IHC 3+	Mono	●			●		
U.S.								
HER2-expressing locally advanced or metastatic UC	IHC 2+ or IHC 3+	Mono	●			●		
HER2-expressing locally advanced or metastatic GC	IHC 2+ or IHC 3+	Mono	●			●		

Notes:

- Abbreviations: 1L = first-line; BC= breast cancer; BTC=biliary tract carcinoma; FISH= fluorescence in situ hybridization; GC= gastric cancer; IHC = immunohistochemistry; UC=urothelial cancer; NSCLC= non-small-cell lung cancer.
- Symbols: ● = complete; ● = in progress (a clinical trial is deemed to have been initiated when we submit trial design and protocol to apply for ethical approval); ● = to be initiated
- denotes the HER2 status in patients criteria of the most advanced clinical trial of an indication.
- Some indications may not require every phase of the clinical trials indicated in this chart to be completed prior to the filing of an NDA. We conducted a Phase I trial in multiple advanced solid tumors to evaluate the safety of disitamab vedotin. Based on the safety data from this trial, we initiated the Phase II trials of various specific cancer indications. For BC, we have initiated a Phase I trial in advanced solid tumors (which enrolled BC patients only) and Phase Ib and II trials in HER2-expressing BC. Based on the data from these trials and our communication with CDE, we have initiated a Phase III clinical trial in HER2 low-expressing BC.
- This trial is designed to include a cohort of 20-50 GC patients to evaluate this combo therapy for the treatment of HER2-expressing GC.

Mechanism of Action

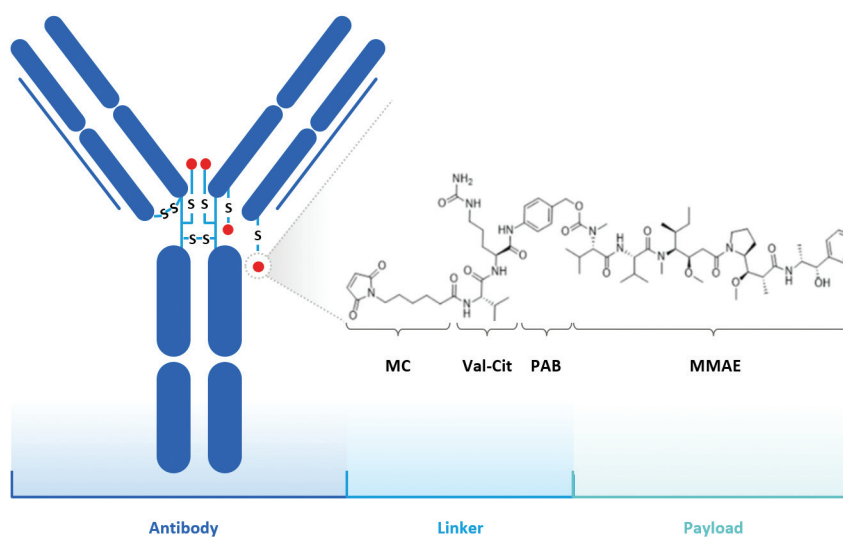
ADCs are a type of cancer treatment designed to specifically and directly deliver chemotherapies to tumor cells while sparing healthy cells. The concept of ADCs is based on exploiting the high specificity of a monoclonal antibody toward a selected tumor

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cell-surface antigen and enhancing the cell-killing capacity of the antibody by attaching a highly cytotoxic agent. Typically, several molecules of a highly potent cytotoxic compound are linked to each antibody molecule to enhance its activity, while retaining the favorable pharmacokinetic and pharmacodynamic properties of the antibody. The key to this type of therapy is getting three distinct molecules—antibody, active drug and linker—to work together.

Unlike traditional chemotherapy that indiscriminately damages healthy cells as well as tumor cells, ADC utilizes monoclonal antibody to bind to tumor-specific antigen targets and then delivers the chemotherapy, a highly potent cytotoxic agent, to kill tumor cells. In this way, ADCs may significantly benefit cancer patients by causing less adverse effects (AEs) or severe adverse effects (SAEs).

Structure of Disitamab Vedotin



Abbreviation: MC = maleimidocaproyl; MMAE = monomethyl auristatin E; PAB = p-aminobenzyl.

Note: MC-Val-Cit-PAB is a cathepsin cleavable ADC linker.

Source: Company data

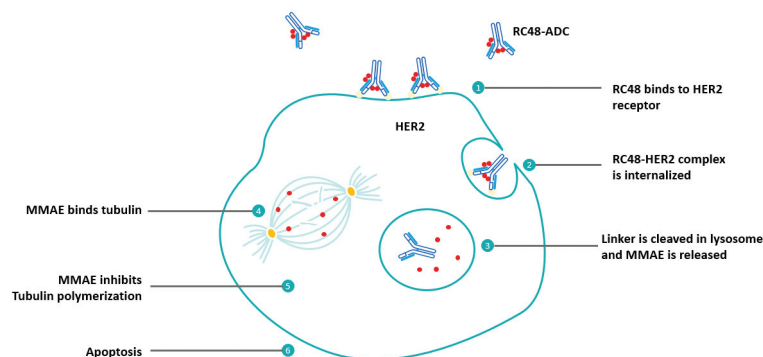
As illustrated in the diagram above, in disitamab vedotin, a novel humanized HER2 antibody and monomethyl auristatin E (MMAE), a potent tubulin binder with a half maximal inhibitory concentration (IC_{50}) in the subnanomolar range, as the cytotoxic payload, are conjugated to each other through a cathepsin cleavable linker, with optimized drug-antibody ratio. The anti-HER2 antibody allows disitamab vedotin to selectively deliver the anti-cancer agent MMAE to HER2-expressing tumor cells.

HER2 is a member of the epidermal growth factor receptor (EGFR) family. It is expressed in many tissues, including the breast, gastrointestinal tract, kidney and heart. Its major role in these tissues is to promote cell proliferation and suppress apoptosis. Amplification of the HER2 gene and overexpression of its product may drive excessive or uncontrolled cell growth and tumorigenesis. Our clinical data support the scientific view that the HER2 pathway may play a key role in the treatment of many cancer types with tumors that express HER2 antigen, such as breast, gastric, lung and urothelial cancers.

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Compared with Roche/Genentech's ado-trastuzuman emtansine (T-DM1) which uses monoclonal antibody trastuzumab, disitamab vedotin comprises a novel HER2 monoclonal antibody that targets a different epitope of, and also shows a higher binding affinity for, HER2 receptors on the tumor cell. Once disitamab vedotin binds to its target (HER2) which is expressed on tumor cell surface, through its antibody component (disitamab), the ADC-HER2 complex is internalized by the tumor cell via endocytosis. The linker connecting antibody and cytotoxic payload is then cleaved in the presence of lysosomal protease. Once the payload, MMAE, is released into cytosol, it binds tubulin and inhibits its polymerization, which triggers apoptosis or the programmed cell death of the HER2-expressing tumor cell. MMAE, once released, also has the capacity to kill neighboring tumor cells (whether HER2-expressing or not), which is known as the bystander-killing effect. Studies have found that ADCs with highly membrane-permeable payloads, such as MMAE, have a more potent bystander killing effect than those ADCs such as ado-trastuzumab emtansine (T-DM1) that have low membrane-permeable payloads, indicating a higher anti-tumor potential for our disitamab vedotin.

Mechanism of Action



Source: Company data

Market Opportunities and Competition

The commercial value of ADC therapy for HER2-expressing cancers is well-recognized by the market. Disitamab vedotin has great potential to address this sizable and growing market.

- Gastric Cancer:

According to the National Cancer Registry and National Bureau of Statistics, gastric cancer (GC) is the second most common cancer type in China in terms of both incidence rate and mortality rate. There were 455,800 and 27,500 new incidences of GC in China and the U.S. in 2019 respectively, which is expected to increase to 613,800 and 34,800 in 2030 respectively, according to Frost & Sullivan. Approximately 22% of GC patients are HER2 positive/high-expressing. In addition to the patients with HER2-positive as defined by IHC 3+ or IHC 2+/FISH+, there are certain percentage of patients who have low level HER2 expression, which is either IHC 1+ or IHC 2+/FISH-.

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As GC is often diagnosed at an advanced stage, systemic chemotherapy is the mainstay of treatment for these patients. The five-year survival rate of GC patients is around 35.1% in China.

In recent years, targeted cancer therapies are widely tested in clinical studies and have been approved to treat various specific types of cancer. Yet, a large unmet medical need continues to exist. Trastuzumab, in combination with chemotherapy, was the first targeted drug to be approved as a new first-line standard of care for patients with HER2-positive/high-expressing advanced GC. However, only approximately 20% of patients with metastatic GC can benefit from the addition of trastuzumab to chemotherapy. Patients beyond progression on second-line therapy continue to lack effective treatment options. In China, for instance, standard third-line therapies for GC patients include apatinib, mono-chemotherapy and PD-1 monoclonal antibody, none of which has demonstrated strong efficacy in terms of survival benefits measured by progress-free survival (PFS) or overall survival (OS) for HER2-expressing GC. The annual treatment cost of apatinib is around RMB126,020, while the annual treatment cost of nivolumab (PD-1 antibody) reaches RMB222,240 under patient assistance programs.

In addition to our disitamab vedotin, several other ADCs are under clinical investigation for GC. For example, Roche’s Kadcyła (T-DM1/ado-trastuzumab emtansine) was studied in Phase III clinical study in previously treated gastric and gastroesophageal junction (GEJ) patients but did not show a better efficacy than control taxane group. DS-8201 ([fam-] trastuzumab deruxtecan) developed by Daiichi-Sankyo is in development for the treatment of multiple HER2-expressing cancer types, including breast cancer and GC. Daiichi-Sankyo out-licensed the global rights to jointly develop and commercialize DS-8201 (except for Japan) to AstraZeneca for a total of US\$6.9 billion, including US\$1.35 billion in upfront payment.

The table below summarizes the development status of ADC targeting HER2-expressing GC in clinical trials or later as of the Latest Practicable Date.

Molecule	Cytotoxic Payload	Company	Indication	Clinical Phase
disitamab vedotin	MMAE	China RemeGen	HER2 over-expressing GC	II (pivotal)
ARX788	AS269	Zhejiang Medicine/ Ambrx	HER2 over-expressing GC	II
DX126-262 (DAC-001)	Tubulysin B analogues	Hangzhou DAC Biotech	HER2 over-expressing GC	I
[fam-] trastuzumab deruxtecan (DS-8201)	deruxtecan	Global (Outside of China) Daiichi-Sankyo/ AstraZeneca	HER2 over-expressing GC	II

Source: Frost & Sullivan Report

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- Urothelial Carcinoma:

Urothelial carcinoma (UC) is the most common type of bladder cancer (90% of cases). UC is the 13th most common cancer worldwide, and the fourth most common cancer in men in the United States. According to Frost & Sullivan, around 508,200 new cases were diagnosed with UC globally in 2019 and it is estimated that there will be 694,400 new cases in 2030. While UC is historically more common in the U.S. and western Europe, the incidence has increased gradually in China in the past few years. There were 76,400 new cases occurred in 2019 in China, and this figure is expected to reach 106,600 in 2030, according to the Frost & Sullivan.

Metastatic or unresectable disease is identified in approximately 20% of patients presenting with invasive UC. In addition, up to 50% of patients will develop metastases following radical cystectomy for clinically localized disease. Unfortunately, limited breakthrough treatments for metastatic UC have emerged in over two decades. The first-line therapy for UC in China is chemotherapy, and the treatment paradigm for UC in China also include systemic immunotherapy, radiotherapy, palliative cystectomy and supportive treatment. Traditional therapeutic options, such as cisplatin-based combination chemotherapy, have subpar efficacy, as reflected in high rates of recurrence and mortality.

In the past five years, five PD-(L)1 inhibitors have been approved by the FDA for the treatment of UC, among which two agents, pembrolizumab and atezolizumab, have also been approved as first-line therapy for a subset of UC patients. None of the PD-(L)1 inhibitors has been approved for first-line treatment of UC in China. Despite durable activity observed in many patients, the majority of UC patients unfortunately do not respond to PD-(L)1 inhibitors and their overall improvements to the survival and quality of life of UC patients are modest. Therefore, the development of new safe and effective therapeutics are urgently needed to address the highly unmet medical needs.

Astellas/Seattle Genetics’s Padcev (enfortumab vedotin), a nectin-4-targeting ADC, was approved by the FDA for the treatment of locally advanced or metastatic UC in December 2019, and became the first and only ADC approved for this indication. To this date, disitamab vedotin is the most advanced ADC in clinical stage targeting HER2-expressing UC.

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The table below summarizes the development status of all ADCs targeting UC in clinical trials as of the Latest Practicable Date.

Molecule	Antibody (Target)	Cytotoxic Payload	Company	Indication	Status
disitamab vedotin	disitamab (HER2)	MMAE	RemeGen	HER2 over-expressing UC	Phase II (pivotal)
				HER2 low-to non-expressing UC	Phase II
Global (Outside of China)					
Padcev (enfortumab vedotin)	enfortumab (Nectin-4)	vedotin	Astellas Pharma (安斯泰來製藥)/ Seattle Genetics	Locally advanced or metastatic UC	Marketed

Source: Frost & Sullivan Report

- **Breast Cancer:**

According to the National Cancer Registry and National Bureau of Statistics, breast cancer (BC) is the most common cancer type among women in China, as the fifth largest cancer in the country in terms of the incidence. There were 326,200 new incidences of BC in China in 2019 and over 2.1 million new incidences globally in 2019. Globally, approximately 20-30% of all BC cases belong to the HER2-positive/high-expressing subtype, which is defined by HER2 protein overexpression and/or HER2 gene amplification. In about 50% of BC, a low-level expression of HER2 without HER2 amplification can be observed. Overexpression or amplification of HER2 in BC is associated with very poor prognosis and increased risk of local growth and distant metastasis, compared with HER2-negative BC.

As of May 2020, six biologics drugs have been approved by the FDA to treat BC, of which most are HER2-targeted therapies and Roche’s Herceptin (trastuzumab) has the largest market share. In 2019, the global sales of Herceptin reached US\$6.1 billion (including sales for other indications). As of May 2020, biologics approved for HER2-positive/high-expressing BC in China included Herceptin (trastuzumab), Perjeta (pertuzumab) and Kadcyla (ado-trastuzumab emtansine).

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Roche’s Kadcyla (T-DM1/ado-trastuzumab emtansine) and Daiichi Sankyo/Astrazeneca’s Enhertu ([fam-] trastuzumab deruxtecan/DS-8201) are currently the only two FDA-approved ADC drugs for the treatment of advanced HER2-positive/high-expressing BC. Kadcyla and Enhertu were initially approved by the FDA in February 2013 and December 2019, respectively. In 2019, Kadcyla recorded global sales of US\$1.4 billion. In China, ado-trastuzumab emtansine (T-DM1) has been approved for the treatment of BC. The annual treatment costs of ado-trastuzumab emtansine (T-DM1) reaches RMB469,150 under patient assistance programs. Although effective in treating advanced breast cancer, all patients eventually develop T-DM1 resistance.

Despite the availability of a number of targeted therapies for HER2-positive/high-expressing BC, there is currently no anti-HER2 therapies approved for breast cancer with a low-level HER2 expression. As a result, these patients are generally treated as HER2-negative BC patients in current clinical practice and eventually progress on current treatments to a point where limited options are available. Clinical evidence suggests a lower activity of T-DM1 against cancers with low-HER2 expression, while DS-8201 is being investigated in clinical trials to evaluate its efficacy in HER2 low-expressing BC.

As of the Latest Practicable Date, there are three HER2-targeted ADC candidates in Phase III clinical trials for BC in China and three in the U.S., among which disitamab vedotin is one of them. For further details, please refer to the paragraph “Industry Overview—3. Oncology Drug Market—3.5 Breast Cancer—3.5.4 Competitive Landscape of Biologics Treatment of Breast Cancer in the U.S. and in China.”

Competitive Advantages of Disitamab Vedotin

Innovative molecular design leads to improved efficacy and reduced resistance with therapeutic potential in HER2-expressing cancer indications

HER2 is a naturally occurring receptor that is expressed in many types of cancer, including UC, GC, BC, ovarian cancer, non-small cell lung cancer and others. In recent years, clinical evidence and research suggest promising therapeutic prospects of HER2-targeting ADC drugs in treating HER2-positive cancer as they provide a much more effective solution of targeted drug delivery than standard chemotherapy. The commercial value of HER2-targeting ADCs is also well recognized in the market, by the impressive sales revenue of Kadcyla (ado-trastuzumab emtansine/T-DM1) and the purchase consideration of DS-8201 ([fam-] trastuzumab deruxtecan) in a recent transaction.

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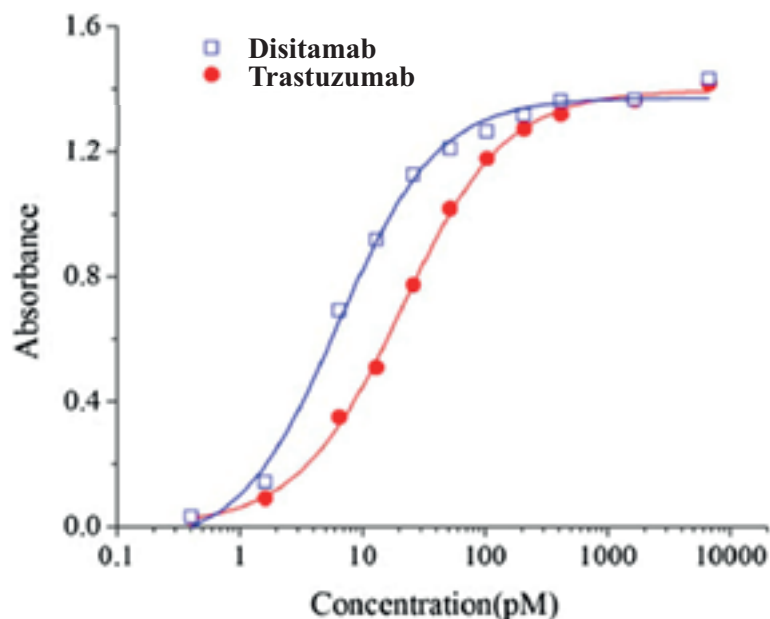
Disitamab vedotin is an innovative HER2-targeting ADC comprising a novel humanized HER2 antibody, a potent cytotoxic payload (MMAE) and a cleavable peptide-linker. Each component of disitamab vedotin has differentiated biological properties as compared with its major competitors, allowing for potentially better targeting, improved efficacy and reduced resistance.

- Novel antibody with higher affinity for HER2 compared to standard of care

Disitamab vedotin contains a novel antibody that targets a HER2 epitope different from that for trastuzumab, and that is highly selective for HER2. The novel HER2-targeting monoclonal antibody can effectively inhibit HER2 signaling to pathways like PI3K or AKT and thus restrict the growth of HER2-expressing tumor cells. Taking advantage of this specific targeting, disitamab vedotin is able to selectively deliver potent cytotoxic drug to tumor cells expressing HER2 without affecting normal cells with little or no HER2 expression, leading to significant improvement of drug efficacy while reducing the side effects.

As illustrated in the figure below, an *in vitro* assay found that disitamab has a higher affinity for HER2 as compared with trastuzumab as the EC₅₀ value of disitamab was 6.4 pM compared to EC₅₀ value of trastuzumab of 20.1 pM.

HER2 Binding Affinity Profiles of Disitamab and Trastuzumab



Source: Yao et al., BCRT (2015), company data

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Further studies have found that the binding ability of disitamab is largely unaffected after conjugating with MMAE. Attributable to the high affinity of the innovative antibody, disitamab vedotin has the potential to respond to significant unmet medical needs of patients with HER2 low-expressing cancer or for whom current HER2-targeting therapies are ineffective.

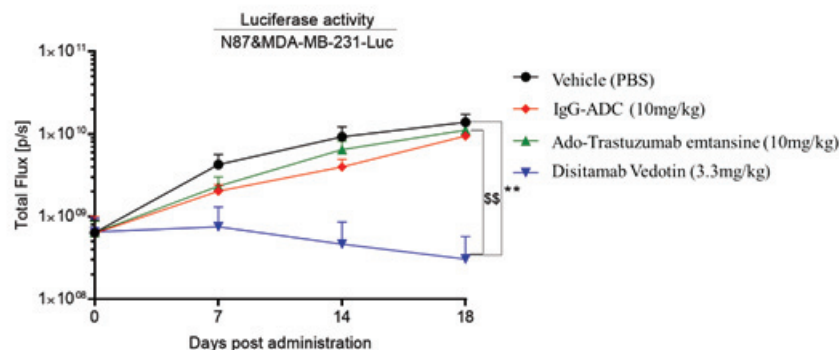
While exhibiting strong activities against the HER2-expressing cells, disitamab vedotin had none or limited effects on HER2-negative cells in our in vitro assay, suggesting the high selectivity of the molecules for HER2-expressing cells and the potential to reduce systemic toxicity of MMAE.

- Potent cytotoxic payload with bystander-killing effects

MMAE is a highly toxic drug that functions as an agent to block polymerisation of tubulin and eventually lead to cell death. MMAE, as the payload of disitamab vedotin, is attached to the antibody component through a cleavable linker, and is only released in the intracellular environment after the molecule is internalized by HER2-expressing tumor cells. Notably, disitamab vedotin showed a more potent bystander-killing effect than T-DM1, which means disitamab vedotin kills both HER2-expressing and HER2-negative cells under coculture conditions.

In vivo study results suggest that MMAE has higher membrane permeability than emtansine (DM1) and, therefore, after disitamab vedotin is internalized into HER2-expressing cells and releases MMAE into the cytoplasm, MMAE could penetrate into adjacent cells to have a bystander-killing effect, whereas it would be difficult for agent with lower membrane permeability to penetrate adjacent cells. In this study, Balb/c nude mice were inoculated with combination of HER2-expressing N87 cancer cells and HER2-negative MDA-MB-231-Luc cancer cells. Luciferase activity of MDA-MB-231 cancer cells reflected HER2-negative tumor burden, and the decrease of luciferase signal suggested the bystander killing of tested ADC drugs. As illustrated by the figure below, 3.3mg/kg disitamab vedotin showed significant stronger bystander killing against MDA-MB-231 cells than 10mg/kg ado-trastuzumab emtansine (T-DM1).

Bystander Killing Effect of Disitamab Vedotin and T-DM1



Source: Company data

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- Cleavable linker with no lysosomal resistance

Disitamab vedotin’s HER2 antibody and cytotoxic agent are bound together by an enzymatically cleavable peptide-linker. Our newly developed drug-linker system has superior stability in plasma and release mechanism in tumor sites. The scission of peptidic bonds of the linker relies on lysosomal proteolytic enzymes, which have very low activities in blood. Therefore, this linker can maintain the stability of disitamab vedotin in plasma during the systemic circulation to ensure that disitamab vedotin reaches and is internalized by the tumor cells in the original formation. After internalization by a tumor cell, the linker can be cleaved by lysosomes in the intracellular environment to trigger the release of the cytotoxic drug at tumor sites.

As compared to non-cleavable linkers, such as the linker used in adotrastuzumab emtansine (T-DM1), the enzymatically cleavable linker is less dependent on the internalization by tumor cells and thus benefits the bystander-killing effect of the ADC. The non-cleavable linker of T-DM1 is stable in both the circulation and the tumor microenvironment, and therefore the release of active emtansine (DM1) requires lysosome degradation in a highly acidic microenvironment in cells. A published study has found that aberrant activity of V-ATPase in lysosomes of gastric cancer cells resulted in a decrease of the T-DM1 metabolite, leading to T-DM1 resistance in these cancer cells. And the study has also shown that HER2-targeted ADCs with cleavable linkers such as disitamab vedotin may be used to overcome this type of T-DM1 resistance because the cleavable linkers may have eliminated disitamab vedotin’s reliance on tumor lysosome V-ATPase activity for payload release.

(2) Strong anti-tumor activity

Disitamab vedotin has demonstrated encouraging efficacy as compared to standard second line therapy in clinical trials of HER2-expressing GC and UC and also shown a potential in treating HER2 low-expressing cancer.

In addition to the *in vitro* assays discussed above, disitamab vedotin also showed stronger antitumor effects compared to other marketed HER2 targeted therapies, including trastuzumab, lapatinib and T-DM1, in *in vivo* studies. Figure 1 below shows the antitumor activity of disitamab vedotin against subcutaneous xenografts of HER2-positive human BC cell line (BT-474) in nude mice. In this study, disitamab vedotin resulted in a much higher tumor inhibition rate (170%) at a dose of 5mg/kg, than that of trastuzumab at 10 mg/kg (81%) and lapatinib at 200 mg/kg (97%). All tested molecules were well tolerated by the tumor-bearing mice. Figure 2 below shows the antitumor activity of disitamab vedotin against subcutaneous xenografts of HER2-positive, trastuzumab-resistant human BC cell line (BT-474/T721) in nude mice. At the dose of 5 mg/kg, disitamab vedotin and T-DM1 achieved a tumor inhibition rate of 108% and 93%, respectively, both of which are better than that of trastuzumab at 10 mg/kg. Figure 3 below shows the antitumor activity of disitamab vedotin against subcutaneous xenografts

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of HER2-positive, trastuzumab-and lapatinib-resistant human BC cell line (BT-474/L 1.9) in nude mice. At the dose of 5 mg/kg, disitamab vedotin had a tumor inhibition rate of 91%, as compared to that of T-DM1 at 58%, suggesting BT-474/L 1.9 is also T-DM1-resistant. The results suggest that disitamab vedotin has an appreciably higher efficacy against trastuzumab- and lapatinib-resistant BT-474/L 1.9 xenografts than T-DM1 at the same dose. All tested molecules were well tolerated by the tumor-bearing mice in these studies.

Figure 1:

Antitumor Activity in HER2-Positive Cells

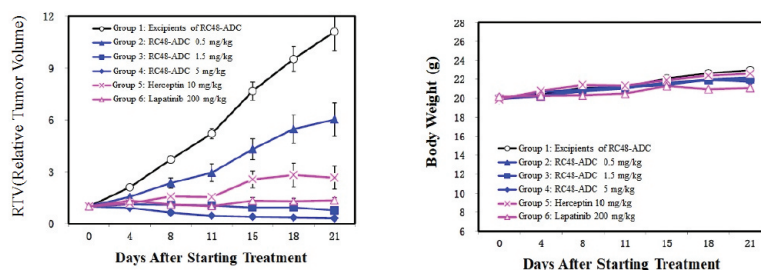


Figure 2:

Antitumor Activity in HER2-Positive, Trastuzumab-Resistant Cells

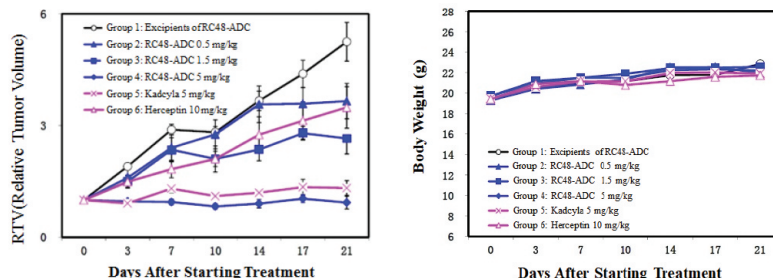
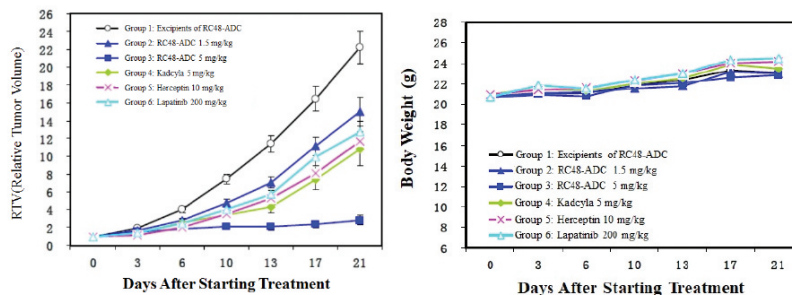


Figure 3:

Antitumor Activity in HER2-Positive, Trastuzumab- and Lapatinib-Resistant Cells



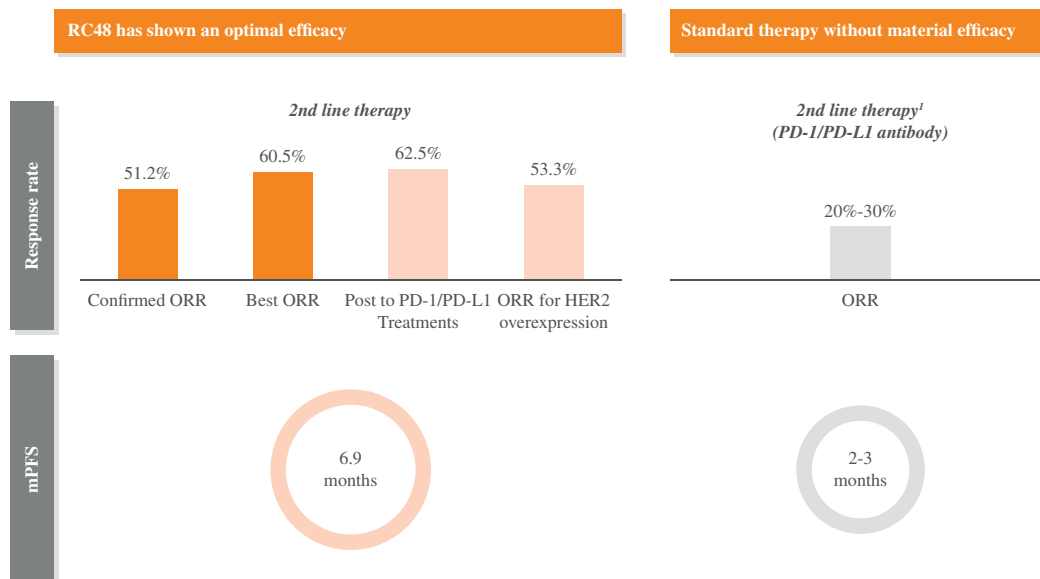
Source: Company data

Strong efficacy of disitamab vedotin in HER2-expressing cancer patients was further demonstrated in our clinical trials.

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In a Phase II registrational trial in HER2 over-expressing (IHC 2+ or IHC 3+) locally advanced or metastatic GC or gastro-esophageal junction (GEJ) cancer, disitamab vedotin achieved an independent review committee (IRC)-assessed confirmed ORR (cORR) of 24.4%, median progression-free survival (PFS) of 4.1 months and overall survival (OS) of 7.6 months as of June 22, 2020. The patients enrolled in this trial had failed at least two lines of chemotherapy treatment for GC. Under the current treatment regime, these heavily pre-treated patients lack effective treatment options and therefore have particularly urgent medical needs. With the promising efficacy and survival benefits observed in this trial, disitamab vedotin demonstrated its potential to become a best-in-class post second-line therapy for patients with both HER2 high-expressing and low-expressing GC who have a large population in China. Based on the data of this trial, we expect to submit an NDA for conditional approval of disitamab vedotin for the treatment of GC in the third quarter of 2020.

In a Phase II trial in patients with HER2 over-expressing (IHC 2+ or IHC 3+) metastatic or unresectable UC, disitamab vedotin brought in best overall response (BOR) of 60.5%, cORR of 51.2% and median PFS of 6.9 months. In comparison with the newly emerging disitamab vedotin, PD-1/PD-L1 inhibitors only had cORR of 20% to 30% and median PFS of 2-3 months in the patients with 2L+ UC in the published clinical trials. Although these are not head-to-head studies, we believe that valuable insight can nonetheless be drawn from the comparisons. The encouraging efficacy observed in this trial indicates disitamab vedotin’s significant potential to satisfy the hugely unmet medical needs of HER2-positive UC patients who failed the first-line treatment.



Note: PD-1/PD-L1 inhibitors approved to use as a second line therapy include pembrolizumab, atezolizumab, nivolumab, durvalumab and avelumab.

Source: Company data, other companies’ press releases

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Notably, patients with HER2 low-expressing cancer also showed encouraging responses to disitamab vedotin in our clinical trials. In a Phase II study in patients with HER2 over-expressing UC, patients with low-level HER2 expression (IHC 2+/FISH-) achieved overall response rate (ORR) of 45.8%. Based on the clinical potential of disitamab vedotin in treating HER2 low-expressing cancer as observed in our clinical trials, we have initiated a Phase III trial and a Phase II trial to evaluate the efficacy and safety of disitamab vedotin for the treatment of HER2 low-expressing (IHC2+/FISH-) BC and HER2 low- to non-expressing (IHC 1+ or IHC 0) UC, respectively.

Favorable safety profile

Disitamab vedotin has demonstrated favorable safety and tolerability in cancer patients in various clinical trials. In a Phase I study in patients with advanced solid tumors, 28 patients (49.1%) experienced Grade 3/4 treatment-related adverse events (TRAEs). In a Phase II study in patients with HER2 over-expressing GC or GEJ cancer, the most commonly reported Grade 3/4 TRAEs were neutrophil count decreased (14.2%), leukopenia (11.8%) and anemia (6.3%). In a Phase II trial in patients with HER2 over-expressing UC, the most commonly reported Grade 3/4 TRAEs were hypoesthesia in 7 patients (16.3%) and neutrophil count decreased in 6 patients (14.0%), and serious adverse event was reported in 14 patients (32.6%). The adverse events reported in this trial were manageable. In a Phase I trial and Phase Ib trial in patients with HER2 high-expressing BC, only 4 patients (5.7%) experienced treatment-related serious adverse events.

Summary of Clinical Trial Results

Disitamab vedotin is the first ADC drug approved for human clinical trials in China. It is currently being studied in multiple late-stage clinical trials across solid tumor types, including a Phase II registrational trial for GC, a Phase II registrational trial for UC and a Phase III trial for HER2 low-expressing BC.

Clinical Trials in Advanced Solid Tumors

Phase I trial in patients with HER2 over-expressing (IHC 2+ or IHC 3+) advanced solid tumors

Trial Design: This trial was an open-label, dose-escalation and expansion study in patients with HER2 over-expressing (IHC 2+ or IHC 3+) advanced solid tumors. The dose escalation phase was initiated by accelerated titration (0.1 and 0.5 mg/kg) and then switched to 3+3 scheme (1.0, 2.0, 2.5 and 3.0 mg/kg). In the dose expansion phase, patients were given disitamab vedotin at 2.0mg/kg Q2W. As of August 20, 2019, 57 patients (including 47 with GC and four with UC) were treated with disitamab vedotin at 0.1 (1 patient), 0.5 (1 patient), 1.0 (3 patients), 2.0 (6 patients in dose escalation and 32 patients in dose expansion), 2.5 (11 patients), and 3.0 mg/kg (3 patients), respectively, and were available for analysis. Most of the patients were at Stage IV (91.2%) or with metastasis (96.5%).

The primary endpoint is to determine maximum tolerated dose (MTD) of disitamab vedotin. It is also designed to evaluate the safety of disitamab vedotin.

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Trial Status: This trial was completed in June 2019. The data cut off at August 20, 2019 was used for the below analyses.

Safety Data: In this trial, dose-limiting toxicity (DLT) was observed in 1, 2, and 1 patient at the dose of 2.0, 2.5, and 3.0 mg/kg, respectively. The MTD was 2.5 mg/kg. Most commonly reported treatment-related AEs (TRAEs) in 57 patients were white blood cell count decreased (66.7%), fatigue (56.1%), neutrophil count decreased (54.4%) and hemoglobin decreased (52.6%). Grade 3/4 TRAEs were reported in 28 patients (49.1%).

Efficacy Data: Confirmed objective response rate (ORR) was 21.1% (8/38) at the dose of 2.0 mg/kg and of 17.5% (10/57) of all patients. Disease control rate (DCR) was 52.6% and 49.1%, respectively. The subgroup ORR was 20.7% (6/29) at 2.0 mg/kg and 18.2% (2/11) at 2.5 mg/kg in the patients with GC, and 50% (2/4) in the patients with UC.

Conclusion: Disitamab vedotin has demonstrated a good safety profile and promising antitumor activity in patients with late-stage solid tumors. Notably, patients with GC and UC showed clinical meaningful responses and PFS improvement at the dose of 2.0 and 2.5 mg/kg. Based on the results of this trial, we initiated the Phase II studies of disitamab vedotin in patients with GC and UC.

Clinical Trial in GC

We have conducted a Phase II registrational trial in China to assess the safety and efficacy of disitamab vedotin for HER2 over-expressing (IHC 2+ or IHC 3+) advanced or metastatic GC. In this trial, disitamab vedotin demonstrated clinically meaningful response and survival benefit in patients with HER2 over-expressing gastric or gastro-esophageal junction (GEJ) cancer who failed at least two lines of prior treatment. Based on the data of this trial, we plan to submit an NDA for conditional approval of disitamab vedotin for the treatment of GC in China in the third quarter of 2020.

Phase II registrational trial in patients with HER2 over-expressing (IHC 2+ or IHC 3+) locally advanced or metastatic GC or GEJ cancer in China

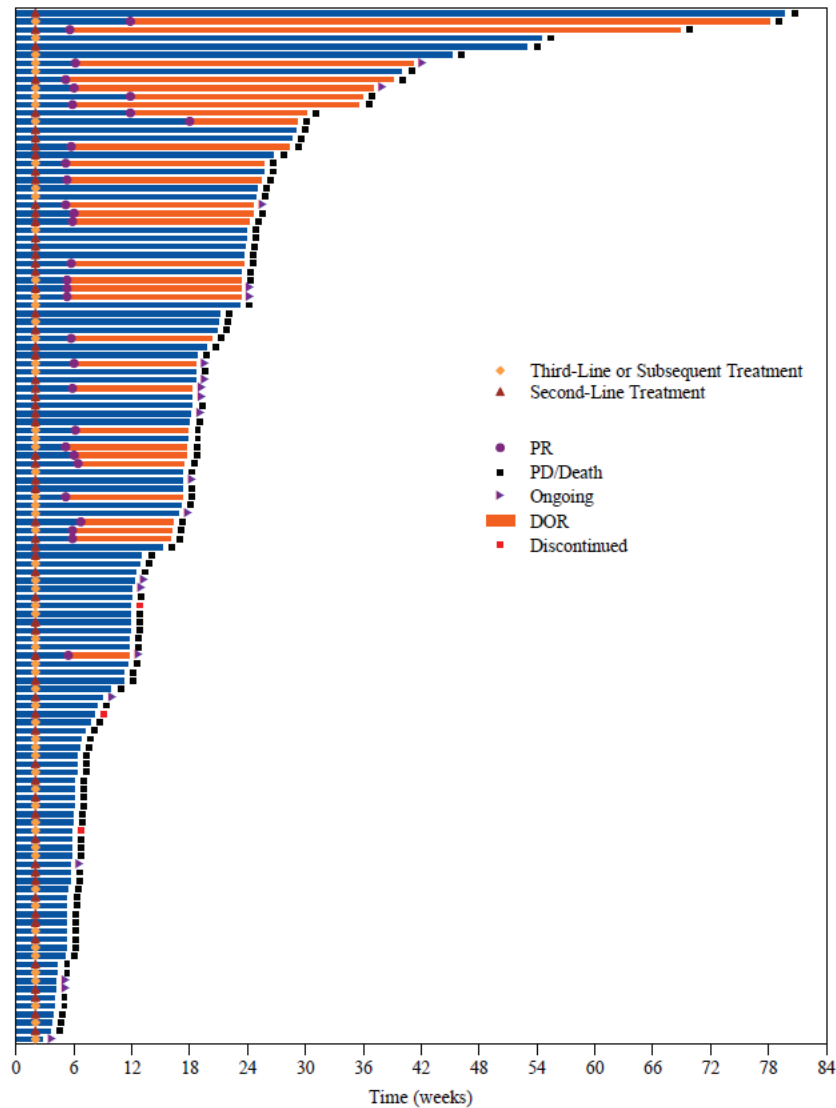
Trial Design: This trial was an open-label, multi-center, single-arm Phase II study. As of June 22, 2020, 127 patients with HER2 over-expressing (IHC 2+ or 3+) GC or GEJ cancer who had previously received at least two lines of chemotherapy treatment were enrolled in this trial, with a median age of 58. 59 patients (46.5%) had received at least three lines of prior treatment. These patients received disitamab vedotin treatment at 2.5 mg/kg once every two weeks for six weeks. The primary endpoint of this trial is ORR. Other endpoints, including progression-free survival (PFS), overall survival (OS) and safety, were also assessed.

Trial Status: Patient enrollment of this trial was completed in November 2019. The data cut off at June 22, 2020 and December 17, 2019 were used for the below efficacy and safety analyses, respectively.

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Efficacy Data: As of June 22, 2020, for all 127 patients, the independent review committee (IRC)-assessed cORR was 24.4% (95% CI: 17.2%, 32.8%), median PFS was 4.1 months (95% CI: 3.5, 4.8) and median OS was 7.6 months (95% CI: 6.6, 9.0). The figure below shows the best overall response for each patient.

Best Overall Response of Disitamab Vedotin in GC or GEJ Cancer Patients

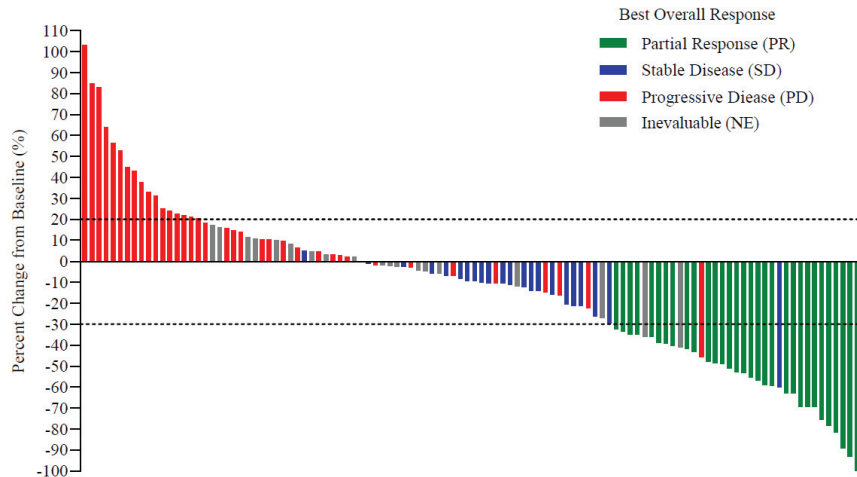


Source: Company data

The below waterfall plot shows the best percent change from baseline in target lesions for each patient.

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Best Change of Target Lesion from Baseline of Disitamab Vedotin in GC and GEJ Cancer Patients



Source: Company data

Safety Data: Among 127 patients, the most commonly reported TRAEs were leukopenia (52.0%), alopecia (51.2%), neutropenia (48.0%), and fatigue (42.5%).

Conclusion: Disitamab vedotin has demonstrated a clinically meaningful response and survival benefit in patients with HER2 over-expressing GC or GEJ cancers. The safety profile was in line with the previously reported data of disitamab vedotin. Disitamab vedotin showed positive benefit/risk ratio for the target population. Based on these trial results, we expect to submit an NDA for conditional approval of disitamab vedotin for the treatment of GC in China in the third quarter of 2020.

Clinical Trials in UC

We have completed a Phase II trial in China to assess the safety and efficacy of disitamab vedotin for HER2 over-expressing (IHC 2+ or IHC 3+) metastatic or unresectable UC. We have two Phase II trials in UC. The data below are all from the first/initial Phase II (non-registrational) trial. Based on these data, and at CDE’s request, we are initiating a second (registrational) Phase II trial in UC and we are in the process of enrolling patients. Our U.S. IND applications are also based on the data presented below from the initial Phase II (non-registrational) trial in UC.

In June 2019, we were invited to present results of our first Phase II study of disitamab vedotin in UC patients at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting held in Chicago, Illinois. We presented positive top line results at this influential meeting, including a 51% confirmed objective response rate (cORR) per independent committee review, which demonstrated clinically meaningful response to our disitamab vedotin in UC patients whose previous treatment failed, a population with highly unmet medical needs. The most common treatment-related adverse events in this trial included hypoesthesia, alopecia and hemotoxicity.

The FDA cleared our IND application in April 2020 based on these results, which would allow us to conduct a Phase II clinical trial of disitamab vedotin in UC in the U.S.

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First Phase II trial in patients with HER2 over-expressing metastatic or unresectable UC (IHC 2+ or IHC 3+) in China

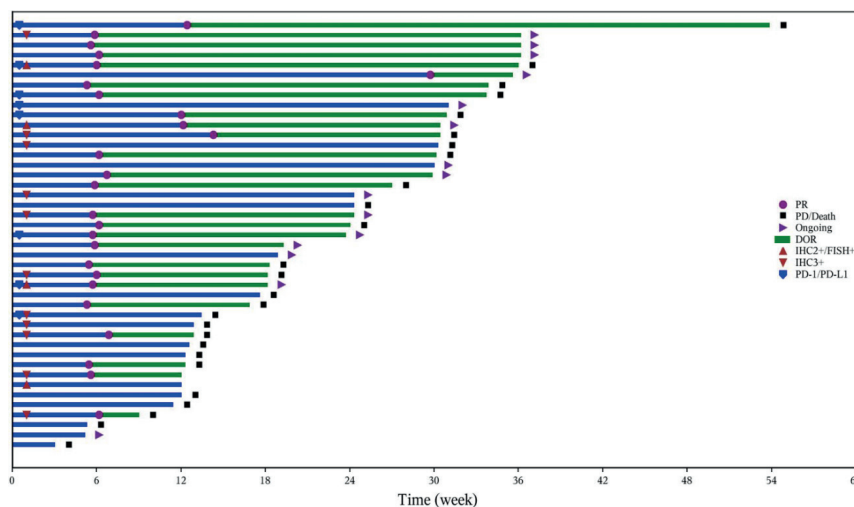
Trial Design: This trial was an open-label, multi-center, single-arm Phase II study. 43 patients with HER2 over-expressing metastatic or unresectable UC who had received previous treatment with systemic chemotherapies were enrolled in this trial, with a median age of 64. Among these patients, 86% had visceral metastases and 28% had two prior lines of chemotherapy treatment. 19% of patients had prior immune checkpoint inhibitor therapy. All patients were HER2 over-expressors as defined by IHC 2+ or 3+. These patients received disitamab vedotin treatment alone (2 mg/kg IV infusion) once every two weeks for six weeks.

The primary outcome measure of this trial is ORR. Other endpoints, including PFS, DOR, overall survival (OS) and safety, were also assessed.

Trial Status: Patient enrollment of this trial was completed in October 2018. The data cut off at April 30, 2019 was used for the below analyses.

Efficacy Data: Overall, the study results demonstrated a 51.2% cORR (22/43). The best overall response (BOR) was PR in 26 patients and stable disease (SD) in 13 patients, bringing to a best overall response rate of 60.5% (26/43) and disease control rate (DCR) of 90.7% (39/43). For patients with liver metastases, the ORR was 60% (12/20). The median PFS was 6.9 months. As shown in the graph below, there are several patients with ongoing responses past 30 weeks.

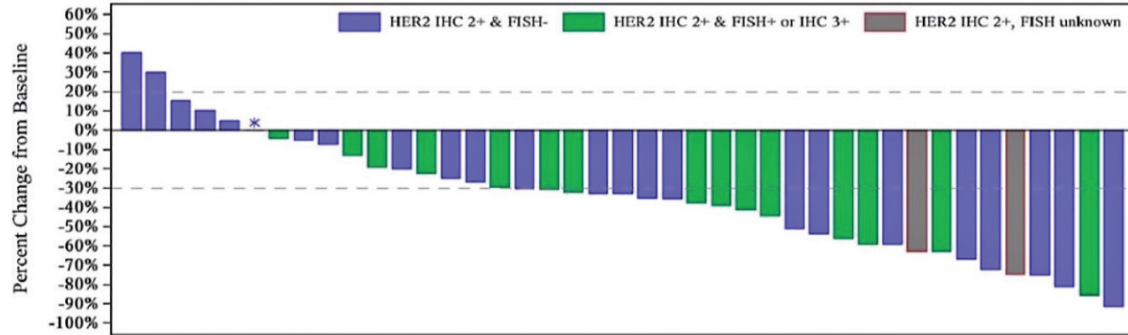
Best Overall Response of Disitamab Vedotin in UC Patients



Source: Company data

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Best Change of Target Lesion from Baseline of Disitamab Vedotin in UC Patients



Note: * means percentage change from baseline of target lesion is 0%.

Source: Company data

As can be seen in the table below, subgroup analysis for confirmed ORR showed consistently robust antitumor effects of disitamab vedotin among different types of metastatic or unresectable UC:

Subgroup Analysis for cORR

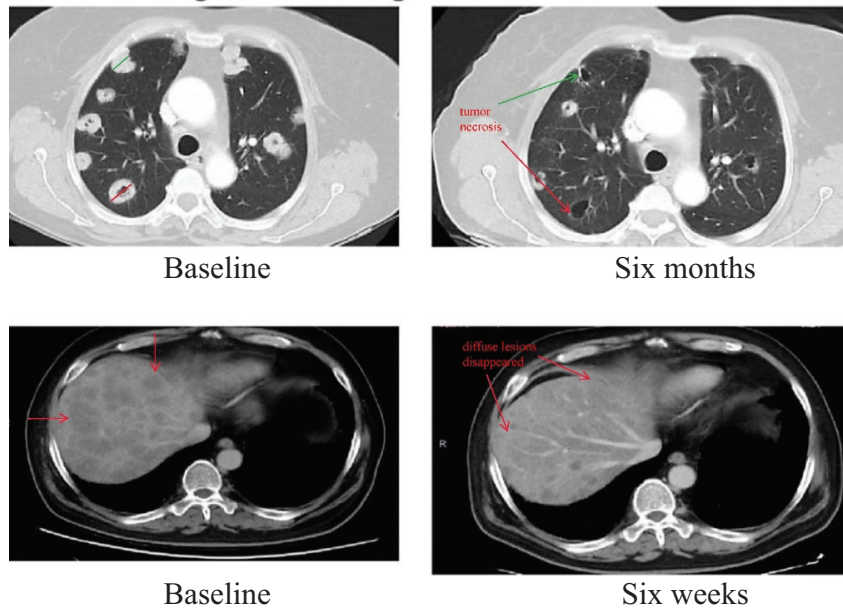
Subgroups	cORR (% , 95% CI)
IHC2+FISH+or IHC3+(n=15)	53.3% (26.6%, 78.7%)
IHC2+FISH-(n=24)	45.8% (25.6%, 67.2%)
Visceral Metastasis (n=37)	56.8% (39.5%, 72.9%)
Metastasis to Liver (n=20)	60.0% (36.1%, 80.9%)
Post to PD1/PDL1 Treatments (n=8)	62.5% (24.5%, 91.5%)
Post to 1 line of Chemotherapy (n=31)	54.8% (36.0%, 72.7%)
Post to ≥2 Lines of Chemotherapy (n=12)	41.7% (15.2%, 72.3%)

Source: Company data

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There were impressive radiographic examples of response as shown below. As shown in the two CT images on the left side, two patients' tumors spread to lung and liver, respectively. After being treated with disitamab vedotin for a certain period, encouraging tumor shrinkage in lung and liver were observed in the two CT images on the right side below.

CT Images of Two Patients Treated with Disitamab Vedotin



Source: Company data

Safety Data: The most common treatment-related adverse events (TRAEs) were hypoesthesia (55.8%), alopecia (55.8%), white blood cell count decreased (55.8%) and neutrophil count decreased (41.9%). The most commonly reported Grade 3/4 TRAEs were hypoesthesia in 7 patients (16.3%) and neutrophil count decreased in 6 patients (14.0%). SAE was reported in 14 patients (32.6%). Most commonly reported SAEs were intestinal obstruction (4.7%) and incomplete intestinal obstruction (4.7%). The adverse events were manageable.

Conclusion: Disitamab vedotin has demonstrated encouraging anti-tumor effects on metastatic or unresectable UC. This study also showed disitamab vedotin was well tolerated in UC patients.

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Clinical Trials in Breast Cancer

We have completed patient enrollment in a Phase I trial in advanced solid tumors, of which all patients enrolled are BC patients. We are also conducting Phase Ib and II trials in BC in China. Based on the pooled analysis of the data from the Phase I dose-escalation trial and part of the data from the Phase Ib trial as below, disitamab vedotin has demonstrated good tolerability and promising efficacy at multiple dose levels in BC patients.

In an additional cohort of the Phase Ib trial, we are specifically exploring the efficacy of disitamab vedotin in HER2 low-expressing BC and have observed promising preliminary outcome. Based on the results of our previous clinical studies and communication with NMPA, we have initiated a Phase III trial to evaluate disitamab vedotin for patients with HER2 low-expressing BC.

Phase I and Ib trials in patients with metastatic BC in China

Trial Design: The Phase I trial was an open-label, dose escalation study (0.5, 1.0, 1.5, 2.0 and 2.5 mg/kg) aiming to evaluate the maximum tolerated dose (MTD) of disitamab vedotin.

The Phase Ib trial was an open-label study with three dose cohorts (1.5, 2.0 and 2.5 mg/kg, Q2W) of patients with HER2-positive/high-expressing (IHC 3+ or IHC 2+/FISH+) BC and one cohort (2.0 mg/kg Q2W) of patients with HER2 low-expressing (IHC 3+ or IHC 2+/FISH-) BC. The data used in the pooled analysis below only include the data from cohorts of HER2 high-expressing BC. This trial was primarily designed to determine Phase II recommended dose.

As of July 3, 2019, a total of 70 patients with HER2 high-expressing BC were enrolled and treated in the above two trials. Most of the patients had visceral metastasis (87.1%) and at least two lines of chemotherapy (78.6%) for metastatic BC. 47 patients (67.1%) had previously received trastuzumab for (neo) adjuvant or metastatic BC treatment. About half of the patients (42.9%) had previously received anti-HER2 tyrosine kinase inhibitor therapy and 24 patients (34.3%) had received at least two lines of anti-HER2 therapy.

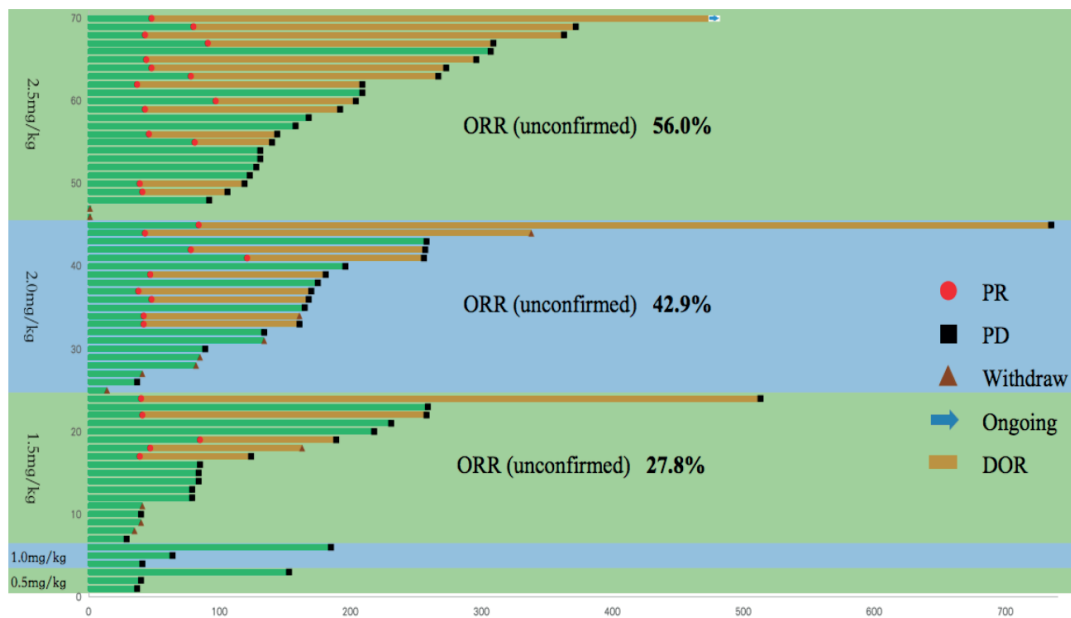
Trial Status: Patient enrollment of the Phase I trial was completed in February 2018. Patient enrollment of the Phase Ib trial was still ongoing. The data cut off at July 3, 2019 was used for the below analyses, and with respect to the Phase Ib trial, the below analysis only included the data of HER2 high-expressing BC cohorts.

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Safety Data: For all 70 patients, the most commonly reported TRAEs were AST increased (62.9%), ALT increased (61.4%), leukopenia (51.4%), hypoesthesia (51.4%) and neutropenia (51.4%). The most commonly reported Grade 3/4 TRAEs were neutropenia (21.4%) and asthenia (15.7%). Treatment-related serious adverse events (SAEs) occurred in 4 patients (5.7%). Gastrointestinal obstruction was the most commonly reported treatment-related SAE (2.9%). In the Phase I trial, MTD was not reached up to 2.5 mg/kg.

Efficacy Data: For all 70 patients, the cORR was 31.4% (22/70), the clinical benefit rate (CBR) was 38.6% (27/70), median PFS was 5.8 months and six-month PFS rate was 47.5%. For the 64 patients who received disitamab vedotin at the dose levels ≥ 1.5 mg/kg, the cORR was 34.4% (22/64), and the median PFS was 6.2 months. For patients received disitamab vedotin at the dose levels of 1.5mg/kg, 2.0mg/kg and 2.5mg/kg, the cORR was 22.2%, 42.9% and 36.0%, respectively, and the median PFS was 6.2 months, 6.0 months, and 6.3 months, respectively. The graph below shows the best overall response of the patients at all dose levels.

Best Overall Response of Disitamab Vedotin in BC Patients

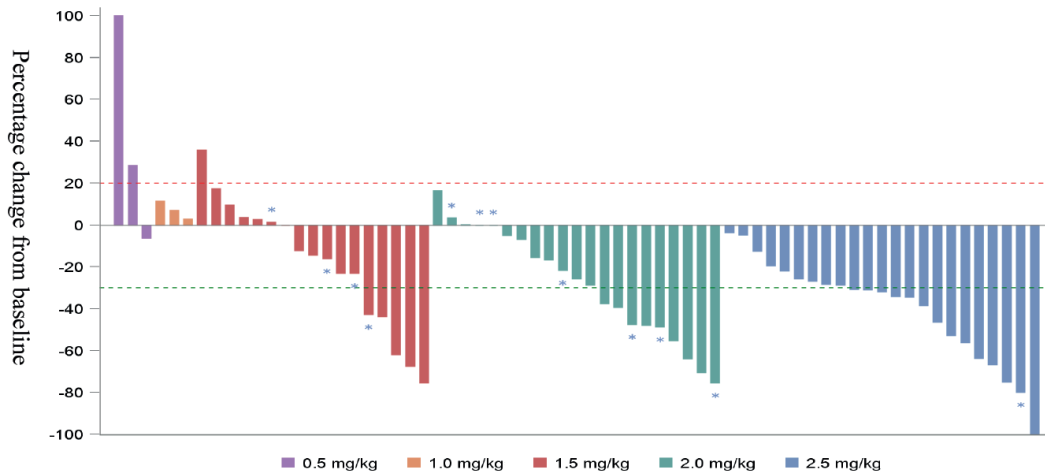


Source: Company data

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The waterfall plot below shows the best percent change from baseline in target lesions for BC patients at all dose levels.

Best Change of Target Lesion from Baseline of Disitamab Vedotin in BC Patients



Source: Company data

Conclusion: Disitamab vedotin demonstrated good tolerability and promising efficacy when administered at 1.5 mg/kg, 2.0 mg/kg, and 2.5 mg/kg Q2W in the patients with HER2 high-expressing metastatic BC. Comparing with the other dose levels, 2.0 mg/kg Q2W was proved to be more favorable in terms of benefit and risk balance. Furthermore, we are exploring preliminary efficacy of disitamab vedotin at the dose level of 2.0 mg/kg Q2W in an additional cohort of low HER2-expressing metastatic BC in the Phase Ib trial.

Clinical Development Plan

We have been developing disitamab vedotin for a variety of HER2-expressing cancer types. Currently, we are strategically focused on clinical investigation of disitamab vedotin as a second-line or third-line therapy for GC, UC and BC, which suggest particularly significant unmet medical needs. We are also exploring the efficacy of disitamab vedotin in other prevalent cancer types with HER2 expression, such as NSCLC and BTC.

Leveraging the promising efficacy and safety data observed so far, we also intend to pursue global clinical development of disitamab vedotin in 2020. We have received FDA approval for a Phase II clinical trial for UC in the U.S. We have initiated communication with the FDA for a phase II clinical trial for GC in the U.S. The FDA already granted an orphan drug designation for disitamab vedotin in GC in 2018.

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The table below sets forth details of our clinical development plan for disitamab vedotin.

Indication	Clinical trial stage	HER2 status	Type of therapy	(Expected) first patient in date	Expected NDA submission date	Location and competent authority
HER2 over-expressing locally advanced or metastatic GC	II (pivotal)	IHC 2+ or IHC 3+	Mono	May 2018	Q3 2020	China/NMPA
HER2 over-expressing locally advanced or metastatic GC	II	IHC 2+ or IHC 3+	Mono	1H 2021	–	U.S./FDA
HER2 over-expressing locally advanced or metastatic GC ⁽¹⁾	I	IHC 2+ or IHC 3+	Combo (PD-1)	Q3 2020	–	China/NMPA
HER2 over-expressing advanced or metastatic UC	II (pivotal)	IHC 2+ or IHC 3+	Mono	December 2018	1H 2021	China/NMPA
HER2 over-expressing advanced or metastatic UC	II	IHC 2+ or IHC 3+	Mono	Q1 2021	–	U.S./FDA
HER2 low- to non-expressing locally advanced UC	II	IHC 1+ or IHC 0	Mono	August 2019	–	China/NMPA
Locally advanced or metastatic UC	Ib/II	All	Combo (PD-1)	Q3 2020	–	China/NMPA
HER2 low-expressing advanced BC	III	IHC 2+/ FISH-	Mono	Q3 2020	–	China/NMPA
HER2 over-expressing or HER2 mutated advanced NSCLC	Ib	IHC 2+ or IHC 3+ or HER2 mutated	Mono	September 2018	–	China/NMPA
HER2 over-expressing metastatic BTC	II	IHC 2+ or IHC 3+	Mono	Q3 2020	–	China/NMPA

Note:

- (1) We have initiated a Phase I clinical trial in patients with various HER2 over-expressing solid tumors, which is expected to include a cohort of 20-50 patients with HER2 over-expressing GC to explore the efficacy and safety of the combo therapy of disitamab vedotin and PD-1 inhibitor for the treatment of HER2 over-expressing GC.

- GC:

We have completed the patient enrollment in our Phase II registrational trial of disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) GC in China in November 2019 and are in the process of collecting and analysing trial data. We plan to submit an NDA of disitamab vedotin for HER2 over-expressing GC to the NMPA in the third quarter of 2020.

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We are also exploring the clinical potential of disitamab vedotin in combination of PD-1 antibody for the treatment of HER2 over-expressing GC. We have initiated a Phase I trial in China to evaluate the efficacy and safety of this combination therapy in patients with various HER2 over-expressing solid tumors. In this trial, we plan to enroll a total of 29-68 patients, including 25-50 patients with HER2 over-expressing GC, and we expect to enroll the first patient with GC in the third quarter of 2020 for this trial.

In the U.S., the FDA has also granted orphan drug designation to disitamab vedotin for GC in July 2018. With the orphan drug designation, we are entitled to a seven-year exclusive marketing period of disitamab vedotin for this indication upon marketing approval. In addition, we plan to initiate a bridging study in the U.S. in 2021 to seek expedited approval. We also aim for the European market, and we anticipate to complete clinical trial application (CTA) filing with the EMA in GC in 2020.

- UC:

We have completed a Phase II trial of disitamab vedotin in the patients with HER2 over-expressing (IHC 2+ or IHC 3+) UC in China. Based on the positive clinical results of this Phase II trial and after communicating with the NMPA, we initiated a multi-center, single-arm and open-label Phase II registrational trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing UC in China. We plan to submit an NDA for this indication to the NMPA in the first half of 2021. We have completed the enrollment of a total of 60 patients in this trial in June 2020. The patient enrollment is expected to be completed in July 2020. The primary endpoint of this trial is the ORR. In addition, we may need to conduct a post-launch Phase III confirmatory trial of disitamab vedotin as treatment for UC subject to discussion with the NMPA.

As promising efficacy of disitamab vedotin was observed in patients with lower-level expression of HER2, we are conducting a single-center, single-arm and open-label Phase II trial to evaluate disitamab vedotin as monotherapy for HER2 low- to non-expressing (IHC 1+ or IHC 0) UC. We have enrolled 9 patients as of June 22, 2020 and plan to enroll a total of 18 patients for this trial. The primary endpoint of this trial is the ORR.

In addition, a Phase Ib/II trial has been initiated to evaluate the combination of disitamab vedotin and PD-1 antibody in UC patients without detecting HER2 status. We plan to enroll a total of 12-36 patients and expect to enroll the first patient in the third quarter of 2020 for this trial.

In the U.S., we have obtained FDA's approval for the IND application for a Phase II trial in UC in April 2020. We plan to initiate the Phase II trial in UC in the U.S. in the first quarter of 2021.

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- BC

As we have observed preliminary efficacy of disitamab vedotin in patients with low-level HER2 expression, we have communicated with the CDE and obtained their consent for us to initiate a Phase III trial of disitamab vedotin in patients with HER2 low-expressing (IHC 2+ and FISH-) BC. The primary endpoint of this trial is the PFS. We plan to enroll a total of 366 patients for this trial and expect to enroll the first patient in the third quarter of 2020. We expect to complete patient enrollment in the fourth quarter of 2021 and potentially file an NDA to the NMPA in 2022.

- NSCLC

We are conducting an open-label Phase Ib trial to evaluate disitamab vedotin as monotherapy for the treatment of HER2 over-expressing (IHC 2+ or IHC 3+) or HER2-mutant NSCLC in China. We have enrolled 27 patients as of June 22, 2020 and plan to enroll a total of 26-38 patients in this trial. The primary endpoint of this trial is the ORR.

- BTC

We are conducting a multi-center, single-arm and open-label Phase II trial to evaluate disitamab vedotin as monotherapy in the patients with HER2 over-expressing (IHC 2+ or IHC 3+) BTC post to the failure of 1L chemotherapy in China. We expect to enroll the first patient in the third quarter of 2020 and plan to enroll a total of 57 patients in this trial. The primary endpoint of this trial is the ORR.

Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize disitamab vedotin. In March 2015, we entered into an agreement with a pre-clinical CRO for their technical support to assist us in the establishment of our ADC platform and the development of an ADC drug candidate based on our platform. Under this agreement, this supplier shall be eligible to receive milestone payments from us upon the achievement of certain development milestones, and to receive royalties from us in the amount of a low single-digit percentage based on the sales of this ADC. With the supporting services provided by this supplier, we developed disitamab vedotin and exclusively own its intellectual property rights and global commercial rights.

Material Communications

We have not received any relevant regulatory agency's concerns or objections to our clinical development plans as of the Latest Practicable Date. As of the Latest Practicable Date, no material unexpected or adverse changes have occurred since the date of issue of relevant regulatory for disitamab vedotin.

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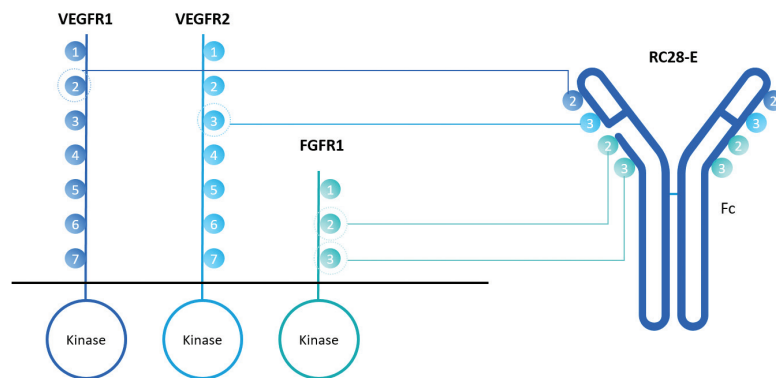
Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET DISITAMAB VEDOTIN SUCCESSFULLY.

RC28

RC28 is an innovative fusion protein targeting both vascular endothelial growth factor (VEGF) and fibroblast growth factor (FGF). We are evaluating, and plan to evaluate, RC28 in clinical studies for several ophthalmic diseases, including wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and diabetic retinopathy (DR). In the Phase I clinical trial, no safety concerns were detected for up to 2.0 mg injection of RC28 in wet AMD patients.

Mechanism of Action

As illustrated in the diagram below, RC28 is a recombinant dual decoy receptor IgG1 Fc-fusion protein, targeting both VEGF and FGF families simultaneously. These two growth factors, VEGF and FGF, are key pathway regulators in the formation of new blood vessels (angiogenesis), and are found in higher levels in patients with diabetes.

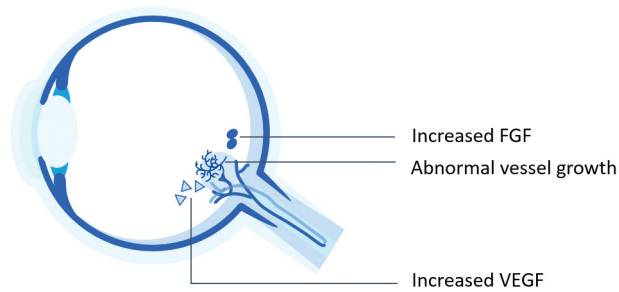


Source: Company data

Certain ophthalmic diseases, such as wet AMD, DME and DR, develop when blood vessels grow into the macula, causing fluid leaked from blood vessels into the eyes. These leak blood or fluid may lead to progressive vision loss and blindness. By binding to both of VEGF and FGF, RC28 can block angiogenesis factors in both VEGF and FGF families, thereby effectively slowing down the growth of new blood vessels and ultimately slowing the disease progression.

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VEGF /FGF



Source: Company data

Market Opportunities and Competition

Ophthalmic diseases present a sizeable market with massive potential driven by global aging population and rising awareness. RC28 targets hard-to-treat ophthalmic diseases including wet AMD and DME, which has a sizable and growing addressable market:

- Wet AMD:

Wet AMD, also known as neovascular exudative AMD, is a chronic eye disorder characterized by the abnormal growth of blood vessels and leakage of fluid and blood into the macula, which is responsible for central vision. Wet AMD is one of two types of age-related macular degeneration. While the other type—dry AMD—leads to a gradual loss of vision, wet AMD, accounting for 10% of total AMD cases, leads to sudden and severe vision loss and is the most advanced form of the disease. In addition, a fraction of dry AMD patients eventually evolve into wet AMD. The most severe form of wet AMD is the leading cause of blindness among older Chinese and Americans. There are more than 3.6 million and 1.8 million wet AMD patients in China and the U.S. in 2019, respectively. On average, around 90% of wet-AMD patients progressed to severe cases of vision loss.

- DME:

Diabetic macular edema (DME) is a complication of diabetes caused by fluid accumulation in the macula, or central portion of the eye, that leads the macula to swell. In people with diabetes, high blood sugar concentration can damage the tiny blood vessels at the back inner wall of the eye (retina) or block them completely. This condition is diabetic retinopathy. Sometimes, tiny bulges (microaneurysms) protrude from the vessel walls, leaking or oozing fluid and blood into the retina. This fluid can cause swelling in the macula, causing vision problems or even blindness. While diabetes is becoming increasingly common globally, its prevalence has been growing faster in China than the rest of the world in recent years and especially in the younger generation. According to the World Health Organization,

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about 10% of Chinese adults live with diabetes, and nearly half of all adults are prediabetic, a condition in which blood glucose levels are higher than normal. There were around 129 million diabetes patients and 6.7 million with DME in China in 2019. Diabetes is also a key and growing health concern in the U.S. In 2019, about 34 million people in the U.S. had diabetes, among which 1.3 million patients had DME.

The emergence of anti-VEGF therapy has revolutionized the treatment of wet AMD and DME by allowing a more direct approach to inhibit choroidal neovascularization. There are several anti-VEGF drugs available that are currently used to treat these diseases, in which four are most commonly used for the condition. Three of these, Bayer’s Eylea (aflibercept), Novartis’s Beovu (brolucizumab) and Lucentis (ranibizumab), marketed by Roche in the U.S. and by Novartis outside the U.S., were designed specifically for the treatment of ophthalmic diseases such as wet AMD and DME. The fourth commonly used drug, Roche’s Avastin (bevacizumab), was originally developed to treat various types of cancer, but is commonly used “off-label” in patients with wet AMD and DME as a less expensive alternative for the other three drugs. In China, Chengdu Kang Hong’s Lumitin (conbercept) was another drug approved for the treatment of wet AMD and DME. Ranibizumab, brolucizumab, and bevacizumab are single-target VEGF monoclonal antibodies, and aflibercept and conbercept are both VEGF-targeting fusion proteins. As of the Latest Practicable Date, there has not been any VEGF/FGF dual-targeted antibody targeting wet AMD or DME that is approved by FDA or NMPA.

Eylea and Lucentis are considered by the American Academy of Ophthalmology (AAO) as clinically indifferent and of minimal differences in risk, while Eylea requires only half of doses of Lucentis per annum (i.e. 6 doses vs. 12 doses p.a.). Since 2015, the global sales of Eylea surpassed Lucentis, acting as a substitute, primarily attributable to its reduced dosing frequency. In 2019, the global sales of Eylea and Lucentis reached US\$7.5 billion and US\$3.9 billion, respectively.

Beovu (brolucizumab) from Novartis obtained approvals from the FDA and the European Commission in October 2019 and February 2020, respectively, for the treatment of wet AMD. Beovu allows for a less frequent dosing than Eylea and Lucentis, i.e. three-month dosing intervals after a three-month loading phase. It is currently the only anti-VEGF treatment approved in Europe for wet AMD.

Competitive Advantages of RC28

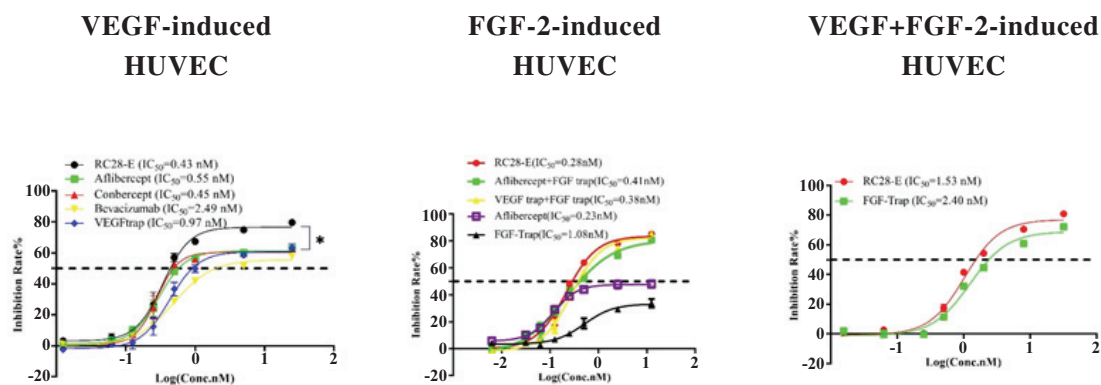
Dual-targeting mechanism leads to effective inhibition of blood vessel growth

A major challenge faced by single-target anti-VEGF therapies is the upregulated expression of other pro-angiogenic factors, such as FGF-2, when the activation of VEGF is inhibited. With the dual-targeting mechanism, RC28 can block angiogenesis factors at both VEGF and FGF families simultaneously and therefore can inhibit the abnormal vessel growth more effectively.

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We conducted *in vitro* and *in vivo* studies to investigate the anti-angiogenesis effects of RC28 and to compare the biological activities of RC28 with other VEGF and FGF antagonists. By blocking both VEGF and FGF-2 pathways, RC28 inhibits the proliferation and migration of endothelial cells during the growth of new blood vessels.

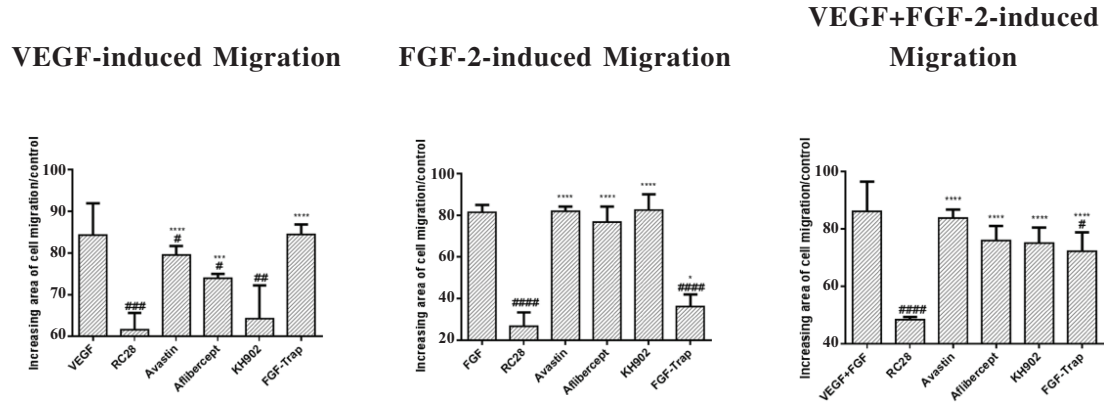
In an *in vitro* study, we assessed the potency of RC28 and other antagonists in the inhibition of proliferation, migration and tube formation of human umbilical vein endothelial cells (HUVEC) induced by VEGF, FGF-2 or VEGF combined with FGF-2. As shown in the figure below, RC28 is able to inhibit proliferation of HUVEC induced by either or both of VEGF and FGF-2 in a concentration-dependent manner. While the anti-proliferative effect of RC28 induced by single factor binding was similar to that of VEGF or FGF antagonists as measured by IC₅₀, the maximum relative inhibition rate of RC28 was higher than other antagonists as shown in all three panels in the figure below. In particular, RC28's ability to block double factors (VEGF+FGF-2)-induced HUVEC proliferation was significantly stronger than the other antagonists, as shown in the right panel of the figure below.



Source: Jiang et al., *Eur. J. Pharm. Sci.*, 121 (2018)

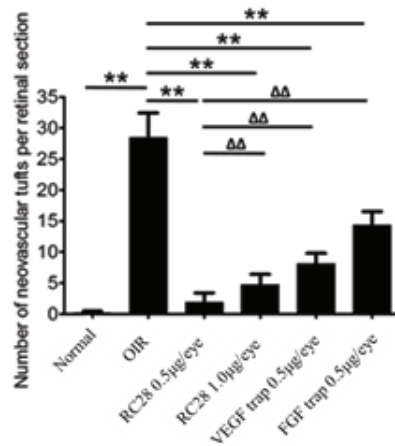
As shown in the figures below, RC28 also exhibited stronger inhibition effects on VEGF-induced migration, as compared to Avastin (bevacizumab) ($P < 0.001$) and aflibercept ($P < 0.005$) at the same concentration (1nM), and on FGF-2-induced migration, as compared to FGF-Trap ($P < 0.05$). Notably, as shown in the right panel below, RC28 resulted in significant inhibition effects on VEGF+FGF-2-induced migration at the half concentration (1nM) among all the tested antagonists (2nM) ($P < 0.001$).

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Source: Jiang et al., Eur. J. Pharm. Sci., 121 (2018)

We also evaluated efficacy of RC28 in oxygen induced retinopathy (OIR) mouse models. High oxygen stress induced neo-vascular nucleus number increase in retina, while normal oxygen stress had no such effect. RC28, VEGF trap (aflibercept) and FGF trap significantly decreased neo-vascular nucleus number in these OIR mice. In addition, the dual-targeting RC28 (0.5µg/eye) showed significant stronger inhibitory effect than equivalent dose of VEGF-trap or FGF-trap.



Note: Nucleus number of neo-vascular in mouse retina by H&E staining.

** P <0.01 vs OIR group; ΔΔP<0.01 vs RC28 0.5 µg/eye group>

Source: Company data

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Potentially better dosing profile translates to reduction in treatment costs

RC28 is constructed as the extracellular domains of VEGFR1, VEGFR2, and FGFR1 are fused with human IgG1 to achieve dual-blockade of VEGF and FGF, and to extend the half-life of the drug in serum. As observed in the mouse model discussed above, RC28 largely reduced neo-vascular nucleus number at the dosage of 0.5µg/eye as compared to other VEGF antagonists at the same dosage. Furthermore, as observed in a monkey choroidal neovascularization (CNV) model, traces of RC28 were detected as dispersing from eyeballs to the liver after 20 days, and a prolonged half-time pharmacokinetic profile was exhibited in this *in vivo* assay. Given the strong efficacy at low dose-level and an extended half-life of the drug, RC28 can potentially allow for a less frequent dosing profile and therefore reduce discomfort of the patients which is important as the drug is directly injected into the eyes.

Summary of Clinical Trial Results

We have completed a Phase I dose-escalation trial of RC28 in wet AMD patients in August 2019. Four dose levels of RC28 (0.25, 0.5, 1.0, and 2.0 mg) were investigated in a dose-escalation paradigm in which three patients were enrolled in each dose cohort. No safety concerns were detected after a single, intravitreal injection of RC28 up to 2.0 mg in this trial. 12 patients completed the study with no dose-limiting toxicity (DLT) and no serious or drug-related adverse events occurred. Moreover, no serum anti-RC28 antibodies were detected. This trial shows that RC28 was well tolerated in wet AMD patients with a single dose of up to 2.0 mg.

Clinical Development Plan

Currently, we are conducting an open-label, single-arm Phase Ib dose-expansion trial to evaluate the efficacy and safety of RC28 in the patients with wet AMD. We have enrolled 20 patients as of June 22, 2020 and plan to enroll a total of 36 patients for this trial. The primary endpoints of this trial are the average change of BCVA from the baseline at Week 12 and 48 and the incidence rate and severity of ocular and non-ocular adverse events.

We plan to initiate Phase II clinical trials for DME and DR in China in the second half of 2020.

Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize RC28. We collaborated with Tongji University in the discovery and development of RC28 pursuant to our collaboration agreement with Tongji University. For details, please refer to the paragraph headed “—Collaboration Agreements—Collaboration with Tongji University.”

Material Communications

We have not received any relevant regulatory agency’s concerns or objections to our clinical development plans as of the Latest Practicable Date. As of the Latest Practicable Date, no material unexpected or adverse changes have occurred since the date of issue of relevant regulatory for RC28.

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Our Other Clinical-Stage Drug Candidates (RC88 and RC98)

RC88

RC88 is a novel mesothelin-targeting ADC we developed for the treatment of solid tumors. It is currently in a Phase I clinical trial in patients with multiple advanced solid tumors, with a particular focus on pancreatic cancer, mesothelioma, ovarian carcinoma, gastric cancer, triple-negative breast cancer and lung adenocarcinoma. Although still in early clinical development, promising efficacy and safety results have been observed in its clinical trial.

Mechanism of Action

Mesothelin (MSLN) is a tumor-associated antigen with limited expression in normal tissues. It is frequently over-expressed on the cell membrane of a number of epithelial malignancies (e.g., mesothelioma, pancreatic, ovarian, lung, triple negative breast and gastric cancers).

Differential over-expression of MSLN in tumors and its role in cell adhesion and tumor metastasis make MSLN a suitable target for cancer therapy.

RC88 is composed of an MSLN-targeted antibody and MMAE connected by a cleavable linker. As described under “—Our Core Drug Candidates—Disitamab vedotin (RC48)—Mechanism of Action,” ADC therapeutics can effectively deliver cytotoxic payload into cancer cells through the internalization of the antibody upon target binding.

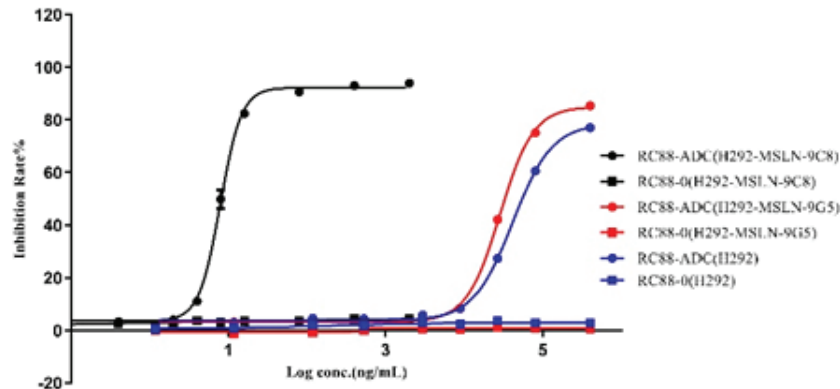
Competitive Advantages of RC88

Based on our pre-clinical data, we believe that RC88 has two potential competitive advantages as compared to standard of care: (1) more target-specific inhibition on tumor growth and (2) stronger efficacy against MSLN-expressing cancer.

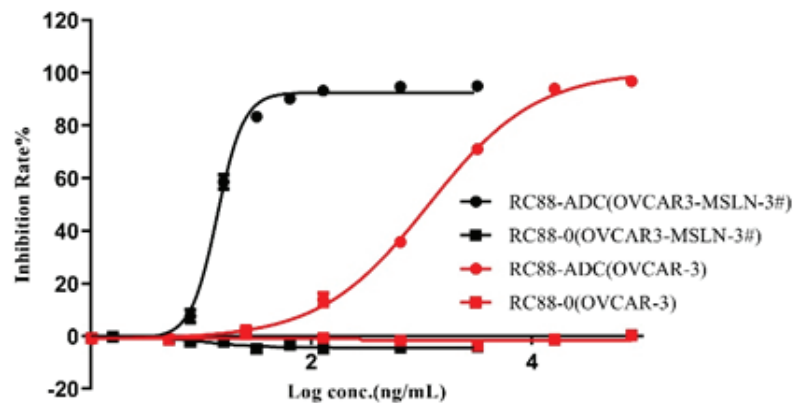
We assessed the anti-tumor activity of RC88 and compared it to that of the antibody component of RC88 (i.e., naked RC88) *in vitro*. In this study, RC88 was shown to be both potent and highly selective in killing MSLN-expressing tumor cells compared with MSLN-negative cells. As indicated in the charts below, RC88 showed a MSLN-dependent cellular cytotoxicity as the IC50 and maximum killing rates of RC88 corresponds to MSLN expression level of different cell lines. By contrast, naked RC88 antibody (RC88-0) showed none or limited tumor-killing effects to either mesothelin-positive or-negative cells.

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Cytotoxic Effect in MSLN+/- H292 Cells



Cytotoxic Effect in MSLN+/- OVCAR-3 Cells



Abbreviations: RC88-0 = naked RC88 antibody

Notes: The MSLN expression level of cell lines used in this study is follows (highest to lowest): H292-MSLN-9C8>OVCAR-3-MSLN-3#>H292-MSLN-9G5>OVCAR-3>H292. RC88-0 had no inhibition effects on cancer cells in this study.

Source: Company data

Clinical Development Plan

We obtained IND approval from the NMPA in November 2018 and have initiated a single-arm, open-label Phase I trial to evaluate the safety, PK, PD, immunogenicity and efficacy of RC88 in patients with advanced solid tumors in China. This trial comprises of a Phase Ia-stage dose-escalation study and a Phase Ib-stage basket study. Patients will be randomized into six treatment groups to receive intravenous drip of RC88 every three weeks (Q3W) at dose levels of 0.1 mg/kg, 0.5 mg/kg, 1.0 mg/kg, 1.5 mg/kg, 2.0 mg/kg and 2.5 mg/kg. We plan to enroll a total of up to 31 patients for the Ia stage of this trial, and enrolled the first patient in May 2020. The primary endpoints are AEs and MTD.

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Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize RC88.

Material Communications

We have not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

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RC98

RC98 is an innovative PD-L1 monoclonal antibody we developed for the treatment of solid tumors. We obtained the IND approval for RC98 from the NMPA in July 2019 and we have initiated a Phase I clinical trial in patients with multiple advanced solid tumors and we expect to enroll the first patient in the third quarter of 2020.

Mechanism of Action

Under normal conditions, T cells will be activated by the immune system in response to antigens. Activated T cells play critical roles in regulating immune response of human body, including recognizing and killing cancer cells. To prevent activated T cells from attacking healthy body tissues, T cells express immune checkpoint receptors, such as PD-1, on its surface to limit overstimulation of the immune system after antigen encounter.

PD-L1 is an important ligand protein that can engage PD-1. The binding of PD-L1, expressed on the surface of normal cells, to PD-1 on the surface of T cells can deliver a negative signal to T-cells, leading to inhibition on immune response. However, it has been found tumor cells can overexpress PD-L1 to protect themselves from being detected and killed by T cells. As a PD-L1 antibody, RC98 is designed to specifically bind to PD-L1 in order to block the PD-1/PD-L1 inhibitory pathway and enable T cells to recover anti-tumor immune response.

Competitive Advantages of RC98

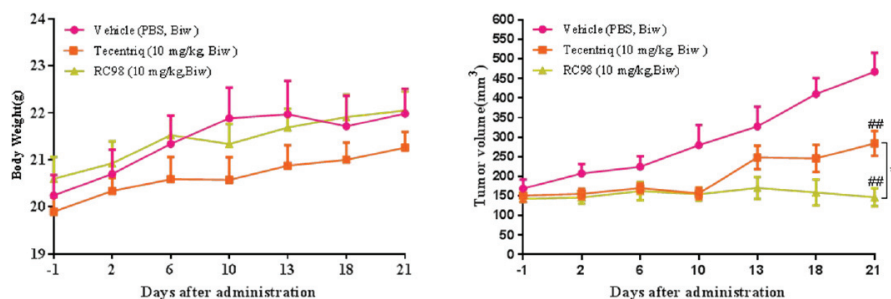
Our pre-clinical research showed that RC98 has two potential competitive advantages as compared to other PD-L1 antibodies: (1) comparable or even better affinity for targets and anti-tumor effects, and (2) significant combination potential with other drug candidates in our pipeline, such as disitamab vedotin and RC88.

In vitro pharmacology studies showed that RC98 has high affinity for PD-L1 and can effectively block the association of PD-L1 with PD-1 by binding to PD-L1 protein expressed on cell surface. RC98 was also shown to induce the proliferation of CD4⁺ T lymphocytes and the production of interleukin-2 (IL-2) and interferon- γ (IFN- γ) to promote immune responses in the *in vitro* studies.

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In vivo studies demonstrated the strong anti-tumor activity of RC98 which is comparable or better than atezulizumab. Atezulizumab (brand name: Tecentriq) is a PD-L1 antibody approved for various cancer types by FDA and NMPA. As shown in the figure on the right below, RC98 showed stronger tumor inhibition effects on clonal tumor cells expressing human PD-L1 than atezulizumab ($P < 0.01$) at the same dose in a mice model, while the figure on the left below suggested that the two molecules met with equivalent tolerability over time.

In Vivo Antitumor Activity of RC98 and Atezulizumab

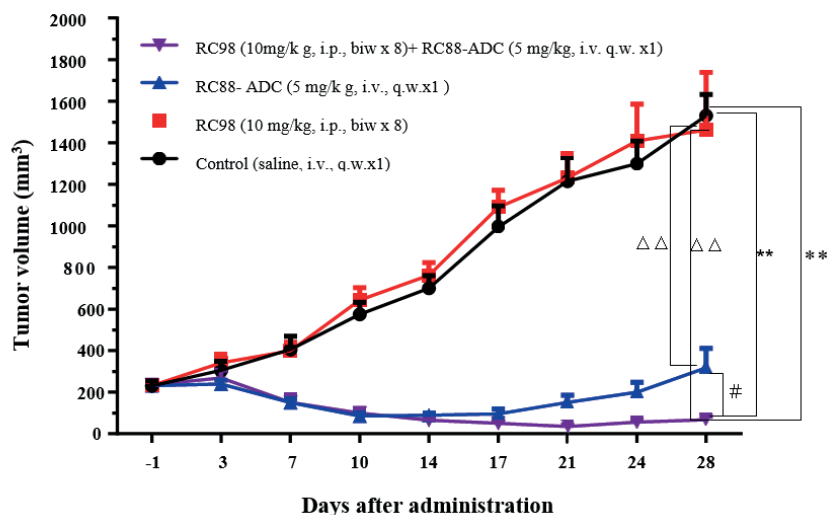


Note: ## $P < 0.01$ vs Vehicle, ** $P < 0.05$ vs Tecentriq (atezulizumab).

Source: Company data

Furthermore, the combination of RC98 and our other oncology drug candidates have shown encouraging synergistic anti-tumor effects in our *in vitro* pharmacology studies. In mice models, we assessed the anti-tumor activities of the combination of RC98 with RC88 (MSLN ADC). As illustrated in figure below, the combination of RC98 and RC88 showed better antitumor effects than either of RC98 and RC88 against pancreatic adenocarcinoma epithelial cell. These results suggested the potent and synergistic tumor inhibitory effects of potential combination therapies using RC98.

In Vitro Antitumor Activity of RC98 + RC88



Note: ** $P < 0.01$ vs Control, ΔΔ $P < 0.01$ vs RC98, # $P < 0.05$ vs RC48-ADC.

Source: Company data

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Clinical Development Plan

We have initiated a single-arm, open-label Phase I trial to evaluate the safety, PK, immunogenicity and efficacy of RC98 in patients with advanced solid tumors in China. We plan to enroll a total of 25 patients for this trial, and expect to enroll the first patient in the third quarter of 2020. The primary endpoints are MTD and the number and rate of AEs. Following this Phase I trial, we plan to further explore the clinical potential of RC98 in combination with our other pipeline assets, such as disitamab vedotin and RC88, for the treatment of advanced solid tumors.

Licenses, Rights and Obligations

We maintain the global rights to develop and commercialize RC98.

Material Communications

We have not received any relevant regulatory agency's objections to our clinical development plans as of the Latest Practicable Date.

Cautionary Statement required by Rule 18A.05 of the Listing Rules of the Hong Kong Stock Exchange: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET RC98 SUCCESSFULLY.

Our IND-Enabling Drug Candidates (RC108, RC118, RC138, RC148 and RC158)

In addition to our clinical-stage drug candidates, we are also developing a number of IND-enabling drug candidates in our rich pipeline. As of the Latest Practicable Date, we are evaluating five of our innovative IND-enabling candidates' pharmacokinetic and toxicokinetic in a variety of pre-clinical studies using in vitro and in vivo laboratory animal testing techniques, and these candidates have shown encouraging preliminary results in our preclinical studies. We are in the process of generating and collecting necessary data in preparation for filing INDs in order to explore their clinical development opportunities both in China and beyond. These five drug candidates include:

RC108: RC108 is a proprietary innovative c-MET-targeted ADC of us. c-MET is a receptor tyrosine kinase that, after binding with its ligand, hepatocyte growth factor, activates a wide range of different cellular signaling pathways, including those involved in proliferation, motility, migration and invasion. It is a well-characterized oncogene that is associated with poor prognosis in many solid tumor types. We are developing RC108 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies, and we aim to file the IND application for RC108 in the third quarter of 2020. We maintain the global rights to develop and commercialize RC108.

RC118: RC118 is a proprietary innovative ADC of us. We are developing RC118 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies, and we aim to file the IND application for RC118 in the second quarter of 2021. We maintain the global rights to develop and commercialize RC118.

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RC138: RC138 is a proprietary innovative HiBody of us. We are developing RC138 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies. We maintain the global rights to develop and commercialize RC138.

RC148: RC148 is a proprietary innovative HiBody of us. We are developing RC148 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies, and we aim to file the IND application for RC148 in the second half of 2021. We maintain the global rights to develop and commercialize RC148.

RC158: RC158 is a proprietary innovative HiBody of us. We are developing RC158 as a monotherapy for the treatment of advanced solid tumors. It is currently being evaluated in multiple pre-clinical studies, and we aim to file the IND application for RC158 in the second half of 2021. We maintain the global rights to develop and commercialize RC158.

OUR PLATFORM

We have built a fully-integrated platform to enable our strategic focus on the research, development and commercialization of innovative biologics in the therapeutic areas of autoimmune diseases, oncology and ophthalmology. Our platform encompasses all the key biologic drug development functionalities and capabilities, which are housed in four main functional divisions: research and development (drug discovery and pre-clinical development), clinical development, manufacturing, and commercialization. These functional divisions have been individually optimized and collectively synergized to produce cross-function integration at various key points in the lifecycle of a drug candidate. We have also built and employ an efficient operating system for all these individual functional divisions, laying a solid foundation for bringing our strong pipeline of innovative drugs from inception through manufacturing and commercialization.

Research and Development Platforms

Led by Dr. Fang, our Co-Founder, CEO and CSO, our in-house research and development function has over 280 members with of drug discovery and development experience in multinational pharmaceutical companies and world-renowned laboratories as of the Latest Practicable Date. Around 55% of our research and development team members have masters or doctorate degrees in biology-related majors. Leveraging our strong research and development capabilities, we have developed a robust pipeline of over ten innovative drug candidates with 17 indications, including five in clinical development stage.

Our world-class biopharmaceutical research and development function consists of three specialized platforms targeting a variety of biological therapeutics. These include an antibody and fusion protein platform, an ADC platform and a bifunctional antibody (HiBody) platform. Our platforms are capable of discovering, screening and engineering novel molecules, developing proprietary technologies, and optimizing processes to produce biologics in an efficient and effective manner, which ensure an end-to-end integration from R&D to commercialization of our pipeline assets.

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Antibody and fusion protein platform

Our antibody and fusion protein discovery and development capabilities are driven by innovative technologies and our expertise in bioinformatics-aided protein design and engineering. Our antibody and fusion protein platform is well-established and includes the following main functionalities: (i) antibody/fusion protein screening and engineering; (ii) cell line/process development; and (iii) drug substance (DS)/drug product (DP) GMP manufacturing.

Led by Dr. Fang, our Co-Founder, CEO and CSO, our R&D team brings us extensive expertise in the engineering and optimization of antibodies and fusion proteins. Dr. Fang has over 20 years of rich experience in biopharmaceutical R&D and manufacturing. He is the inventor for conbercept, a recombinant fusion protein which was approved in China for the treatment of wet AMD in 2013 and for the treatment of pathological myopia choroidal neovascularization (pmCNV) in 2017. Conbercept is also the first biologic wet AMD drug developed in China with over 40% market share of anti-VEGF therapeutics in China in 2019.

Our antibody and fusion protein platform features generation of novel monoclonal antibodies and fusion proteins through our internal studies. We can generate high affinity monoclonal antibodies in house using various technologies, including murine hybridoma, human B cell cDNA phage-display library and llama nanobody phage-display library. We have extensive knowledge in bioinformatics-aided protein design and engineering for Fc fusion proteins. We humanize antibody sequences to generate murine antibodies by hybridoma technology. We have generated a number of monoclonal antibody molecules using these technologies, some of which have been advanced to preclinical development stage as our drug candidates or for the use in companion diagnostic kits.

Indeed, synthetic fusion proteins such as our recombinant TACI-Fc fusion protein (telitacicept) could be designed to achieve improved efficacy or new functionalities by synergistically incorporating multiple protein fragments. Among other hypothetical benefits, the fusion of two or more protein domains could enhance bioactivities or generate novel functional combinations with a wide range of biotechnological and biopharmaceutical applications. In the case of telitacicept, for instance, the TACI-Fc fusion protein is bioinformatics-optimized and incorporates the extracellular BLyS/APRIL-binding domain of human TACI to the maximum extent. The structural design allows for telitacicept’s enhanced dual-target binding affinity and better biological activity. The structure-based advantages of telitacicept are demonstrated by encouraging efficacy and favorable safety profile observed in its clinical trials for a variety of autoimmune diseases. Based on its clinical trial results for the treatment of SLE, the NMPA accepted our NDA of telitacicept for SLE in November 2019, which has been granted priority review in December 2019.

RC28 is another example that showcases the R&D capabilities of our platform. Our RC28 is an innovative fusion protein targeting both vascular endothelial growth factor (VEGF) and fibroblast growth factor (FGF). We are evaluating RC28 in clinical studies for several ophthalmic diseases, including wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and diabetic retinopathy (DR).

In addition to R&D capabilities, this platform also has the capacity to manufacture complex fusion proteins of high quality in large scale, which is proven by our successful track record of producing our fusion protein products, including telitacicept and RC28, for clinical trials.

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ADC platform

Our ADC platform allows us to discover and develop ADCs which are designed to deliver chemotherapies specifically and directly to tumor cells while sparing healthy cells that could otherwise be subject to other treatments' undifferentiated attacks.

We are one of only a few biopharmaceutical companies that have a fully-integrated ADC platform with in-house capabilities covering the whole process of ADC development and manufacturing. Our ADC platform includes the following main functionalities: (i) screening platform for ADC linker and payload optimization; (ii) proprietary Thiel-bridge conjugation technology; (iii) process development for linker, payload and conjugation; (iv) GMP syntheses of linker, payload, and link-payload; and (v) GMP manufacturing of ADC DS and DP.

Leveraging this platform, we have discovered and are developing more than 5 ADC drug candidates, among which two have been advanced to clinical stage. Our leading ADC product, disitamab vedotin, is a novel ADC which we have independently developed to treat HER2-expressing solid tumors. Disitamab vedotin is the first ADC drug approved for human clinical trials in China and has demonstrated an excellent safety profile in clinical trials.

The key to ADC discovery and development is to get three distinct components to work together: (i) a monoclonal antibody that binds to a protein or antigen overexpressed on the surface of tumor cells, (ii) an active cytotoxic drug molecule (chemotherapy) that is designed to kill a tumor cell once it is internalized, and (iii) a stable molecular linker between the foregoing antibody and active cytotoxic drug, which is cleavable once internalized. Given the complicated structure of ADCs, the process development and manufacturing of ADC involve additional technical difficulties and complexities that are not presented in conventional manufacturing of monoclonal antibody, such as the antibody-drug conjugation reaction and subsequent drug substance purification.

Through around eight years of ADC research, we accumulated extensive expertise on choice of conjugation chemistry and linker and optimization of the conjugation reaction parameters. For each ADC drug candidate, we screen a large panel of combinations of conjugation methods, linkers and payloads to optimize molecular composition. For example, we used a cleavable linker in disitamab vedotin to bridge the HER2 antibody and the cytotoxic payload. The cleavability of this linker enables the payload to be released efficiently which enhances the therapeutic effects of the ADC. We developed a proprietary Thiel-bridge conjugation technology to yield more homogeneous ADC products that can improve pharmacodynamics and increase therapeutic window.

We also have global GMP-compliant manufacturing facility for entire ADC manufacturing process, including antibody production, syntheses of payloads, linkers, and payload-linkers, ADC conjugation, and fill/finish. The establishment and operation of such manufacturing facilities are capital intensive and require well-trained and specialized personnel.

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Bifunctional antibody (HiBody) platform

Our bifunctional antibody platform focuses on the research and development of next-generation bifunctional antibodies that help us implement an emerging new therapeutic strategy. This bifunctional antibody (HiBody) technology is based on novel molecular format and is versatile in generating various bispecific antibodies, which have the potential to increase the efficacy and specificity of the antibody-based therapy.

Our HiBody platform includes the following main functionalities: (i) R&D on proprietary bifunctional antibody (HiBody) format for multiple products; (ii) R&D on next generation immune oncology therapeutics; and (iii) high manufacturability and product quality.

Using this novel molecular format, we have constructed a number of bifunctional antibody molecules and have three drug candidate in pipeline (RC138, RC148, and RC158). Our RC138 is the most advanced one among these product candidates. RC138 is a novel bifunctional antibody composed of a monoclonal antibody and a decoy receptor, which are implicated in two key pathways with independent and complementary immunosuppressive functions. RC138 has shown promising biological activities in pre-clinical studies and is expected to be further evaluated in clinical trials for the treatment of cancer in the future.

For many bispecific platforms, manufacturability is a key issue that often results in project failure. Our HiBody drug candidates have shown high expression level in our system and have constantly had product yield similar to conventional antibodies. The products from this HiBody platform are homogeneous and easy to be adapted to our manufacturing process. This platform was invented by Dr. Fang, our Co-Founder, CEO and CSO, and we have filed an invention patent for the molecular format of HiBody with broad claims.

Clinical Development Team

The clinical development function of our fully integrated platform manages clinical trials and in-house carries out a comprehensive suite of clinical development activities, including clinical trial design, implementation, and the collection and analysis of trial data.

Our clinical development efforts are led by our Chief Medical Officer, Dr. Ruyi He, and builds on Dr. He’s expertise in and familiarity with regulatory review processes both in China and beyond, including the approval and conduct of registrational trials around the world. Dr. He has worked for the NMPA in China and the FDA in the U.S. for nearly 20 years, where he held a number of strategic leadership positions and chaired several working groups that were tasked with drafting and finalizing guidelines for the industry. He was also responsible for approving numerous applications for INDs and NDAs/BLAs in the regulatory authorities. He has published more than 20 research papers and abstracts in the field of internal medicine and drug regulatory science. As of the Latest Practicable Date, our clinical team consists of 200 employees.

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As of the Latest Practicable Date, we have designed and implemented more than 30 clinical studies, including seven Phase II/III registrational trials. We rely on our strong medical team to manage substantially all stages of our clinical trials in-house, including trial protocol design, selection of investigators and sites, and implementation of clinical trial programs. Leveraging extensive knowledge and experience in clinical trials, our clinical development experts are particularly good at identifying unique therapeutic opportunities for our drug candidates based on the differentiating properties observed in the trials and improving their clinical plans accordingly.

Our clinical development team also possesses expertise in bioinformatics research and omics data analytics. We utilize proprietary algorithms to process and analyze a vast amount of genetic and molecular data in order to facilitate drug discovery and clinical studies. We also conduct translational research and use data to assess the effectiveness of treatment, evaluate different ways to customize therapies, and improve personalized medicine guidelines. These insights help further guide us toward new directions in novel drug and biomarker discovery.

Our clinical function has established long-term partnerships with numerous hospitals and principal investigators in various therapeutic areas and from different regions of China and the U.S. that offer us readily available clinical trial facilities and services. We believe that the size and geographic diversity of these facilities provide us a significant advantage in implementing large-scale global clinical trials and also enable us to conduct multiple clinical trials concurrently. We also work with highly reputable contract research organizations (CROs) to support our pre-clinical and clinical studies and provide regulatory and technical advises. Please refer to the paragraph headed “—Raw Materials and Suppliers” for details.

Manufacturing

As our lead products near the commercialization stage, we are preparing for commercial-scale manufacturing capabilities to ensure large scale delivery of high quality biologics. We have built manufacturing facilities with world-class production capacity of 6 x 2,000L disposable bag bioreactors in Yantai, China, which we plan to increase to 36,000L by 2021 and to 80,000L by 2025. Our manufacturing team in Yantai consists of approximately 319 employees as of the Latest Practicable Date.

We have in-house capabilities to manufacture our drug candidates, and we employ advanced technology to synthesize complicated drug compounds, such as ADCs, fusion proteins, and HiBodies. Our manufacturing facilities in Yantai recently passed the GMP inspection of an auditor from the European Union. We expect our manufacturing facilities in Yantai will have sufficient capacity to meet our commercial manufacturing needs in the foreseeable future.

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Our existing and new manufacturing facilities are designed in compliance with global GMP standards. Our existing manufacturing facilities have a total floor area of approximately 31,862 m² and consist of (i) antibody manufacturing suites with production capacity of 2.3 million vials per year and (ii) ADC drug substances (DS) and drug products (DP) manufacturing suites with an annual output of 1.5 million vials. In anticipation of large needs of our drugs upon the commercialization, we purchased the use right to two additional pieces of land with an aggregate area of 81,038.47 m² and have started construction of new manufacturing facilities. The new construction project features an anticipated annual production capacity of seven million vials for antibody and six million vials for ADC. We expect to complete building the facilities and commence operation by 2025. In order to meet our near-term needs for telitacicept’s global multi-center clinical trial, we plan to complete the first stage of the new construction project and commence operations by 2022, which is expected to have an anticipated annual production capacity of two million vials.

Our manufacturing facilities are equipped with system and equipment from industry-leading, highly reputable manufacturers and suppliers around the world. The up-stream manufacturing system uses disposable bag bioreactors of Sartorius and the down-stream manufacturing system is equipped with AKTA’s device. We use purification equipment produced by General Electric. Our quality control system has been validated/audited by regulators for multiple times and meets rigorous and comprehensive requirements under Chinese and international standards. We obtained the drug manufacturing license issued by Shandong Provincial Medical Products Administration with the valid term until August 13, 2021 and were certified as Level-3 Standardized Safe Production Enterprise.

Our manufacturing team also performs the quality assurance (QA) and quality control (QC) function to oversee the quality of our facilities and our products, as well as the quality systems in research and development, manufacturing and commercialization of drug candidates and potential future commercial products. The tasks for QA and QC include (i) ensuring quality control throughout the manufacturing process, including specification of the drug substance and the drug product, testing of raw materials, and product quality assessments; (ii) establishing a quality assurance system across the entire business, including employee training programs, audits of various business segments and product manufacturing; and (iii) validation of facilities and equipment, which includes laboratory tests to verify that a particular process, method, program, equipment or material works properly.

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Commercialization

We have established our sales and marketing department dedicated to the commercialization of our pipeline products. By the time we receive marketing approval of telitacicept in the fourth quarter of 2020, we expect our sales and marketing department to initially have around 100 members with rich experience in the commercialization of autoimmune therapeutics in the second half of 2020. As of the Latest Practicable Date, the leadership team of sales and marketing department is in place with department head, and a majority of director-level personnel and regional sales directors on board. Along with the increasing market penetration of telitacicept down the road, we expect to double the size of this department to 200 members in the second 12-month period of its commercial launch.

Our sales and marketing department will consist of a marketing team and a sales team:

- Our marketing team will initially have around ten members led by two department directors, and is mainly responsible for product positioning, market strategy, promotional activity planning and patient assistance.
- Our sales team will consist of a total of 90 members, including five to six regional sales directors, 12-16 sub-regional sales managers, and approximately 70 sales representatives. The sales team is mainly responsible for the formulation of detailed sales plan, the implementation of marketing and promotional activities, and the communication with, and training for, medical experts. This team will be split into several forces to cover different sales regions in order to ensure adequate market coverage in most of the provinces and municipalities in China and increase market penetration.

The leadership team of our sales and marketing department has significant expertise in commercialization of rheumatic, autoimmune and other biologic therapeutics. The head of our sales and marketing department, Mr. Jingping Wu, was previously general manager of Sunshine Guojian Pharmaceutical (Shanghai) Co., Ltd. (“三生國健藥業(上海)股份有限公司”), in charge of the overall sales and marketing work of Yisaipu (“益賽普”) and other biologics products of the business unit. Mr. Wu is supported by key commercial leadership members who have an average of ten years of commercial experience in leading multinational and domestic pharmaceutical companies and have strong relationship with hospital administrators, physicians and leading experts, particularly in the field of rheumatology. We also intend to build a separate sales team for our immuno-oncology therapies when disitamab vedotin and other oncology drug candidates comes to the market.

Leveraging the expertise and industry connections of our team, we will market the products primarily through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders and physicians in the respective therapeutic areas to promote the differentiating clinical aspects of our products. Such marketing efforts are expected to commence several months before the expected approval for the commercialization of a drug candidate. In preparation for the sales of telitacicept, we have

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identified a number of hospitals, clinics and physicians specialized in the treatment of SLE, classified them into several levels based on the patient bases and academic influence, and have started to visit the sites and physicians in person for pre-launch training and liaison.

As telitacicept is a fully domestically-developed innovative biologics and has the potential to be a first-in-class and best-in-class therapy for SLE, we are, and will continue, sponsoring numerous investigator-led clinical trials to generate local clinical data and accumulate relevant clinical experience. We believe that these academic-oriented marketing efforts will be beneficial for improving alignment of expert opinions on, and promoting clinical use of, telitacicept after it becomes available for sale. We will also support leading experts to report the results of their researches at international and domestic conventions, symposia and other notable events to promote our brand at the forefront of the industry. Moreover, we will actively organize academic conferences and seminars to publicize the clinical data and research results in relation of our drug candidates in order to raise our brand awareness and recognition.

In addition, we benefit significantly from our management team's successful experience with founding and operating RC Pharma, our strategic partner and a leading pharmaceutical company in China. Among other invaluable assets, our management team brings us nearly three decades of substantial operational, managerial and commercialization experience, resources and expertise, especially market access and distribution resources that are often coveted but cannot be easily replicated.

We are also pursuing co-development and licensing relationship with global pharmaceutical companies to promote and market our products worldwide. To implement our global marketing strategy, we have applied for patents regarding molecules of our core products in major regions and countries across the world. As of the Latest Practicable Date, we have 19 patents issued in China, five in the U.S., and 58 in a number of other major target markets, including South Korea, Russia, Australia, Canada, Japan and Hong Kong of China. We also have 21 pending patent applications in China, four pending patent applications in the U.S., nine pending patent applications under the Patent Cooperation Treaty and 33 pending patent applications under review in various other major target markets.

COLLABORATION AGREEMENT

Collaboration with Tongji University

In January 2011, we entered into a co-development agreement with Tongji University whereby we agreed to collaborate on a program to discover and conduct pre-clinical research of a VEGF/FGF dual inhibitor. Tongji University is one of most selective and most prestigious comprehensive universities in China. We co-discovered RC28 with Tongji University through this collaboration. Both parties agreed to make joint efforts in the discovery and pre-clinical development of the molecule and to jointly evaluate the development status of the program every year. Tongji University will not participate in the development of RC28 in the clinical stage.

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Pursuant to the agreement, we and Tongji University agreed to co-file the patent applications covering such product, and Tongji University assigned its rights to the patent application to us such that we will be the sole owner of any and all patents granted to such product. Upon our consent, Tongji University can use the research results relating to this product in the application for other research program grants. Each party has the right to make improvements to the inventions and enjoy the title to such improvements, while the other party should be notified of, and have a first right of refusal to acquire, such improvements. Any improvements to the inventions co-developed by both parties will be jointly owned.

We are responsible for all the costs associated with the development activities subject to the term of the agreement, which are not refundable even if the program is terminated. According to this agreement, we will pay a total amount of up to RMB8 million as reimbursement for research and development expenses incurred by Tongji University and in consideration for Tongji University's assignment of its patent application rights to us in relation to RC28. As of the Latest Practicable Date, we had paid a total of RMB8 million to Tongji University under this agreement. The parties will equally share any government grants relating to preclinical development of such product if the parties jointly applied for and obtained any such grants, while the party who individually applies for and obtains any grant is entitled to receive such grant in its entirety.

INTELLECTUAL PROPERTY

Intellectual property, including patents, trade secrets, trademarks and copyrights, is critical to our business. Our success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our drug candidates, novel discoveries, product development technologies, inventions, improvements and know-how. Our success also depends in part on our ability to defend and enforce our patents including any patent that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and other confidential or proprietary information, and operate without infringing, misappropriating, or otherwise violating the valid and enforceable patents and intellectual property rights of other parties.

We have a global portfolio of patents to protect our drug candidates and technologies. As of the Latest Practicable Date, we owned (i) 19 issued patents in China, (ii) five issued patent in the U.S., (iii) 58 issued patents in other jurisdictions, and (iv) 67 pending patent applications, including 21 Chinese patent applications, four U.S. patent applications, nine patent applications under the Patent Cooperation Treaty and 33 patent applications in other jurisdictions.

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As of the Latest Practicable Date, with respect to our three core drug candidates, telitacicept, disitamab vedotin and RC28, we own three issued Chinese patents, six pending Chinese patent applications, two issued U.S. patents, one pending U.S. patent applications, four pending PCT applications, 36 issued patents and 15 patent applications in other jurisdictions. In particular:

- **Telitacicept:** As of the Latest Practicable Date, we owned 11 issued patents, including one in China, one in the U.S. and nine in other jurisdictions, one patent application in other jurisdiction and one pending PCT application directed to telitacicept, our novel recombinant TACI-Fc fusion protein. The expected expiration for the issued patents and any patents that may issue from the currently pending PCT patent application ranges from 2027 to 2039, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.
- **Disitamab vedotin:** As of the Latest Practicable Date, we owned 20 issued patents, including one in China, one in the U.S. and 18 in other jurisdictions, three pending Chinese patent applications and 14 patent applications in other jurisdictions, and two pending PCT applications directed to disitamab vedotin, our novel anti-HER2 monoclonal antibody-drug conjugate. The expected expiration for the issued patents and any patents that may issue from the currently pending patent applications ranges from 2034 to 2040, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.
- **RC28:** As of the Latest Practicable Date, we owned ten issued patents, including one in China and nine in other jurisdictions, three pending Chinese patent applications, and one patent application in other jurisdiction and one pending PCT application, directed to RC28, our novel VEGF/FGF dual-targeted fusion protein. The expected expiration for the issued patents and any patents that may issue from the currently pending patent applications ranges from 2031 to 2039, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

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The following table summarizes the details of the material granted patents and filed patent applications by our Company in connection with our clinical drug candidates.

Product	Title of Patent/ Patent Application	Jurisdiction	Status	Applicant	Patent Expiration⁽¹⁾	Our Commercial Rights
Telitacicept	Optimized TACI-Fc Fusion Proteins	China	Granted	Company	June 15, 2027	All rights
	Optimized TACI-Fc Fusion Proteins	U.S., EPO (Germany, France, England, Switzerland, Italy), Japan, Republic of Korea, Russia, India	Granted	Company	June 16, 2028	All rights
	Optimized TACI-Fc Fusion Proteins	Brazil	Pending	Company	June 16, 2028	All rights
Disitamab vedotin	TACI-Fc Fusion Protein and Use thereof	PCT	Pending	Company	December 24, 2039	All rights
	Anti-HER2 Antibody and Conjugate thereof	China, U.S., EPO (Germany, France, Great Britain, Switzerland, Italy, Holland, Denmark, Sweden, Ireland, Belgium), Japan, Republic of Korea, Russia, Australia, Canada, Hong Kong	Granted	Company	November 18, 2034	All rights
	Anti-HER2 Antibody and Conjugate thereof	China, EPO, Japan, Brazil, India	Pending	Company	November 18, 2034	All rights
	Formulation of anti HER2 Antibody Drug Conjugate	Taiwan (China)	Pending	Company	March 26, 2040	All rights

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Product	Title of Patent/ Patent Application	Jurisdiction	Status	Applicant	Patent Expiration⁽¹⁾	Our Commercial Rights
	Formulation of anti HER2 Antibody Drug Conjugate	PCT	Pending	Company	March 25, 2040	All rights
	Use of Anti-HER2 Antibody- Drug Conjugate in Treating Urothelial Carcinoma	PCT, China, U.S., EPO, Japan, Australia, Russia, Canada, India, Brazil	Pending	Company	August 19, 2039	All rights
	Use of Anti-HER2 Antibody- Drug Conjugate in Treating Urothelial Carcinoma	Taiwan (China)	Pending	Company	August 28, 2039	All rights
RC28	Fusion Protein for Antagonizing Angiogenesis Inducible Factors and Uses thereof	China	Granted	Company	May 20, 2031	All rights
	Fusion Protein for Antagonizing Angiogenesis Inducible Factors and Uses thereof	EPO (Germany, France, Great Britain, Switzerland, Italy), Russia, Australia, Canada, Hong Kong	Granted	Company	May 18, 2032	All rights
	Fusion Protein for Antagonizing Angiogenesis Inducible Factors and Uses thereof	China	Pending	Company	February 11, 2035	All rights
	Use of Dual Targeting Vascular Inhibitor in the Manufacture of a Medicament for Preventing or Treating Fibrosis	China	Pending	Company and Binzhou Medical College	July 11, 2039	All rights

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Product	Title of Patent/ Patent Application	Jurisdiction	Status	Applicant	Patent Expiration⁽¹⁾	Our Commercial Rights
	Bifunctional Vascular Inhibitor and Use thereof	PCT, China	Pending	Company	December 4, 2039	All rights
	Bifunctional Vascular Inhibitor and Use thereof	Taiwan (China)	Pending	Company	December 6, 2039	All rights
RC88	Process for Preparing Intermediate of Antibody Drug Conjugate	PCT, China, U.S., EPO, Japan, Australia, Russia, Canada, India, Brazil	Pending	Company	May 20, 2039	All rights
	Anti-Mesothelin Antibody and Antibody – Drug Conjugate Thereof	PCT, China, U.S., EPO, Australia, Russia, India, Canada	Pending	Company	May 15, 2039	All rights
	Anti-Mesothelin Antibody and Antibody – Drug Conjugate Thereof	Taiwan (China)	Pending	Company	May 21, 2039	All rights

Abbreviation: PCT = Patent Cooperation Treaty.

Note:

(1) Patent expiration date is estimated based on current filing status, without taking into account any possible patent term adjustments or extensions and assuming payment of all appropriate maintenance, renewal, annuity and other government fees.

To protect proprietary technology of our specialized platforms, we have also filed three patent applications, including two patent applications in China and Taiwan (China) respectively and one PCT application, in relation to the Thiel-bridge conjugation technology of our ADC platform in 2019, and one patent application in China in relation to the molecular format of HiBody in 2020. These patent applications are currently pending.

As of the Latest Practicable Date, we owned 13 issued Chinese utility model patents and 4 Chinese utility model patent applications for our various innovative technologies that are utilized throughout our drug development and manufacturing process, including without limitation those related to mesothelin test, tunnel oven, unpacking tool and cooling equipment. These utility model patents have a term of ten years from the date of filing and are expected to expire in and after 2028.

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The term of individual patents may vary based on the jurisdictions in which they are obtained. In most jurisdictions in which we file patent applications, including China and the United States, the term of an issued patent is generally 20 years from the filing date of the earliest non-provisional patent application to which the patent claims priority. In the United States, a patent's term may be extended or adjusted to account for administrative delays during prosecution by the USPTO, in excess of a patent applicant's own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date.

In addition, with respect to any issued patents in the United States and Europe, we may be entitled to obtain an extension of the patent's term provided we meet the applicable requirements for obtaining such patent term extensions. For example, in the United States, we may apply for a patent term extension of up to five years as compensation for the patent term lost during clinical trials and the FDA regulatory review process under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The exact duration of the extension depends on the time we spend in clinical studies, as well as getting a BLA approval from the FDA. However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only once a patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Furthermore, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In certain other foreign jurisdictions, similar extensions as compensation for regulatory delays are also available.

In the future, if and when our product candidates receive approval from the FDA in the United States or similar governmental authorities in other jurisdictions, we expect to apply for patent term adjustments and extensions on issued patents covering those product candidates in jurisdictions where such adjustments and extensions are available; however, there is no guarantee that the applicable authorities, including the USPTO and FDA, will agree with our assessment of whether such adjustments and extensions should be granted, and even if granted, the length of such adjustments and extensions.

The actual protection afforded by a patent varies on a claim-by-claim and jurisdiction-by-jurisdiction basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular jurisdiction and the validity and enforceability of the patent. We cannot provide any assurance that patents will issue with respect to any of our owned or licensed pending patent applications or any such patent applications that may be filed in the future, nor can we provide any assurance that any of our owned or licensed issued patents or any such patents that may be issued in the future will be commercially useful in protecting our drug candidates and methods of manufacturing the same. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields in which we are developing our drug candidates. For example, we are aware of a third-party issued patent in the U.S. that may be alleged to cover the use of our telitacicept in treating autoimmune disease which will expire in 2021, and a third-party issued patent in Europe that

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may be alleged to cover the use of our telitacicept in treating mild-to-moderate SLE, although we do not expect to commercially launch telitacicept in the U.S. before the expiration of the third-party patent in the U.S. and telitacicept targets to treat moderate-to-severe SLE. Moreover, we are aware of third-party issued patents in the U.S. and Europe that may be alleged to cover our disitamab vedotin, and pending third-party patent applications in the U.S., Europe and mainland China that may be alleged to cover our disitamab vedotin’s potential combination with immune checkpoint therapies. In addition, we are aware of a third-party issued patent in the U.S. that may be alleged to cover our RC88 which will expire in 2022, although we do not expect to commercially launch RC88 in the U.S. before the expiration of this third-party patent. We may need to obtain the license for using the patented technology from the third parties before the commercialization of our products in relevant jurisdictions and to pay license fees; otherwise, third parties may assert that we are using technology in violation of their patent or other proprietary rights. There can be no assurance that we would be able to obtain the license from third parties at a reasonable fee rate, or at all. For further details, please refer to the paragraph headed “Risk Factors – Risks Relating to Our Business – Risk Relating to Our Intellectual Property – Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain, and we may be subject to substantial costs and liability, or be prevented from using technologies incorporated in our drug candidates or future drugs, as a result of such litigation or other proceedings relating to patent or other intellectual property rights.”

We may also rely, in some circumstances, on trade secrets, confidential information, know-how, unpatented technology and other proprietary information to protect aspects of our technology. We seek to protect our trade secrets and other proprietary or confidential technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors, and invention assignment agreements with our employees. We have entered into confidentiality agreements and non-competition agreements with our senior management and key members of our R&D team and other employees who have access to our trade secrets and other proprietary or confidential information relating to our business. Our standard employment contract is executed with each of our employees, contains an invention assignment clause, under which we own the rights to all inventions, technology, know-how and trade secrets resulting from work performed for us or relating to our business and conceived or completed during the course of such employee’s work.

These agreements may not provide sufficient protection of our trade secrets and other proprietary or confidential information. These agreements may also be breached, resulting in the misappropriation of our trade secrets and other proprietary or confidential information, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and other proprietary or confidential information may become known or be independently developed by a third party, or misused by any collaborator or other third party to whom we disclose such information. Despite any measures taken to protect our trade secrets, confidential or proprietary information and other intellectual property, unauthorized parties may attempt to or successfully copy aspects of our products or to obtain or use information that we regard as proprietary without our consent. As a result, we may be unable to sufficiently protect our trade secrets and proprietary information.

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We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. Despite any measures taken to protect our data and intellectual property, unauthorized parties may attempt to or successfully gain access to and use information that we regard as proprietary. Please refer to the paragraph headed “Risk Factors – Risks Relating to Our Business – Risk Relating to Our Intellectual Property” for a description of risks related to our intellectual property.

We conduct our business under the brand name of “RemeGen” (“榮昌生物”). As of the Latest Practicable Date, we had registered 15 trademarks in China and filed 13 trademark applications in China and other jurisdictions. We are also the registered owner of seven domain names and have irrevocable licenses for seven domain names.

We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property and gain access to the intellectual property of others. For more information, please see the paragraph headed “– Collaboration Agreements.”

As of the Latest Practicable Date, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement, misappropriation or other violations of third-party intellectual property and we are not involved in any proceedings in respect of any intellectual property rights that may be threatened or pending and that may have an influence on its research and development for any Core Product in which we may be a claimant or a respondent.

Please refer to the paragraph headed “Statutory and General Information – B. Further Information about the Business of our Company – 2. Intellectual Property Rights” in Appendix VII to this document for further information.

CUSTOMERS

During the Track Record Period, all of our revenue was generated from the provision of contract research and pre-clinical development services to Rongchang Zibo, our related party, in 2018. Rongchang Zibo engaged us to provide research and pre-clinical development services for the development of certain biologics in 2018. For further details, please refer to the paragraph headed “Financial Information – Description of Selected Components of Statements of Profit or Loss and Other Comprehensive Income Items – Revenue”.

RAW MATERIALS AND SUPPLIERS

We procure raw materials and equipment for the development and manufacture of our drug candidates from industry-leading and highly reputable manufacturers and suppliers around the world. We also engage a limited number of reputable CROs to support our internal team in managing and conducting pre-clinical and clinical studies of our pipeline candidates in China. For further details, please refer to the paragraph headed “– Our Platform.”

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For the years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, our purchases from our five largest suppliers in the aggregate accounted for 28.1%, 17.3% and 20.3% of our total purchases (including value added tax), respectively. Our purchases mainly include raw materials, third-party contracting services for research and development purposes, machines and equipment, clinical trials, project construction and administrative services. To the best of our knowledge, all of our five largest suppliers during the Track Record Period are independent third parties. None of our Directors, their respective associates or any shareholder who, to the knowledge of our Directors, owned more than 5% of our issued share capital as of the Latest Practicable Date, has any interest in any of our five largest suppliers during the Track Record Period.

In addition, we believe that adequate alternative sources for such supplies exist and we have developed alternative sourcing strategies for these supplies. We will establish necessary relationships with alternative sources based on supply continuity risk assessment. Other than the agreements with certain CROs, we order supplies and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

GOVERNMENT GRANTS, AWARDS AND RECOGNITIONS

We have received numerous national, provincial and local level government research grants and a wealth of awards and recognitions for our innovative drug development achievements. Some of national-level government research grants as well as significant awards and recognition that we have received are set forth in the tables below:

National-level Government Research Grants

Drug Candidate	Grant Type	Project Name	Grant Period
Telitacept	National Scientific and Technological Major Project for “Major Drug Innovation” – First Batch of Drug Candidates of the “Eleventh Five-Year” Plan	Research and development of TACI-Fc fusion protein (telitacept) as Category I innovative drug for the treatment of autoimmune diseases	Jan 2009 – Dec 2010
Telitacept	National “Major Drug Innovation”	Clinical study of TACI-Fc antibody fusion protein for the treatment of neuromyelitis optica spectrum disorder	2019
Telitacept	National “Major Drug Innovation”	Phase II and III clinical study of RC18	2018
Disitamab vedotin	National Scientific and Technological Major Project for “Major Drug Innovation”	Research on significant novel antibody-drug conjugate (ADC) and related technologies for the treatment of malignant tumors	Jan 2014 – Dec 2016
Disitamab vedotin	National Scientific and Technological Major Project for “Major Drug Innovation”	Research on significant novel antibody-drug conjugate (ADC) and related technologies for the treatment of malignant tumors – Phase I clinical trial of “novel anti-Her 2 ADC drug”	Jan 2014 – Dec 2016
Disitamab vedotin	National “Major Drug Innovation”	Research on diagnostic test of molecular phenotype in companion with HER2 ADC drug for the treatment of malignant tumors	2019

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Drug Candidate	Grant Type	Project Name	Grant Period
Disitamab vedotin	National “Major Drug Innovation”	Clinical study of recombinant humanized HER2 antibody-MMAE conjugate (RC48) for injection	2020
RC28	Research and Development Program of Drug Types and Key Technology related to Key Tasks of National Scientific and Technological Major Project for “Major Drug Innovation” (Triple-Key Program)	Innovative dual-targeting anti-tumor receptor-IgG fusion protein drug (VF-28)	Jan 2013 – Dec 2015
RC28	National “Major Drug Innovation”	Clinical study of a dual-targeting antibody fusion protein drug (RC28-E) for the treatment of diabetic macular edema	2019
/	National Scientific and Technological Major Project for “Major Drug Innovation”	Protein-engineering platform and incubation center for research and development of innovative drugs	Jan 2013 – Dec 2015
/	National “Major Drug Innovation”	Innovative antibody-drug conjugate (ADC) drug and key technologies	2019

Key Awards and Recognitions

Award/Recognition Name	Recipient	Year	Certification Level
National Large-scale Integrated New Drug Research and Development Technology Platform – (Shandong) Model Enterprise of Industrialization	RemeGen, Ltd.	2010	National
National (Shandong) Innovative Drug Incubation Base	RemeGen, Ltd.	2010	National
Post-doctoral Scientific Research Center	RemeGen, Ltd.	2013	National
Academician’s Research Center	RemeGen, Ltd.	2018	Shandong Province
Shandong Province Model Engineering Technology Research Center	RemeGen, Ltd.	2014	Shandong Province
Provincial-level Key Laboratory of Shandong Province	RemeGen, Ltd.	2015	Shandong Province

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COMPETITION

The pharmaceutical and biopharmaceutical industries are highly competitive and subject to rapid and significant change. While we believe that our robust pipeline of innovative drug candidates in clinical and pre-clinical trials, strong research and development capability, fully-integrated platform and world-class leadership team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications against which we develop our drug candidates, in particular in the fields of autoimmune diseases, oncology and ophthalmology. These include major pharmaceutical companies, such as GlaxoSmithKline, Novartis, Daiichi-Sankyo, Roche and Sichuan Kanghong, specialty pharmaceutical and biotechnology companies of various sizes, such as BeiGene, Junshi, Innovent and Akeso, academic institutions, government agencies and research institutions. Any drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future. For more information on the competitive landscape of our drug candidates, please refer the paragraph headed “—Our Drug Candidates.”

EMPLOYEES

As of the Latest Practicable Date, we had 998 employees in total. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Function	Number	% of Total
Research and development	285	28.6%
Clinical development	197	19.7%
Manufacturing and quality	319	32.0%
Commercial, general and administrative	197	19.7%
Total	998	100%

Among the 998 employees, 794 of our employees are stationed in Yantai, Shandong Province, and 204 of our employees are based in 34 other cities including Beijing, Shanghai and Hefei in China and Fremont, California and Washington, D.C. in the U.S.

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. We also enter into separate confidentiality and non-competition agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

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To maintain the quality, knowledge and skill levels of our workforce, we provide continuing education and training programs, including internal and external training, for our employees to improve their technical, professional or management skills. We also provide trainings programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects.

We provide various incentives and benefits to our employees. We offer competitive salaries, bonuses and share-based compensation to our employees, especially key employees. In China, during the Track Record Period and up to the Latest Practicable Date, we have made contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds for our employees in accordance with applicable Chinese laws. As of the Latest Practicable Date and up to the Latest Practicable Date we had complied with all statutory social security insurance fund and housing fund obligations applicable to us under Chinese laws in all material aspects.

We consider our relations with our employees to be good. Our employees are represented by a labor union. During the Track Record Period and up to the Latest Practicable Date, we did not experience any strikes or labor disputes which had a material effect on our business.

LAND AND PROPERTIES

We own our main campus on 107,702 m² of land in Yantai, Shandong province, China, in which we built manufacturing, R&D, administrative and ancillary buildings with a total of 36,999 m² of floor space. Our existing manufacturing facilities occupy 31,862 m² of floor space, which houses 12,000 L of bioreactors. 68,000 L biologics manufacturing facilities are currently being constructed on two pieces of land with an aggregate area of 81,038 m², some of which will be reserved for future expansion. Our main campus also includes laboratories, offices, water treatment facilities, warehouses for storing drugs and chemicals, and other facilities for employees.

As of the Latest Practicable Date, we also rent a total of 5,297 m² of office space in Yantai, Beijing and Shanghai for laboratory use and for administrative functions. The relevant rental agreements provide lease expiration date ranging from September 2020 to May 2024.

The property valuation report from JLL, set out in Appendix III to this document, sets forth details of our property interest at our main campus in Yantai, Shandong province as of March 31, 2020. JLL valued such property interest at an amount of RMB200.4 million as of March 31, 2020, which does not include the value of a piece of land of 69,727 m² we acquired after March 31, 2020. For further details, please refer to Appendix III to this document. Save for the above-mentioned property interest, no single property interest that forms part of our non-property activities had a carrying amount representing 15% or more of our total assets as of March 31, 2020.

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ENVIRONMENTAL MATTERS AND WORKPLACE SAFETY

We are committed to operate our business in a manner that protects environment and provides a safety workplace for our employees. Our operations involve the use of hazardous chemicals. We implemented safety guidelines setting out information about potential safety hazards and procedures for operating in the manufacturing facilities, and we installed video surveillance systems inside the manufacturing facilities to monitor the operation process.

Our operations also produce waste water and chemical waste. We treat the waste water existing our bioreactors in our biological waste disposal facilities, and store hazardous wastes in special warehouse. We also contract with third parties for the disposal of hazardous materials and wastes. During the Track Record Period and up to the Latest Practicable Date, we did not incur material cost of compliance with relevant environment protection laws and regulations.

During the Track Record Period and up to the Latest Practicable Date, we complied with the relevant environmental and occupational health and safety laws and regulations and we did not have any incidents or complaints which had a material and adverse effect on our business, financial condition or results of operations during the period.

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. The table below sets forth the relevant details of the material licenses we hold for our operation in China:

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Drug Manufacturing License	RemeGen, Ltd.	Shandong Provincial Medical Products Administration	August 14, 2016	August 13, 2021
Certificate of Filing for Pathogenic Microorganism Laboratory and Science Experiments in Shandong Province (Microorganism Laboratory)	RemeGen, Ltd.	Yantai Municipal Health and Family Planning Committee	August 14, 2017	August 13, 2022
Certificate of Filing for Pathogenic Microorganism Laboratory and Science Experiments in Shandong Province (Molecular Biology Laboratory)	RemeGen, Ltd.	Yantai Municipal Health and Family Planning Committee	June 27, 2017	/

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INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our principal insurance policies cover property loss due to accidents or natural disasters, employee benefits liability and personal injury. We currently do not maintain insurance for adverse events in clinical trials as we estimate the risk exposure to be minimal. We currently do not maintain product liability insurance or key person insurance.

LEGAL PROCEEDINGS AND COMPLIANCE

As of the Latest Practicable Date, we were not a party to any actual or threatened legal or administrative proceedings which would have a material and adverse impact on our business, financial condition or results of operations. We are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business. However, we may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business.

Compliance

Substantially all of our operations are in the PRC. During the Track Record Period and as of the Latest Practicable Date, we did not experience any non-compliance that, in the opinion of our Directors, is likely to have a material adverse effect on our business, financial condition or results of operations. As advised by our PRC Legal Advisor, during the Track Record Period and up to the Latest Practicable Date, we have been in compliance with related laws and regulations in all material respects, and have obtained all necessary licenses, permits and certificates that are material in respect of our business in the PRC.

Set forth below is a summary of our systemic non-compliance matters under Guidance Letter HKEX-GL63-13 issued in July 2013 and last updated in March 2019 by the Stock Exchange during the Track Record Period and up to the Latest Practicable Date.

Deviation from intended use of loan proceeds

Background

For the year ended December 31, 2019, our Company has obtained a credit line of RMB52 million from Bank A and a credit line of RMB70 million from Bank B (together with Bank A, the “Lending Banks”), which were secured by pledging our Company’s assets. For the three months ended March 31, 2020, our Company has increased the credit line from Bank B from RMB70 million to RMB143 million, secured by pledging our Company’s assets.

Under these approved credit lines, our Company made drawdowns by entering into four loan contracts to draw down an aggregate amount of RMB146 million for the year ended December 31, 2019 and three loan contracts to draw down an aggregate amount of RMB60 million for the three months ended March 31, 2020 with the Lending Banks (the “Loan

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Contracts”) (the “Loans”). The Loans were revolving in nature and the maximum outstanding balance of the Loans at any time was RMB86 million during the year ended December 31, 2019 and RMB90 million during the three months ended March 31, 2020. We have fully repaid these Loans before March 31, 2020. Details of the Loan Contracts are as follows:

	<u>Lending banks</u>	<u>Loan amount</u> <i>(RMB million)</i>	<u>Interest rate</u>	<u>Loan drawdown date</u>	<u>Loan repayment date</u>
1	Bank A	26	5.50%	June 25, 2019	December 25, 2019
2	Bank B	40	6.31%	September 10, 2019	December 27, 2019
3	Bank B	20	6.31%	September 20, 2019	December 27, 2019
4	Bank B	60	6.31%	December 30, 2019	March 13, 2020 ⁽¹⁾
5	Bank B	30	6.31%	January 13, 2020	March 13, 2020
6	Bank B	25	6.31%	February 12, 2020	March 13, 2020
7	Bank B	5	6.31%	February 26, 2020	March 13, 2020

Note:

(1) RMB30 million was repaid on January 7, 2020 and the remaining RMB30 million was repaid on March 13, 2020.

To expedite the drawdown procedure, the Company submitted contracts with MabPlex and CelluPro (the “Connected Suppliers”) as supporting documents for each drawdown application (the “Supplier Contracts”). The transaction amounts stated in such Supplier Contracts were greater than the aggregate actual transaction amounts for the same period between our Company and the Connected Suppliers for the purchase of reagents and culture medium in the ordinary and usual course of business. Our Company, MabPlex and CelluPro were fellow subsidiaries of RC Pharma prior to the completion of the Reorganization in December 2019. Each of MabPlex, CelluPro and RC Pharma will be our connected persons upon [REDACTED].

The Loan Contracts provided that the loan proceeds should be used to make payment to the Connected Suppliers under the Supplier Contracts. Instead, the Connected Suppliers transferred the total Loan proceeds to our Company upon receiving the same from the Lending Banks (the “Bank Loan Transfer Arrangements”), we then used them for different purposes including settlements with MabPlex, settlement of related party loans and payables owed to RC Pharma and other general working capital uses.

Since the Lending Banks required a separate supplier’s contract to support each drawdown application and given that the average transaction amount of our supplier contracts was generally lower than the amount of the Loans applied for, the Lending Banks had indicated their preference for us to submit contracts with the Connected Suppliers (with aggregated amounts of our actual financial needs) as supporting documents in order to avoid the administrative burden of having to approve a large number of drawdown applications and for administrative convenience purpose. As such, it was mutually agreed between the Lending Banks and our Company that we would submit contracts with the Connected Suppliers to apply for the drawdowns, whilst the transaction amounts of such contracts would be increased to

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include our other financial needs. As confirmed by the Lending Banks, they were aware of the financial needs of our Company through their due diligence process before approving the credit lines and were aware of the abovementioned actual uses.

Our Directors confirmed that we obtained financing via the Bank Loan Transfer Arrangements because: (i) the Bank Loan Transfer Arrangements were administratively convenient for both the Lending Banks and our Company given the large number of drawdown applications which would otherwise be required; (ii) the Lending Banks were aware of the deviation from the stated use of loan proceeds; (iii) the Lending Banks did not take the view that the Bank Loan Transfer Arrangements were non-compliant; (iv) the responsible personnel of the Company were not aware of the non-compliant nature of this arrangement due to lack of proper legal advice; and (v) it was a practicable and expedient way to meet our financing needs.

Legal Impact

In preparing for the [REDACTED], we were advised by our PRC Legal Advisor that the Bank Loan Transfer Arrangements were not in strict compliance with the relevant PRC regulations. Upon becoming aware of such non-compliance, our Company ceased the Bank Loan Transfer Arrangements and repaid all outstanding principal amounts and interests of the Loans by March 2020, and no penalty has been imposed on us during the Track Record Period and up to the Latest Practicable Date.

As advised by our PRC Legal Advisor, the Bank Loan Transfer Arrangements were not in strict compliance with Article 19(iii) of the General Rules of Loans (中華人民共和國貸款通則) issued by the People’s Bank of China (“PBOC”) (the “General Rules”) which states that “obligations of a borrower are to: ... use a loan for the purposes as agreed in the loan contract”. It is not explicitly provided in the General Rules that our Company would be subject to administrative penalties imposed by the relevant PRC competent government authorities for the violation of Article 19(iii). This was supported by the following confirmations obtained in May and June 2020 from governmental authorities which, as advised by the PRC Legal Advisor, are the relevant PRC competent government authorities in respect of the Bank Loan Transfer Arrangements:

- i. The Yantai Office of China Banking and Insurance Regulatory Commission (中國銀行保險監督管理委員會煙台監管分局) (the “CBIRC”), the competent authority for the banking and insurance industries in Yantai, confirmed that, within its supervision scope, since 2017: (i) no activities of our Company for the purpose of illegally obtaining of bank loans have been found; (ii) our Company, our shareholders, directors and senior management have not been in violation of laws and regulations in respect of bank loan that will lead to administrative penalties; (iii) no record of administrative penalties has been found against them; and (iv) the Lending Banks, but not our Company, are subject to the regulations of the CBIRC and accordingly, no administrative penalties will be imposed on our Company in relation to the Bank Loan Transfer Arrangements or the Bill Transfer Arrangements (as defined below).

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- ii. The Yantai Central Branch of the People’s Bank of China (中國人民銀行) (the “PBOC”) confirmed that (i) no activities of the Company in respect of using of bills have been found to be in violation of the rules promulgated by PBOC; (ii) no administrative penalties have been found against our Company, our shareholders, directors and senior management; and (iii) the business of our Company is not within the PBOC’s scope of authority for imposing penalties.
- iii. The Financial Administration Bureau of Yantai Economic and Technological Development Area (煙台經濟技術開發區財政金融局) (the “Financial Bureau”, together with the CBIRC and PBOC, the “PRC Governmental Authorities”) confirmed that (i) use of the Bank Loan Transfer Arrangements was not for the purpose of obtaining bank loans illegally or fraudulently and the Bill Transfer Arrangements did not amount to finance fraud, bill fraud or illegal financing; (ii) our Company has repaid all bank loans when they were due on time since January 1, 2017; and (iii) the Bank Loan Transfer Arrangements and the Bill Transfer Arrangements do not constitute material non-compliance and the Financial Bureau will not impose any penalties against our Company, our shareholders, directors and senior management.

In addition, the Lending Banks confirmed that: (i) all principal amounts and interests under the Loans had been fully repaid; (ii) the Lending Banks did not take the view that the Bank Loan Transfer Arrangements were non-compliant; (iii) the Lending Banks would not hold our Company liable, or initiate any claims against our Company, for breach of the Loan Contracts or of PRC laws and regulations applicable to the Bank Loan Transfer Arrangements, including but not limited to claiming penalty; (iv) the Lending Banks would have extended the same principal amount to our Company with the same interest rates regardless of the specified use of proceeds; and (v) our Company’s business relationship with the Lending Banks would not be adversely affected by the Bank Loan Transfer Arrangements.

Based on the above, our PRC Legal Advisor is of the opinion that:

- on the bases of (i) the confirmations from the Lending Banks; and (ii) the fact that our Company has fully repaid the Loans, the likelihood of claims by the Lending Banks against our Company for the Bank Loan Transfer Arrangements is remote;
- on the basis of the confirmation from our Company, the Bank Loan Transfer Arrangements did not involve any fraud or dishonesty or any intent to obtain loans from the Lending Banks illegally, and our Company did not obtain any illegal benefits from such arrangements;
- on the basis of the confirmations from the PRC Governmental Authorities, our Company is not involved in any illegal or non-compliant activities in obtaining the Loans,

accordingly, our PRC Legal Advisor has advised that the Bank Loan Transfer Arrangements do not amount to any material non-compliances or criminal activities, and that

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our Company will not be subject to any administrative penalties by the PRC Governmental Authorities for the Bank Loan Transfer Arrangements. As such, the Bank Loan Transfer Arrangements are not expected to have any material adverse legal impact on our Company.

Financial impact

As a pre-revenue biotech Company, our financial needs have historically been funded by related party loans, bank borrowings, third party investments and government grants. Our Directors confirmed that, during the year ended December 31, 2019 and the three months ended March 31, 2020, our Group’s operating activities did not rely on the Loans in any material respect and the funds obtained could have been sourced elsewhere. For the analysis of our financial independence, please refer to the paragraphs headed “Relationship with our Controlling Shareholders – Independence from our Controlling Shareholders – Financial Independence” in this document.

The maximum outstanding balance of the Loans at any time was RMB86 million during the year ended December 31, 2019, and RMB90 million during the three months ended March 31, 2020. This was approximately 6.86% and 6.99%, respectively, of the total financial resources available to the Company under the abovementioned fundraising channels during the year ended December 31, 2019 and the three months ended March 31, 2020.

Since the completion of the Reorganization in December 2019, our Company has relied on our own independent fundraising ability, raising RMB826 million in total as of the Latest Practicable Date from the 2019 Subscription and the 2020 Subscription. Further, as of March 31, 2020, we had cash and cash equivalent of RMB288 million and, as of the Latest Practicable Date, we had a total of unutilized credit facilities of RMB630 million which were granted by Yantai Bank upon its approval for drawdowns.

Our Directors confirmed that, because of the foregoing, our Group’s financial position would not be adversely affected in any material respect without such Loans and therefore, we have not made any provision for the Bank Loan Transfer Arrangements.

Operational Impact

As a pre-revenue biotech company, our Company is primarily engaged in the research and development, application and commercialization of innovative biologics. As we would have sufficient financial resources available to carry out our principal business activities without the Loans, our Directors are of the view that the operations of our Company would not be affected without the Loans. Our Directors believe that the Bank Loan Transfer Arrangements have not had, and are not reasonably likely to have in the future, a material adverse impact on our business and operations.

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Rectification measures and internal control

Upon becoming aware of the non-compliance and with the advice of our professional advisors, our Company ceased the Bank Loan Transfer Arrangements since March 1, 2020 and has fully repaid all of the Loans under the Bank Loan Transfer Arrangements by March 13, 2020.

We have also implemented the following internal control measures to prevent recurrence of the non-compliant financing arrangements:

- (a) **Engagement of Internal Controls Consultant:** Since January 2020, we have engaged an independent internal control consultant (the “IC Consultant”). The IC Consultant has performed a thorough review of the Bank Loan Transfer Arrangements in the course of its engagement, including meetings, interviews and discussions with various departments and representatives of the Company. In March 2020, it provided recommendations on rectification measures, accordingly, we ceased the Bank Loan Transfer Arrangements and implemented the recommended policies (including the new loan management policy and fund management rules) to strengthen the monitoring of our Company’s internal fund flow process. In April 2020, the IC Consultant completed its review of our Company’s internal control systems and was of the view that the remedial measures have been properly implemented and no further deficiencies have been identified. For details of such remedial measures, please refer to the paragraph headed “(d) Adoption of Policies” below.
- (b) **Appointment of chief financial officer:** In preparation of the [REDACTED], our Company has appointed Mr. Li Jia as our chief financial officer, responsible for overseeing the financial management of the Group. In particular, Mr. Li supervises matters relating to the approval, reporting and monitoring of loans and bill-related transactions to prevent the recurrence of the non-compliant incidents. Mr. Li will also become our Company’s joint company secretary upon [REDACTED]. Given Mr. Li’s experience, our Directors believe that he will guide our Company to comply with the relevant rules and regulations when performing his duties. For details of Mr. Li’s biographical information, please refer to the section headed “Directors, Supervisors and Senior Management” in this document.
- (c) **Training:** In February and May 2020, members of our management team received trainings which covered relevant laws and regulations relating to the Bank Loan Transfer Arrangements, the Bill Transfer Arrangements, new policies to be adopted, and disciplinary actions for breach of such policies. Our Company will continue to conduct regular internal trainings and engage external professionals, including our PRC Legal Advisor, to meet its ongoing compliance obligations.

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- (d) Adoption of Policies: Since April 2020, our Company has implemented the new loan management policy and fund management rules. Under the new policies, the approval process will distinguish between two types of loans:
- (1) monthly and annual loan plans under our Company's annual budget will be submitted to the Board for approval annually; and
 - (2) for loans beyond the annual budget, our Company's finance department will be required to submit a loan application to the financial controller, who will review the requisite documentation and intended use of proceeds. In addition to Board authorization, the request will be subject to the approval of: (i) the chief financial officer, for loans below RMB10 million, (ii) a designated team, along with review by the internal audit department, for loans between RMB10 million and RMB30 million, and (iii) our Audit Committee, for loans over RMB30 million.
- (e) Enhanced Corporate Governance Structure: In preparation for the [REDACTED], we have also enhanced our corporate governance structure to strengthen its reporting and review structure. Our Company has established an Audit Committee comprising three independent non-executive directors, in compliance with Rule 3.21 of the Listing Rules. Our Audit Committee is responsible for reviewing and supervising our internal controls in relation to financial management periodically. From a perspective of ensuring strict compliance with the new loan management policy, it will approve loans which are over RMB30 million and beyond our annual budget. In addition, together with our internal audit department, it will also review our loan transactions on a quarterly basis.
- (f) External Review: We have engaged Rainbow Capital (HK) Limited as our compliance advisor in accordance with Rule 3A.19 of the Listing Rules upon the [REDACTED]. Our Company will also extend the engagement of the IC Consultant to continue to review our internal controls in relation to financial management on a quarterly basis until 24 months after the [REDACTED]. This would enable the IC Consultant to conduct further reviews on such internal control measures after the [REDACTED].

In light of the above, our Directors believe that the internal control measures adopted are sufficient and effective to prevent the recurrence of the non-compliant incidents in relation to the Bank Loan Transfer Arrangements, and nothing has come to the attention of the Joint Sponsors, as non-experts with respect to internal control, that would reasonably cause the Joint Sponsors to cast doubt on the Directors' views above.

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Indemnity given by the Controlling Shareholders

Pursuant to the Deed of Indemnity dated [●], our Controlling Shareholders have undertaken to fully indemnify us against, amongst other things, any and all liabilities arising from the Bank Loan Transfer Arrangements.

Bill Transfer Arrangements

Background

As a pre-revenue biotech company, our financial needs have historically been met by related party loans, bank borrowings, third party investments and government grants. Given that we were a wholly-owned subsidiary of RC Pharma prior to the completion of the Reorganization in December 2019, related party loans provided by RC Pharma has been a major source of financing for our Company historically and such related party loans have been provided in the form of cash or transfer of bank acceptance bills (the “Bills”). Both cash loans and transfer of Bills are treated as related party loans from an accounting perspective and there is no difference between the interest rates on cash loans and the transfer of Bills (i.e. at prevailing market interest rate comparable to what third party commercial banks would charge). Same as the terms for the cash loans, the repayment of the Bills to RC Pharma were settled in the form of cash payment in the amount of the face value of the Bills transferred plus interest. The Bills transfer arrangements were conducted as part of the then intra-group financial management to facilitate allocation and use of funds amongst RC Pharma and its subsidiaries (including our Company). RC Pharma, as the then sole shareholder of our Company, determined in its sole discretion the form of related party loan to be extended to our Company. Our officers who authorized the Bill Transfer Arrangements confirmed that they were previously not aware that the intra-group financial management involving the Bill Transfer Arrangements would not strictly comply with PRC laws or regulations as they did not have the relevant legal knowledge.

In its ordinary and usual course of business, many customers of RC Pharma settle their trade payables with RC Pharma by transferring Bills to it. The Bills obtained by RC Pharma from its customers were supported by genuine underlying transactions between RC Pharma and its customers. As Bills were obtained from customers of RC Pharma and were readily available for its use and for our utilization, RC Pharma considered the transfer of Bills an expedient method of extending related party loans to our Company. For the years ended December 31, 2018 and 2019, RC Pharma transferred the Bills in the aggregate amount of RMB86.8 million and RMB25.6 million to our Company, respectively. Our Company has then used such Bills for settlement of the payables to some of its suppliers which, in each and every case, were all supported by genuine underlying transactions.

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The interest rate RC Pharma charged us on the borrowings under the Bill Transfer Arrangements was 6.25% and 5.96% during the years ended December 31, 2018 and 2019, respectively, which are generally in line with the interest rates charged on the loans obtained by our Company directly from third party commercial banks. As confirmed by our Directors, no extra payment is charged or received by RC Pharma in connection with the Bill Transfer Arrangements. Neither our Directors, senior management nor any of their associates received any amount as a rebate in connection with the Bill Transfer Arrangements during the years ended December 31, 2018 and 2019.

Upon becoming aware of such non-compliance and the advice of our professional advisors, we ceased conducting such Bill Transfer Arrangements since March 31, 2019. The relevant Bills had been repaid and released by March 31, 2019. In addition, our Group has been operating in compliance with the PRC Negotiable Instruments Law (《中華人民共和國票據法》) since then.

Legal Impact

Article 10 of the PRC Negotiable Instruments Law states that bank acceptance bills must be transferred with and on the basis of the actual underlying transactions.

Although the Bills were supported by genuine underlying transactions between RC Pharma and its customers, such Bills were transferred to the Company as part of the then intra-group financial management without conducting actual transactions between RC Pharma and our Company (the “Bill Transfer Arrangements”). According to our PRC Legal Advisor, such arrangements were not in strict compliance with Article 10 of the PRC Negotiable Instruments Law and the Measures for Payment and Settlement (支付結算辦法) issued by the PBOC.

However, there are no provisions in the PRC Negotiable Instruments Law or any other relevant laws or administrative regulations that impose any administrative liability on Bill Transfer Arrangements, and during the Track Record Period and as of the Latest Practicable Date, no penalty has been so imposed. As such, our PRC Legal Advisor is of the view that the Bill Transfer Arrangements did not constitute any material non-compliance under PRC law.

According to the Review Report on the Draft PRC Negotiable Instruments Law (《中華人民共和國票據法(草案)》) by the Legal Committee of the National People’s Congress in May 1995, the Legal Committee had expressed the review opinion that “a major issue which emerged during the usage of the bills is that some parties issue bills without underlying transactions and use such bills to conduct fraudulent activities, therefore, it is proposed that the PRC Negotiable Instrument Laws shall include provisions such that the issuance, acceptance and transfer of bills shall be based on the principle of good faith and shall be supported by genuine underlying transactions and contractual relations”. Based on such review opinion by the Legal Committee of the National People’s Congress, our PRC Legal Advisor is of the view that Article 10 of the PRC Negotiable Instruments Law is intended to prevent and regulate the fraudulent activities in connection with the issuance of bills without support by genuine

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underlying transactions. Given that the Bills have been issued with support by genuine underlying transactions, the likelihood that the Bill Transfer Arrangements, as a subsequent transfer of legally issued bills, will be actually regulated or corrected by Article 10 of the PRC Negotiable Instruments Law is extremely low.

Further, pursuant to Article 3 of the PRC Criminal Law (中華人民共和國刑法), an act not expressly defined by criminal legislation shall not be convicted and sentenced. As the Bill Transfer Arrangements do not fall under any criminal legislation, our PRC Legal Advisor does not consider the Bill Transfer Arrangements to be a criminal act or constitute any criminal offence as a result.

The opinions above were supported by the confirmations obtained from the PRC Governmental Authorities as set out under the paragraph headed "Business – XIII. Legal Proceedings and Compliance – Compliant – Deviation from intended use of loan proceeds – Non-compliance with the General Rules of Loans and legal consequences" above. As advised by our PRC Legal Advisor, the PRC Governmental Authorities are the relevant PRC competent government authorities in respect of the Bill Transfer Arrangements.

Based on the above, our PRC Legal Advisor is further of the opinion that:

- on the bases that: (i) our Company ceased all Bill Transfer Arrangements since March 31, 2019; (ii) the confirmations obtained from the PRC Governmental Authorities that no administrative penalties from relevant governmental authorities have been imposed on our Company as of the date of this submission; and (iii) the fact that all the Bills involved in the Bill Transfer Arrangements had been repaid and released, the Bill Transfer Arrangements did not constitute material non-compliances and there are no provisions in the PRC Negotiable Instruments Law or any other relevant laws or administrative regulations that impose any administrative penalty on our Company from the relevant government authorities due to the Bill Transfer Arrangements;
- on the bases that: (i) the confirmation obtained from the PRC Governmental Authorities and confirmation from our Company that the Bill Transfer Arrangements did not involve any fraud or dishonesty; and/or (ii) pursuant to the PRC Criminal Law (中華人民共和國刑法), the Bill Transfer Arrangements are not considered to be a criminal act, and do not constitute any violation of criminal laws and regulations. Therefore, our Company would not be subject to any criminal liability; and

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- on the bases that: (i) all the Bills involved in the Bill Transfer Arrangements had been repaid and released and there is no dispute or civil claim between RC Pharma, our Company, or any other third parties in connection with the Bill Transfer Arrangements as of the date of this submission; (ii) the confirmations obtained from the PRC Governmental Authorities confirming that no administrative penalties have been imposed on our Company, our shareholders, directors and senior management and that there were no fraudulent activities involved in the Bill Transfer Arrangements, our Company will not be subject to any administrative penalties by the PRC Governmental Authorities for the Bill Transfer Arrangements, and the likelihood that any interested party would initiate any civil proceedings on our Company is low.

Accordingly, our PRC Legal Advisor has advised that the Bill Transfer Arrangements do not give rise to any material adverse legal consequences to our Company.

Financial Impact

Our Directors are of the view that, since the transfer of Bills from RC Pharma was merely a form of related party loan provided by RC Pharma, if our Company had not used such Bill Transfer Arrangements, RC Pharma would have provided related party loans by way of cash or in other forms. Furthermore, our Company could also obtain working capital through other financial resources such as bank borrowings, third party investments and government grants. During the years ended December 31, 2018 and 2019, the monthly incurred amount of the loans under the Bill Transfer Arrangements was immaterial as compared to the financial resources available to our Company during the same periods.

After we ceased the Bill Transfer Arrangements since March 31, 2019, RC Pharma has continued to provide related party loans by way of cash bearing an average interest rate of 5.96%, which are similar to the interest rates on the loans under the Bill Transfer Arrangements. Further, during the years ended December 31, 2018 and 2019, the interest rates charged by banks on loans we obtained directly from them are either 5.50% or 6.31%. As such, our Group did not achieve material savings as to financing costs, nor any artificial enhancement of our financial performance using the loans under the Bill Transfer Arrangements.

Our Directors confirmed that, because of the foregoing, our Group's financial position would not be adversely affected in any material respect without the loans under Bill Transfer Arrangements and therefore we have not made any provision for the Bill Transfer Arrangements.

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Operational Impact

As we did not rely on the Bill Transfer Arrangements to support our working capital or principal business activities in any material way, our Directors are of the view that our operating activities would not be affected even if the loans obtained under the Bill Transfer Arrangement was not available.

Enhanced Internal Control Procedures

Our Directors are of the view that the enhanced internal control measures as set out under the paragraphs headed “Compliance – Deviation from intended use of proceeds – rectification measures and internal control” in this section are also sufficient and effective to prevent the recurrence of the non-compliant incidents in relation to the Bill Transfer Arrangements.

Indemnity given by the Controlling Shareholders

Pursuant to the Deed of Indemnity dated [●], our Controlling Shareholders have undertaken to fully indemnify us against, amongst other things, any and all liabilities arising from the Bill Transfer Arrangements.

Directors’ and Joint Sponsors’ confirmation

Our Directors are of the view that the Bank Loan Transfer Arrangements and the Bill Transfer Arrangements (together, the “Arrangements”) do not, individually or in aggregate, constitute material non-compliance under Guidance Letter HKEX-GL63-13 issued in July 2013 and last updated in March 2019 by the Stock Exchange, and do not have any material impact on the suitability of our Directors under Rules 3.08 and 3.09 of the Listing Rules and the suitability of our Company under Rule 8.04 of the Listing Rules because: (i) our Directors are of the view that the Arrangements did not have, and are reasonably unlikely to have in the future, a material financial or operational impact on our Company; (ii) the internal control measures adopted are sufficient and effective to prevent future non-compliances in relation to Arrangements; (iii) the Arrangements did not involve any fraud or dishonesty on the part of our Company or of our Directors, nor did our Company obtain any inappropriate benefits from the Arrangements; (iv) neither our Directors, senior management nor any of their associates received any rebate or other financial interest in connection with the Arrangements; (v) our Company did not benefit from any material savings in interest expenses by using the Loans or the Bills given that their interest rates were consistent with the prevailing market interest rate for ordinary commercial loans; (vi) our enhanced corporate governance structure (including the appointment of independent non-executive Directors and the setting up of the Audit Committee in accordance with the requirements of the Listing Rules) will be beneficial for us to prevent the reoccurrence of non-compliance related to the Arrangements; and (vii) as our Directors were mainly focused on the R&D activities of the Company, their inadvertent oversight to identify the technical non-compliant nature of the Arrangements at the time should be assessed holistically bearing the core business operation of the Company in mind. As far as our Directors are aware, save for the Arrangements, there has not been any material issues with our compliance record. Accordingly, our Directors are of the view that the systemic non-compliant incidents in relation to the Arrangements should not affect their suitability or competence to act as our Directors.

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Based on: (i) the confirmations obtained by the Company from the PRC Governmental Authorities; (ii) the above opinions of the Company’s PRC Legal Advisor; (iii) the rectification measures and internal control procedures adopted by the Company; and (iv) the independent due diligence conducted by the Joint Sponsors (including but not limited to independent interviews with the Company’s management, suppliers and the Lending Banks, obtaining and reviewing relevant underlying transaction documents, and discussions with the IC Consultant on the progress and effectiveness of the Company’s rectification measures and internal controls), nothing has come to the Joint Sponsors’ attention in relation to the Arrangements, individually or in aggregate, that would lead them to cast doubt on the Directors’ views above.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We are exposed to various risks in our business operations and we recognize that risk management is critical to our success. Please refer to the section headed “Risk Factors” for a discussion of various operational risks and uncertainties we face. We are also exposed to various market risks, in particular, credit, liquidity, interest rate and currency risks that arise in the normal course of our business. Please refer to “Financial Information – Market Risk Disclosure” for a discussion of these market risks.

We have adopted a serious of risk management policies which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an on-going basis. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors. Our audit committee, and ultimately our Directors supervise the implementation of our risk management policies.

To monitor the ongoing implementation of risk management policies and corporate governance measures after the [REDACTED], we have adopted or will continue to adopt, among other things, the following risk management measures:

- Our audit committee will oversee and manage the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) reviewing and approving our corporate risk tolerance; (iii) monitoring the most significant risks associated with our business operation and our management’s handling of such risks; (iv) reviewing our corporate risk in the light of our corporate risk tolerance; and (v) monitoring and ensuring the appropriate application of our risk management framework across our Group.

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- Our Board will be responsible for (i) formulating our risk management policy and reviewing major risk management issues of our Company; (ii) providing guidance on our risk management approach to the relevant departments in our Company; (iii) reviewing the relevant departments’ reporting on key risks and providing feedbacks; (vi) supervising the implementation of our risk management measures by the relevant departments; and (v) reporting to our audit committee on our material risks.
- The relevant departments in our Company, including but not limited to the finance department, the legal department and the human resources department, are responsible for implementing our risk management policy and carrying out our day-to-day risk management practice. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, prioritization, measurement and categorization of all key risks that could potentially affect their objectives; (iii) prepare a risk management report annually for our chief executive officer’s review; (iv) continuously monitor the key risks relating to their operation or function; (v) implement appropriate risk responses where necessary; and (vi) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

We consider that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

Internal Control

Our Board is responsible for establishing our internal control system and reviewing its effectiveness. We have engaged an independent internal control consultant (the “Internal Control Consultant”) to perform certain agreed-upon procedures (the “Internal Control Review”) in connection with the internal control during the period from January 1, 2018 to December 31, 2019 of our Company and our major operating subsidiaries in certain aspects, including financial reporting and disclosure controls, corporate-level control, human resources and payroll management, general controls of IT system and other procedures of our operations. The Internal Control Consultant performed the Internal Control Review in January 2020 and follow-up reviews in May 2020. As of the Latest Practicable Date, there were no material outstanding issues relating to our Group’s internal control.

During the Track Record Period, we regularly reviewed and enhanced our internal control system. Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding each aspect of our business operation, such as related party transaction, risk management, protection of intellectual property, environmental protection and occupational health and safety.

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For more information, please refer to the paragraph headed “– Intellectual Property” and “– Environmental Matters and Workplace Safety.” We provide periodic training about these measures and procedures to our employees as part of our employee training program. Our internal audit department conducts audit field work to monitor the implementation of our internal control policies, reports the weakness identified to our management and audit committee and follows up on the rectification actions.

- Our Directors (who are responsible for monitoring the corporate governance of our Group) with help from our legal advisors, will also periodically review our compliance status with all relevant laws and regulations after the [REDACTED].
- We have established an audit committee which (i) makes recommendations to our Directors on the appointment and removal of external auditors; and (ii) reviews the financial statements and renders advice in respect of financial reporting as well as oversees internal control procedures of our Group.
- We have engaged Rainbow Capital (HK) Limited as our compliance advisor to provide advice to our Directors and management team until the end of the first fiscal year after the [REDACTED] regarding matters relating to the Listing Rules. Our compliance advisor is expected to ensure our use of funding complies with the section headed “Future Plans and Use of [REDACTED]” in this document after the [REDACTED], as well as to provide support and advice regarding requirements of relevant regulatory authorities in a timely fashion.
- We plan to provide various and continuing trainings to update our Directors, senior management, and relevant employees on the latest PRC laws and regulations from time to time with a view to proactively identify any concerns and issues relating to any potential non-compliance.
- We intend to maintain strict anti-corruption policies among our sales personnel and distributors in our sales and marketing activities and we believe we will therefore be less affected by the increasingly stringent measures taken by the PRC government to correct corruptive practices in the pharmaceutical industry. We will also ensure that our sales and marketing personnel comply with applicable promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations, also known as off-label use, and limitations on industry-sponsored scientific and educational activities.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

OVERVIEW

As of the Latest Practicable Date, Mr. Wang was the sole director of RongChang Holding Group LTD. and the sole executive partner of each of the Onshore ESOP Platforms and Yantai Rongda Venture Capital Center (Limited Partnership) (煙台榮達創業投資中心(有限合夥)) (“Yantai Rongda”), as such, he controlled the exercise of the voting rights attached to a total of 160,557,199 Shares held by RongChang Holding Group LTD., the Onshore ESOP Platforms and Yantai Rongda. As of the Latest Practicable Date, Dr. Fang directly owned 26,218,320 Shares and was indirectly interested in 39,600,000 Shares through I-NOVA Limited, a BVI entity wholly-owned by Dr. Fang.

On April 16, 2020, Mr. Wang, Dr. Fang and each of the other Concert Parties entered into a concert party agreement to confirm that they have acted in concert in the management, decision-making and all major decisions of our Group. As of the Latest Practicable Date, the Concert Parties are entitled to exercise voting rights of approximately 56.35% of the total issued share capital of our Company. Immediately upon completion of the [REDACTED] (assuming the [REDACTED] is not exercised), the Concert Parties will be entitled to exercise voting rights of approximately [REDACTED]%. Therefore, the Concert Parties are considered as our Controlling Shareholders upon [REDACTED].

DELINEATION OF BUSINESS

Business of our Group

We are a commercial-ready biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics for the treatment of autoimmune, oncology and ophthalmic diseases with unmet medical needs in China and globally (the “Core Business”). As of the Latest Practicable Date, we had a robust pipeline of more than 10 innovative drug candidates including five that have entered into the clinical trials and targeting 17 indications.

Excluded Businesses

RC Pharma

As of the Latest Practicable Date, our Controlling Shareholders are indirectly interested in 63.93% equity interest in RC Pharma, a leading platform based in the PRC with subsidiaries engaging in the pharmaceutical industry focusing on the research and development of small molecule drugs and Chinese medicines, sale of drugs, CDMO and biomedical incubation businesses in China and the U.S. Our Directors are of the view that such businesses are unlikely to give rise to any direct or indirect competition with the business of our Group, the details of such subsidiaries are set out below:

- (a) *Rongchang Pharma (Zibo) Co., Ltd.* (榮昌製藥(淄博)有限公司) (“Rongchang Zibo”)

Rongchang Zibo is a wholly-owned subsidiary of RC Pharma. It is primarily engaged in the research and development, manufacturing and sales of various drugs and ointments for the treatment of a variety of conditions such as hemorrhoid bleeding, insomnia, heartburn, dizziness, coughing, fever and headache, etc. and they do not target any autoimmune diseases, or conditions in the oncology or ophthalmology areas. Rongchang Zibo is focused on products with ingredients traditionally found in Chinese medicines and Rongchang Zibo is in the possession of its own know-how, technologies and other intellectual property during the conduct of its business. Given that its products

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

are of a different nature with different targeting conditions or therapeutic areas as compared to our innovative biologics which are mainly focused in the therapeutic areas of autoimmune diseases, oncology and ophthalmology, our Directors are of the view that the business of Rongchang Zibo is unlikely to give rise to any direct or indirect competition with the business of our Group.

(b) *Beijing Rongchang Medicament Research Institute Co., Ltd.* (北京榮昌藥物研究院有限公司) (“*Beijing Rongchang*”)

Beijing Rongchang is a wholly-owned subsidiary of RC Pharma. It is principally engaged in handling registrational affairs, safety and compliance matters, as well as intellectual properties and trademark related matters for the RC Pharma Group. The business model of Beijing Rongchang and our Group is materially different and Beijing Rongchang is not involved in research, development and commercialization of drugs. As such, our Directors are of the view that the business of Beijing Rongchang is unlikely to give rise to any direct or indirect competition with the business of our Group.

(c) *Yantai Lida Medicine Co., Ltd.* (煙台立達醫藥有限公司) (“*Lida*”)

Lida is a wholly-owned subsidiary of RC Pharma. It is primarily engaged in the sales of drugs produced by the RC Pharma Group and provision of relevant ancillary services. The business model of Lida and our Group is materially different and they are not involved in research, development and commercialization of drugs. As such, our Directors are of the view that the business of Lida is unlikely to give rise to any direct or indirect competition with the business of our Group.

(d) *Yantai Yeda International Biomedical Innovation Incubation Center Co., Ltd.* (煙台業達國際生物醫藥創新孵化中心有限公司) (“*Yeda Incubation*”) and its subsidiaries (“*Yeda Incubation Group*”)

RC Pharma established Yeda Incubation with Yantai Yeda Economic Development Group Co., Ltd. (煙台業達經濟發展集團有限公司), a company wholly-owned by the Yantai State-owned Assets Supervision and Administration Commission of the State Council, in May 2017. RC Pharma is interested in 55% equity interest in Yeda Incubation. The Yeda Incubation Group is an incubator platform that provides a full range of services and support throughout the healthcare R&D cycle of its clients. One of Yeda Incubation’s subsidiaries, Shanghai Kangkang Medical Technology Co., Ltd. (上海康康醫藥科技有限公司) (“Kangkang”), is a CRC service provider and is principally engaged in the provision of management services for clinical trials. Yeda Incubation Group advises and facilitates the business development of its incubation portfolio company or provides clinical trial management services to its customers and does not engage in the research, development and commercialization of drugs, and the business model of Yeda Incubation Group and our Group is materially different. As such, our Directors are of the view that the business of Yeda Incubation Group is unlikely to give rise to any direct or indirect competition with the business of our Group.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

(e) MabPlex and its subsidiaries (the “MabPlex Group”)

As of the Latest Practicable Date, MabPlex is held as to 41.96% by and is a subsidiary of RC Pharma through control of the composition of a majority of the board of directors of MabPlex. The MabPlex Group is a global contract development and manufacturing organization (“CDMO”) and undertakes contract development and manufacturing of biopharmaceuticals, including monoclonal antibodies, recombinant proteins, antibody drug conjugates and bispecifics. MabPlex has operations in both China and the U.S. MabPlex Group operates at a different segment of the pharmaceutical development industry chain and derives its revenue from pharmaceutical developers who engages MabPlex Group for its contract development and manufacturing services. Therefore, the MabPlex Group operates on a fundamentally different revenue model from our Group. It does not engage in research, development or manufacturing of its own drugs, and the business model of MabPlex and our Group is materially different. As such, our Directors are of the view that the business of MabPlex is unlikely to give rise to any direct or indirect competition with the business of our Group.

(f) CelluPro

CelluPro is a modern high-tech enterprise specialized in the development, production and sales of cell culture medium. RC Pharma and MabPlex holds 49% and 51% of CelluPro’s share capital, respectively. As of the Latest Practicable Date, CelluPro does not engage in research, development or manufacturing of its own drugs, and the business model of CelluPro and our Group is materially different. As such, our Directors are of the view that the business of CelluPro is unlikely to give rise to any direct or indirect competition with the business of our Group.

Clear Delineation of Business

As described above, each of RC Pharma, Rongchang Zibo, Beijing Rongchang, Lida, the Yeda Incubation Group, the MabPlex Group and CelluPro (the “Excluded Companies”) has different products, business focuses and business models from the Group. Accordingly, the other businesses and companies in which our Controlling Shareholders are interested are different in nature from our Core Business. Given the clear delineation between our Core Business and the Excluded Companies’ businesses as well as the non-competition arrangements in place, our Board is satisfied that our business is and will continue to be independent of our Controlling Shareholders. Given the difference in business focuses, our Controlling Shareholders has no current intention of injecting other businesses from the Excluded Companies into our Group upon [REDACTED]. For details of the non-competition arrangements entered into among our Group and our Controlling Shareholders, please refer to paragraphs headed “– Non-competition Undertaking” in this section.

Save as disclosed above, as of the Latest Practicable Date, our Controlling Shareholders confirm that they did not have an interest in a business, apart from the business of our Group, which competes or is likely to compete, directly or indirectly, with our business, that requires disclosure under Rule 8.10 of the Listing Rules.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

INDEPENDENCE FROM OUR CONTROLLING SHAREHOLDERS

We believe that we are capable of carrying on our business independently from our Controlling Shareholders and their associates upon [REDACTED] for the following principal reasons:

Operational Independence

Although our Controlling Shareholders will retain a controlling interest in us after [REDACTED], for the reasons stated below, we have full rights to make all decisions on, and to carry out, our own business operations independently. We have our independent and separate senior management team and our own staff to support the operations and management of our Core Business. We have registered the relevant intellectual property rights relating to relevant technologies of our business and our drug candidates. We hold the licenses and qualifications necessary to carry on our current business, and have sufficient capital, facilities, technology and employees to operate the business independently from our Controlling Shareholders. We own the land use rights and building ownership certificates of our main campus on 107,702 m² of land located in Yantai. We have access to suppliers and customers independently from and not connected to our Controlling Shareholders for sources of suppliers and customers.

We have conducted certain connected transactions or continuing connected transactions with the Excluded Companies, including purchase of materials, property leases, research and development and manufacturing services, CRC services and general services. For reasons and further details on such transactions, please refer to the section headed “Connected Transactions” in this document.

Notwithstanding such connected transactions or continuing connected transactions, we have been operating and will continue to operate independently from the Excluded Companies on the following bases:

- i. although we will continue to purchase materials such as cell culture medium from CelluPro, there are other readily available suppliers in the market and such products may be purchased from Independent Third Parties at reasonable prices;
- ii. although we will continue to use research and development and manufacturing services of MabPlex due to its familiarity with our drug candidates and service requests, there are other readily available CDMO service providers in the market. We may also seek alternative service providers who are Independent Third Parties without any material adverse effect on our business and operations;
- iii. although we will continue to use the CRC services provided by Kangkang, such services may be sourced from Independent Third Parties at reasonable fees. We may also seek alternative service providers who are Independent Third Parties without any material adverse effect on our business and operations;
- iv. the general services provided by RC Pharma including but not limited to utilities billing and other miscellaneous services are standardized services provided by RC Pharma to all corporations located in the Rongchang Biopharmaceutical Park. We own the land use rights and building ownership certificates of our buildings located in the Rongchang Biopharmaceutical Park;

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- v. we use the properties leased from Yeda Incubation as incubation facilities, office premises and cleanrooms fulfilling relevant GMP requirements, such leases are a transitional arrangement pending completion of our buildings under construction. We may also seek appropriate alternative locations from Independent Third Parties without any material adverse effect on our business and operations;
- vi. the revenue derived from our property leases with Lida and MabPlex are ancillary in nature and unrelated to our Core Business as an innovative drug developer and we do not rely on such revenue for our business and operations;
- vii. such connected transactions or continuing connected transactions are entered into during our ordinary and usual course of business based on arm’s length negotiations and on normal commercial terms, which are fair and reasonable, and are in the interest of our Company and Shareholders as a whole; and
- viii. we have put in place certain internal review procedures for our non-exempt continuing connected transactions. For details, please refer to the paragraphs headed “Connected Transactions – Internal Control Measures for Non-exempt Continuing Connected Transactions” in this document.

Based on the above, our Directors are satisfied that there is no operational dependence by us on our Controlling Shareholders.

Management Independence

Our Board and senior management function independently from our Controlling Shareholders. Our Board comprises four executive Directors, two non-executive Directors and three independent non-executive Directors. The table below sets forth the details of directorship and senior management in our Company and within the Excluded Companies:

Name of Director/ Senior Management	Positions in our Company	Positions at the Excluded Companies
Mr. Wang	executive Director and chairman of our Board	Chairman of RC Pharma; director of MabPlex (not involved in day-to-day operations)
Dr. Fang	executive Director, chief executive officer and chief scientific officer	Director of RC Pharma; Chairman of MabPlex (not involved in day-to-day operations)
Mr. Lin Jian	executive Director	None
Dr. He Ruyi	executive Director, chief medical officer and head of clinical research	None
Dr. Wang Liqiang	non-executive Director (not involved in our day-to-day operations)	General manager and director of RC Pharma and Lida; chairman and legal representative of Rongchang Zibo; Chairman of Yeda Incubation

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<u>Name of Director/ Senior Management</u>	<u>Positions in our Company</u>	<u>Positions at the Excluded Companies</u>
Dr. Su Xiaodi	non-executive Director	None
Ms. Yu Shanshan	independent non-executive Director	None
Mr. Hao Xianjing	independent non-executive Director	None
Dr. Lorne Alan Babiuk	independent non-executive Director	None
Dr. Fu Daotian	president	None
Mr. Wen Qingkai	secretary to our Board	Director of RC Pharma and MabPlex (not involved in day-to-day operations)
Mr. Li Jia	chief financial officer and joint company secretary	None

Our Board comprises four executive Directors, two non-executive Directors and three independent non-executive Directors. Other than Mr. Wang, Dr. Fang, Mr. Wang Liqiang and Mr. Wen Qingkai, none of our other Directors or senior management holds any directorship or senior management role in the Excluded Companies. Although (i) Mr. Wang is the chairman of RC Pharma and a director of MabPlex, (ii) Dr. Fang is a director of RC Pharma and the chairman of MabPlex, and (iii) Mr. Wen is a director of RC Pharma and MabPlex, their respective roles at RC Pharma and MabPlex are of a non-executive nature. They are primarily responsible for overall strategic development and high level supervision of and do not participate in the day-to-day management or operations of RC Pharma and MabPlex, the daily operation of each of these entities are handled by their independent management teams. All of Mr. Wang, Dr. Fang and Mr. Wen have a track record of devoting sufficient time and energy to discharge their duties as our Directors and senior management and they will continue to focus exclusively on our Group’s business. When performing their duties as executive Directors and senior management, they have been and will continue to be supported by the separate and senior management team of our Group.

Further, Dr. Wang Liqiang is our non-executive Director and is responsible for supervising the management of our Board, but is not involved in the day-to-day management or operations of our business. Thus, his roles in the Excluded Companies will not affect his abilities to discharge his duties as our non-executive Director.

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

In the event that the three overlapping Directors are required to abstain from any Board meeting of our Company on any matter which may give rise to a potential conflict of interest with the Excluded Companies, the remaining Directors will have sufficient expertise and experience to fully consider such matter. Notwithstanding the three overlapping Directors, our Directors, including the independent non-executive Directors, believe that our Board and senior management are able to perform their roles in our Company independently and that we are capable of managing our business independently from our Controlling Shareholders for the following reasons:

- (i) our Group's overlapping Directors have had dual roles in the Excluded Companies because our Company was a subsidiary of RC Pharma prior to the Reorganization. Given the Excluded Companies do not and are not likely to compete, directly or indirectly, with our Core Business and with the corporate governance measures in place to manage existing and potential conflicts of interests, the dual roles assumed by the overlapping Directors will not affect the requisite degree of impartiality required of our Directors in discharging their fiduciary duties owed to our Company;
- (ii) in the event of a conflict of interest arising out of any transactions to be entered into by the Group, the Directors with a conflicting interest shall abstain from voting in respect of such transactions and shall not be counted in forming a quorum at the relevant Board meetings;
- (iii) except for Dr. Wang Liqiang, all of our Directors, including our three independent non-executive Directors, will not have any role in the daily management of operation in the Excluded Companies, and these Directors will be able to exercise independent judgment free of any conflict of interest. With these Directors comprising approximately 90% of our Board, there will be sufficiently robust and independent voices on our Board to address any actual or potential conflict of interest and to protect the interests of the Company and of the Shareholders as a whole;
- (iv) our independent non-executive Directors have extensive experience in different areas and have been appointed in accordance with the requirements under the Listing Rules to ensure that the decision of the Board are made only after due consideration of independent and impartial opinions. In addition, certain matters of our Company, including continuing connected transactions and other matters referred to in the Deed on Non-Competition, must always be referred to the independent non-executive Directors for review and they will confirm in our annual report that our continuing connected transactions have been entered into in our ordinary and usual course of business, are on normal commercial terms or better and on terms that are fair and reasonable and in the interests of our Shareholders as a whole;
- (v) each of our Directors is aware of his/her fiduciary duties as a Director, which require, among other things, that he/she acts for the Company's benefit and best interests and do not allow any conflict between his/her duties as a Director and his personal interests; and

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- (vi) the other Directors, Supervisors and senior management members (other than Mr. Wen Qingkai) are independent from our Controlling Shareholders. They have substantial experience in the industry which we are engaged in. Accordingly, they are able to discharge their duties independently from our Controlling Shareholders.

Financial Independence

As a pre-revenue biotech company, our financial needs have historically been met by related party loans, bank borrowings, third party investments and government grants. Prior to the Reorganization, our Company was a wholly-owned subsidiary of RC Pharma and the related party loans provided by RC Pharma as intra-group financing have been a major source of financing for our Company. Nonetheless, since the completion of the Reorganization in December 2019, we have relied on our own fundraising ability independently from our Controlling Shareholders and have successfully raised RMB826 million in total as of the Latest Practicable Date from the 2019 Subscription and the 2020 Subscription. Also, the [REDACTED] will further broaden our financing options to support our financial independence.

Our financial management system and our financial decision-making process are independent from our Controlling Shareholders. We have established our own finance department with a team of financial staff, who are responsible for financial control, accounting, reporting, group credit and internal control functions of our Company, independent from our Controlling Shareholders. We can make financial decisions independently and our Controlling Shareholders do not intervene with our use of funds. We have also established an independent audit system, a standardized financial and accounting system and a complete financial management system. In addition, we have been and are capable of obtaining financing from third parties without relying on any guarantee or security provided by our Controlling Shareholders or their respective associates and we have readily available financial resources to support our operations. In preparation of the [REDACTED], we have appointed a chief financial officer who is responsible for overseeing the financial management of our Group. We have also established an Audit Committee comprising our three independent non-executive Directors in compliance with Rule 3.13 of the Listing Rules.

During the Track Record Period, we received certain interest bearing related party loan from RC Pharma. As of the Latest Practicable Date, a related party loan with a principal amount of RMB404.6 million and interest payment of RMB12.4 million remaining outstanding and owed to RC Pharma. Notwithstanding the outstanding interest bearing related party loan, the Directors believe that our Group will not be financially dependent on our Controlling Shareholders upon the [REDACTED] as we intend to utilize our internal financial resources and approximately 15% of the net [REDACTED] from the [REDACTED] to fully repay the borrowings from RC Pharma shortly after the [REDACTED], for details of our proposed use of net [REDACTED] from the [REDACTED], please refer to “Future Plans and Use of [REDACTED]” in this document.

DIRECTORS’ INTEREST IN COMPETING BUSINESS

As of the Latest Practicable Date, save as disclosed in this section, none of our Directors had an interest in any business which competes or is likely to compete, either directly or indirectly, with our business, that requires disclosure under Rule 8.10 of the Listing Rules.

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NON-COMPETITION UNDERTAKING

Deed of Non-Competition

In order to ensure that competition does not develop between us and other business activities and/or interests in businesses of our Controlling Shareholders (collectively, the “Covenantors” and each a “Covenantor”), the Covenantors entered into the Deed of Non-competition in favor of the Company. Pursuant to the Deed of Non-competition, the Covenantors have undertaken to us (for ourselves and for the benefit of our subsidiaries) that they would not and would use their best endeavors to procure that their respective associates (except any members of the Group) would not, directly or indirectly, or as principal or agent either on their own account or in conjunction with or on behalf of any person, firm, company or entity, carry on, engage in, invest in, participate in, attempt to participate in, hold any right or have any financial interests in or otherwise be involved in or interested (economically or otherwise) in, any business or investment activities which are the same as, similar to or in competition with our core business, being discovery, development and commercialization of biologics for the treatment of autoimmune diseases, oncology and ophthalmology diseases (the “**Restricted Business**”) (whether alone or jointly with another person and whether directly or indirectly or on behalf of or to assist or act in concert with any other person).

The Covenantors have further irrevocably undertaken that during the Restricted Period (as defined below), they should first offer new business opportunities to us in the following manner when any business, investment or other business opportunities (a “New Business Opportunities”) related to the Restricted Business becomes available to them:

- (a) They will make referral of the New Business Opportunities to us, and will as soon as possible inform us in writing (“Offer Notice”) about all necessary and reasonably required information in respect of any New Business Opportunities (including but not limited to details of the nature and investment or acquisition cost of the New Business Opportunities) for us to consider (a) whether the relevant New Business Opportunities will compete with our business, and (b) whether taking up the New Business Opportunities is in the interest of our Group.
- (b) Upon receipt of the Offer Notice, the independent non-executive Directors will consider whether to pursue the New Business Opportunities, taking into account whether the relevant New Business Opportunities would be able to achieve a sustainable profitability level, whether they are in line with the prevailing development strategies of our Group, and whether they are in the best interest of the Shareholders. Our Company must inform the Covenantors in writing within 20 Business Days after receipt of the Offer Notice about its decision on whether the New Business Opportunities will be pursued.
- (c) Only when (a) the Covenantors have received our notice to reject the New Business Opportunities and our confirmation that the relevant New Business Opportunities are not considered to be able to compete with our core business; or (b) the

RELATIONSHIP WITH OUR CONTROLLING SHAREHOLDERS

Covenantors have not received the relevant notice from our Company within the period as stated above in paragraph (ii) after the Offer Notice has been received by us, then the Covenantors will be entitled to take up the New Business Opportunities on terms and conditions that are not more favorable than those specified in the Offer Notice issued to us.

If material changes occur in the terms and conditions of the New Business Opportunities after the referral of which have been made or procured to be made to us by the Covenantors, referral of the revised New Business Opportunities shall be made by the Covenantors to us again in the manner as stated above.

The above undertaking does prevent the Covenantors from:

- (a) holding and/or being interested in, directly or indirectly, an interest in the Group from time to time;
- (b) holding and/or being interested in, directly or indirectly, an investment or interest in units or shares of any company, investment trust, joint venture, partnership or other entity which engage in any Restricted Business (collectively the "Competing Entity") where the aggregate number of shares held by the Covenantors and/or their respective associates (except any members of the Group) does not exceed 10% of the issued shares of that class of shares of such Competing Entity provided that (i) such investment or interest does not grant, nor does any Covenantor and/or its associates (except any members of the Group) otherwise hold, any right to control the composition of the board of directors or managers of such Competing Entity nor any right to participate, directly or indirectly, in such Competing Entity; and (ii) none of the Covenantors and their respective associates (except any members of the Group) is the controlling shareholder of such Competing Entity;
- (c) any Restricted Business which our Group has decided not to make an investment as approved in writing by all the independent non-executive Directors; or
- (d) an investment or commercial opportunity relating to the Restricted Business has first been offered or made available by any of the Covenantors to us, and either we do not respond to the offer by the due date, or after decision by our independent non-executive Directors we decline in writing to accept such an opportunity.

Under the Deed of Non-competition, each Covenantor has further undertaken jointly and severally, to us (for ourselves and as trustee for the benefit of each of our subsidiary from time to time) the following:

- (i) each Covenantor has acknowledged that the independent non-executive Directors will review, where necessary and at least on an annual basis, the compliance with the undertaking contained in the Deed of Non-competition;

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- (ii) it will provide, and will procure its associates (other than members of our Group) to provide, where necessary and at least on an annual basis, all information necessary for the review by our independent non-executive Directors, subject to any relevant laws, rules and regulations or any contractual obligations, to enable the independent non-executive Directors to enforce the Deed of Non-competition;
- (iii) without prejudicing the generality of paragraph (i) above, it will provide to us with an annual declaration on its compliance with the terms of the Deed of Non-competition for inclusion in our annual report;
- (iv) each Covenantor has acknowledged that our Company will make disclosures in our annual reports or by way of announcements regarding the decisions and the rationale of those decisions (as appropriate) of our independent non-executive Directors on matters referred to in the Deed of Non-competition and each of them gives its general consent to such disclosure; and
- (v) in the event that any disagreement between the Covenantors and us as to whether or not any activity or proposed activity of the Covenantors constitutes a Restricted Business, the matter shall be determined by our independent non-executive Directors whose majority decision shall be final and binding; and
- (vi) each Covenantor shall excuse themselves from, and abstain from voting and not be counted as quorum of, any meetings of Shareholders for consideration and approval of any matters referred to in the Deed of Non-competition which have or may give rise to conflicts of interest, actual or potential.

Pursuant to the Deed of Non-competition, the above restrictions would apply throughout the Restricted Period, being the period commencing from the [REDACTED] and ending on the earlier of the following date:

- (1) the Covenantors and/or their respective associates (other than any member of the Group) ceasing to hold, directly or indirectly, an aggregate of at least 30% of the issued share capital (or ceasing the control to exercise the voting rights of such shareholding) of our Company;
- (2) the Covenantors and/or their respective associates (other than any member of the Group) considered together as if they were one single Shareholder ceasing to be the largest single Shareholder; or
- (3) our Shares ceasing to be listed on the Stock Exchange (except for temporary suspension of trading of our Shares).

CORPORATE GOVERNANCE

Our Company will comply with the provisions of the Corporate Governance Code in Appendix 14 to the Listing Rules (the "Corporate Governance Code"), which sets out principles of good corporate governance.

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Our Directors recognize the importance of good corporate governance in protection of our Shareholders’ interests. We would adopt the following measures to safeguard good corporate governance standards and to avoid potential conflict of interests between our Group and the Controlling Shareholders:

1. where a Shareholders’ meeting is to be held for considering proposed transactions in which the Controlling Shareholders or any of their respective associates has a material interest, the Controlling Shareholders will not vote on the resolutions and shall not be counted in the quorum in the voting;
2. our Company has established internal control mechanisms to identify connected transactions. Upon the [REDACTED], if our Company enters into connected transactions with a Controlling Shareholder or any of his/her/its close associates, our Company will comply with the applicable Listing Rules;
3. our independent non-executive Directors will review, on an annual basis, whether there is any conflict of interests between our Group and the Controlling Shareholders (the “Annual Review”) and provide impartial and professional advice to protect the interests of our minority Shareholders;
4. the Controlling Shareholders will undertake to provide all information necessary, including all relevant financial, operational and market information and any other necessary information as required by the independent non-executive Directors for the Annual Review;
5. our Company will disclose decisions (with basis) on matters reviewed by the independent non-executive Directors either in its annual report or by way of announcements;
6. where our Directors reasonably request the advice of independent professionals, such as financial advisors, the appointment of such independent professionals will be made at our Company’s expenses; and
7. we have appointed Rainbow Capital (HK) Limited as our compliance advisor to provide advice and guidance to use in respect of compliance with the Listing Rules, including various requirements relating to corporate governance.

Based on the above, our Directors are satisfied that sufficient corporate governance measures have been put in place to manage conflicts of interest between our Group and the Controlling Shareholders, and to protect minority Shareholders’ interests after the [REDACTED].

CONNECTED TRANSACTIONS

OUR CONNECTED PERSONS

We have entered into a number of agreements with our connected persons in our ordinary and usual course of business. The table below sets forth such connected persons and the nature of their connection with our Group upon [REDACTED].

<u>Connected Person</u>	<u>Connected Relationship</u>
RC Pharma	RC Pharma is owned as to 63.93% by our Controlling Shareholders. As such, RC Pharma is a connected person of our Company under Rule 14A.12(1)(c) of the Listing Rules.
MabPlex	MabPlex is owned as to 41.96% by and is a subsidiary of RC Pharma. As such, MabPlex is a connected person of our Company under Rule 14A.12(1)(c) of the Listing Rules.
Lida	Lida is a wholly-owned subsidiary of RC Pharma. Lida is therefore a connected person of the Company under Rule 14A.12(1)(c) of the Listing Rules.
Yeda Incubation	Yeda Incubation is owned as to 55% by and is a subsidiary of RC Pharma. Yeda Incubation is therefore a connected person of the Company under Rule 14A.12(1)(c) of the Listing Rules.
Kangkang	Kangkang is owned as to 90% by and is a subsidiary of Yeda Incubation. As such, Kangkang is therefore a connected person of the Company under Rule 14A.12(1)(c) of the Listing Rules.
CelluPro	CelluPro is owned as to 51% by MabPlex and 49% by RC Pharma. As such, CelloPro is a connected person of the Company under Rule 14A.12(1)(c) of the Listing Rules.

OUR ONE-OFF CONNECTED TRANSACTIONS

We have entered into certain transactions with parties who are our connected persons on a one-off basis, thereby constituting one-off connected transactions of our Group under Chapter 14A of the Listing Rules.

1. Equipment Lease Agreement

We have entered into an equipment lease agreement dated March 27, 2019 and a supplemental equipment lease agreement dated September 27, 2019 with Yeda Incubation (the “Equipment Lease Agreement”) pursuant to which our Company has agreed to lease from Yeda Incubation eight pieces of equipment used in our research and development activities for a fixed term of 5 years at an aggregate rental of RMB1,271,350 per year. The equipment rental

CONNECTED TRANSACTIONS

fee charged by Yeda Incubation is determined by our Company and Yeda Incubation through arm’s length negotiation taking into account (i) the purchase price paid by Yeda Incubation when they acquired such equipment; (ii) a consumer price index of 5% and (iii) the annual amortization amount of the leased equipment.

The Equipment Lease Agreement has been entered into in the ordinary and usual course of business of our Group and of Yeda Incubation. We require certain equipment for our research and development activities and have leased them from Yeda Incubation to save costs for buying such equipment ourselves. As an incubator, Yeda Incubation leases out equipment used by drug developers in their ordinary and usual course of business.

In accordance with IFRS 16 applicable to our Company and pursuant to the guidance issued by the Stock Exchange, when an issuer enters into a lease transaction as a lessee and where the lease is subject to an agreement with fixed terms, it is treated as a one-off connected transaction (i.e., an acquisition of capital assets). As such, the transaction under the Equipment Lease Agreement will be recognized as acquisition of right-of-use assets and constitutes one-off connected transaction of our Company. For details of the application of IFRS 16 to our Group, please refer to the paragraph headed “Financial Information – Basis of Preparation – IFRS 16” in this document.

2. Yeda Incubation Leases

Our Company has entered into an incubation agreement dated September 15, 2019 and a property management agreement dated October 15, 2019 and a supplemental incubation agreement and a supplemental property management agreement, both dated June 28, 2020 with Yeda Incubation (together, the “Incubation Center Lease”) pursuant to which our Company has leased from Yeda Incubation certain facilities at the incubation center operated by Yeda Incubation (the “Incubation Center”). The Incubation Center is located at 1 Rongchang Road, Economic Technology Development Zone, Yantai, Shandong Province, which is near to the Rongchang Biopharmaceutical Park (the “Park”) where our headquarters are located.

Our Company has also entered into a property lease agreement dated May 7, 2020 and a supplemental property lease agreement dated June 28, 2020 with Yeda Incubation (together, the “Incubation Building Lease”, together with the “Incubation Center Lease”, the “Yeda Incubation Leases”) pursuant to which our Company has leased from Yeda Incubation certain premises at the Incubation R&D Building owned by Yeda Incubation (the “Incubation Building”). The Incubation Building is located in the Park.

Yeda Incubation also provides general property management services for the premises leased by our Company and for the common area.

CONNECTED TRANSACTIONS

Set out below are the details of the Yeda Incubation Leases:

Premises	Term of the lease	Location	Area	Rentals, utilities charges and management fees
Incubation facilities comprising three kinds of laboratories, namely, non-sterilized laboratory, Class D sterilized laboratory and Class C sterilized laboratory	September 15, 2019 to December 31, 2022	Incubation Center	<ul style="list-style-type: none"> • Non-sterilized laboratory: 267 m² • Class D sterilized laboratory: 835.8 m²; and • Class C sterilized laboratory: 206.7 m² 	<ul style="list-style-type: none"> • Non-sterilized laboratory: annual rentals of RMB80,100; annual utilities charges of RMB53,400; and annual property management fees of RMB11,214 • Class D sterilized laboratory: annual rentals of RMB334,320; annual utilities charges of RMB501,480 • Class C sterilized laboratory: RMB103,350; annual utilities charges of RMB144,690
Office premises and GMP Cleanrooms	May 7, 2020 to December 31, 2022	Incubation Building	<ul style="list-style-type: none"> • Office premises: 13,452 m²; and • GMP Cleanrooms: 10,868 m² 	<ul style="list-style-type: none"> • Office premises: annual rentals of RMB9,371,000; and • GMP Cleanrooms: annual rentals of RMB21,364,000

Reasons for the Yeda Incubation Leases:

- *Laboratories:* As we have a robust pipeline complemented with many early stage drug candidates, the incubation facilities provided by Yeda Incubation facilitates our better management and coordination of the drug development progress. As the Incubation Center is located near to the Park, it provides convenient access for our personnel involved in the research and development activities of our drug candidates. Further, our Company has started to lease and use the laboratories for our research and development activities throughout the Track Record Period, any relocation may cause unnecessary disruption to our business operations and incur unnecessary costs.

CONNECTED TRANSACTIONS

- *Office premises and GMP Cleanrooms:* As our business expands, our own facilities cannot accommodate all of our staff and our increasing level of research and development activities; we are in need of office space for our staff and GMP Cleanrooms for our ongoing research and development activities. Given that the leased properties are in close proximity to our facilities and allow our business activities to continue seamlessly. It is currently expected that the construction works of our buildings under construction will be completed by 2022 and 2025, respectively, pending which the Incubation Building Lease is temporary.
- Although we have spare GMP-compliant manufacturing facilities, such manufacturing facilities cannot be converted into research and development facilities due to different GMP requirements. As our business expands, our research and development facilities are not sufficient to accommodate increasing number of staff and our growing research and development activities for our drug candidates. As such, we need to lease such facilities from Yeda Incubation.

Accounting treatment of the Yeda Incubation Leases: In accordance with IFRS 16 applicable to our Company and pursuant to the guidance issued by the Stock Exchange, when an issuer enters into a lease transaction as a lessee and where the lease is subject to an agreement with fixed terms, it is treated as a one-off connected transaction (i.e., an acquisition of capital assets). As such, the transactions under the Yeda Incubation Leases will be recognized as acquisitions of right-of-use assets and constitute one-off connected transactions of our Company. For details of the application of IFRS to our Group, please refer to the paragraph headed “Financial Information – Basis of Preparation – IFRS 16” in this document.

Property Valuer Opinion: JLL, the independent property valuer of our Company, has confirmed that, (i) the terms of the Yeda Incubation Leases are at arm’s length, on normal commercial terms and reasonable for contracts of the relevant type, and (ii) the rentals of the Incubation Center Lease for an aggregate of 1,309.5 m², and of the Incubation Building Lease for an aggregate of 24,320 m² are fair and reasonable and represent the prevailing market rates for properties of similar size situated in the locality that are used for similar purposes in the PRC.

CONNECTED TRANSACTIONS

OUR CONTINUING CONNECTED TRANSACTIONS

A. Continuing Connected Transactions Fully Exempt from the Reporting, Annual Review, Announcement and Independent Shareholders’ Approval Requirements

1. *Public Utilities Service Agreement*

Parties: Our Company and RC Pharma.

Reasons for the transactions: Rongchang Biopharmaceutical Park (the “Park”) is located in Yantai with a total area of approximately 300,000 m². Our headquarters are located in the Park and it is also where the headquarters of our connected persons including RC Pharma, MabPlex, Yeda Incubation and CelluPro are located. Although we own our land use rights and building ownership certificates for our properties, the Park is centrally managed by RC Pharma which also maintains the utilities accounts for all the buildings located in the Park. As our utilities accounts for our buildings cannot be separated from RC Pharma’s account, we will continue to use utilities billing services provided by RC Pharma.

Principal terms and Listing Rules Implications: Pursuant to the public utilities service agreement dated June 24, 2020 entered into by our Company and RC Pharma, our Company is required to share the payment of government charges for using public utilities (including electricity and water) and pay such amount to RC Pharma. The payment to be made by the Company to RC Pharma equals to the actual amount to be charged by the relevant government authorities for the public utilities consumed by our Group as recorded on the relevant electricity meters. Accordingly, the payment for public utilities charges under the Public Utilities Service Agreement on a cost basis are fully exempt continuing connected transactions pursuant to Rule 14A.97 of the Listing Rules.

2. *Lida Property Lease*

Parties: Our Company and Lida.

Principal terms: Our Company has entered into a property lease agreement dated December 16, 2019 and a supplemental property lease agreement dated June 16, 2020 with Lida (together, the “Lida Property Lease”) pursuant to which our Company has agreed to lease to Lida a cold storage room of an area of approximately 40 m². The principal terms of the Property Lease Agreement with Lida are as follows:

- Our Company leases to Lida a cold storage room of an area of approximately 40 m²;
- **pricing policy:** the rental for the leased property is RMB6,200 per month, such rental was determined by our Company and Lida through arm’s length negotiation with reference to factors such as the prevailing market rent of similar property located in the vicinity; and

CONNECTED TRANSACTIONS

- **term:** the Lida Property Lease is from December 16, 2019 to December 31, 2020.

Reasons for the transactions: Our Company currently has sufficient cold storage rooms for our own use and leasing out the cold storage room to Lida provides an additional source of income. Lida has started to lease and use the cold storage room during the Track Record Period. As our Company continues to expand our operations and requires the cold storage room for our manufacturing activities starting from 2021, the Lida Property Lease will end on December 31, 2020.

Historical amount: Since the Lida Property Lease only began in December 2019, there is no historical payment from Lida for the year ended December 31, 2018. The rental payments recognized by our Company from Lida for the year ended December 31, 2019 and the three months ended March 31, 2020 was RMB3,000 and RMB17,000 (exclusive of tax), respectively.

Annual cap and basis: According to the terms of the Lida Property Lease, for the year ending December 31, 2020, the total rental payments receivable by our Company from Lida under the Property Lease Agreement with Lida shall not exceed RMB74,400.

JLL, the independent property valuer of our Company, has confirmed that, (i) the terms of the Lida Property Lease are at arm’s length, on normal commercial terms and reasonable for contracts of the relevant type, and (ii) the rentals of the abovementioned cold storage room of a total area of approximately 40 m² are fair and reasonable and represent the prevailing market rates for properties of similar size situated in the locality that are used for similar purposes in the PRC.

Listing Rules Implications: Since the applicable percentage ratio calculated for the purpose of Chapter 14A of the Listing Rules for the transactions under the Lida Property Lease will be less than 0.1%, the transactions under the Lida Property Lease will constitute *de minimis* transactions of our Company and will be exempt from the reporting, announcement, annual review and independent Shareholder’s approval requirements under Chapter 14A of the Listing Rules.

B. Continuing Connected Transactions Subject to the Reporting, Annual Review and Announcement Requirements but Exempt from the Independent Shareholders’ Approval Requirement

1. CRC Services Framework Agreement

Parties: Our Company and Kangkang.

Principal terms: Our Company has entered into a framework agreement dated [●], 2020 with Kangkang (the “CRC Services Framework Agreement”) pursuant to which our

CONNECTED TRANSACTIONS

Company has agreed to engage Kangkang and Kangkang has agreed to provide certain clinical trials management services. The principal terms of the CRC Services Framework Agreement are as follows:

- Kangkang provides certain clinical trials management services to our Company, including but not limited to coordinating clinical research, providing training to clinical research coordinators who shall assist investigators in their clinical trials according to the requests of our Company and providing supporting services for investigators (the “CRC Services”);
- with respect to specific service requests that may be identified in the future, our Company and Kangkang will enter into separate individual agreements or work orders to provide for the specific terms and conditions according to the principles provided in the CRC Services Framework Agreement;
- **pricing policy:** service fees will be charged at rates no more favourable than rates at which our Company pays independent third parties for comparable transactions and will be determined by our Company and Kangkang through arm’s length negotiation based on a number of factors applicable to all service providers, including but not limited to the nature, complexity and value of tasks completed by Kangkang at each stage under each work order, the personnel and working hours estimated to be equipped and spent on providing specific service, the fees charged for historical transactions of similar nature and the then prevailing market rates; and
- **term:** the CRC Services Framework Agreement is valid from the [REDACTED] until December 31, 2022, and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

Reasons for the transactions: As more of our drug candidates enter the clinical trial phase, CRC services are essential to our development process and such CRC services require sophisticated knowledge that are better handled by service providers with such capabilities. It is a common industry practice for biopharmaceutical companies to engage third party service providers to provide assistance for clinical trials. We have outsourced such CRC Services to Kangkang during the Track Record Period. We believe that Kangkang can provide CRC services that most appropriately suit our needs.

Historical amount: For the years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, the amounts incurred by our Company for the services provided by Kangkang under the CRC Services Framework Agreement were nil, RMB390,000 and RMB1,209,000, respectively.

Annual cap: For the three years ending December 31, 2020, 2021 and 2022, the total amount payable by our Company to Kangkang for the services under the CRC Services Framework Agreement shall not exceed RMB19,000,000, RMB19,000,000 and RMB19,000,000, respectively.

CONNECTED TRANSACTIONS

Basis of cap: In determining the above annual caps, our Directors have considered: (i) the historical transaction amounts paid by our Company to Kangkang; (ii) the volume of CRC services our Company expects to procure from Kangkang based on the clinical development of our pipeline drug candidates, including the clinical trials of telitacicept, disitamab vedotin and RC28; and (iii) the number of relevant personnel and their work hours required for clinical trials, and their respective prevailing hourly rates. As more of our drug candidates go into clinical trials, our need for CRC services increases as compared to such need during the Track Record Period.

Listing Rules Implications: Since the applicable percentage ratio calculated for the purpose of Chapter 14A of the Listing Rules for the transactions under the CRC Services Framework Agreement will be less than 5% on an annual basis, under Rule 14A.76 of the Listing Rules, the transactions under the CRC Services Framework Agreement will be subject to the reporting, announcement and annual review requirements but will be exempt from the independent Shareholders’ approval requirements under Chapter 14A of the Listing Rules.

2. *General Services Framework Agreement*

Parties: the Company and RC Pharma.

Principal terms: Our Company has entered into a general services framework agreement dated December 6, 2019 and a supplemental general services framework agreement dated June 24, 2020 with Rongchang Pharma (together, the “General Services Framework Agreement”) in relation to general services provided by RC Pharma in the Park. The principal terms of the General Services Framework Agreement are as follows:–

- The scope of such general services include (i) provision of steam for our business operations; (ii) provision of coordination and management services in relation to construction works; and (iii) provision of other miscellaneous services such as canteen, business cars hire and supporting facilities services;
- **pricing policy:** service fees will be charged at rates no less favourable to our Company than rates at which RC Pharma charges independent third parties and other connected persons for comparable transactions and will be determined by the relevant parties through arm’s length negotiation based on factors applicable to all service providers, the factors applying to each of the three types of services are as follows:
 - i. provision of steam: the provision of steam will be charged at the procurement costs paid by RC Pharma for the natural gas required for producing steam plus service charge for the maintenance of facilities and equipment for converting the same into steam;
 - ii. coordination and management services for construction works: the number of staff involved and the time spent by such staff on the relevant coordination and management services;

CONNECTED TRANSACTIONS

- iii. miscellaneous service: the actual number of people and the number of meals consumed, the actual usage of transportation services and costs of supporting facilities services, together with the corresponding service fees.
- **term:** the General Services Framework Agreement is valid from the [REDACTED] to December 31, 2022, and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

Reasons for the transaction: RC Pharma constructed and maintained the facilities and equipment for producing steam and provides the same to all corporations located in the Park. In order to maintain the same standard and architectural style for all buildings within the Park, RC Pharma provides centralized coordination and management services for construction works undertaken by all corporations located in the Park. Such services include design of the buildings, management of the construction progress, procurement of materials for the construction works, etc. Further, RC Pharma operates the canteen at the Park and provides other standardized services such as business cars hire and supporting facilities services to all corporations located in the Park for efficient and centralized management of the Park.

Historical amounts: For the years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, the total transaction amounts under the General Services Framework Agreement were RMB7,146,126, RMB9,541,997 and RMB2,177,048, respectively.

Annual caps: For the years ending December 31, 2020, 2021 and 2022, the maximum aggregate annual amount of service fees under the General Services Framework Agreement shall not exceed RMB7,646,000, RMB9,011,000 and RMB9,111,000, respectively.

Basis of caps: In determining the above annual caps, our Directors have considered: (i) the historical transaction amounts under the General Services Framework Agreement; (ii) the expected demand for steam, the coordination and management services for our manufacturing facilities under construction and the miscellaneous services and the corresponding service charges under the General Services Framework Agreement; and (iii) the expected increase in the costs of the steam.

Listing Rules Implications: Since the applicable percentage ratio calculated for the purpose of Chapter 14A of the Listing Rules for the transactions under the General Services Framework Agreement will be less than 5% on an annual basis, under Rule 14A.76 of the Listing Rules, the transactions under the General Services Framework Agreement will be subject to the reporting, announcement and annual review requirements but will be exempt from the independent Shareholders' approval requirement under Chapter 14A of the Listing Rules.

CONNECTED TRANSACTIONS

3. *MabPlex Master Service Agreement*

Parties: Our Company and MabPlex.

Principal terms: We entered into a M16120 master service agreement dated January 4, 2019 and a supplemental master service agreement dated [●] with MabPlex (together, the “MabPlex Master Service Agreement”), pursuant to which MabPlex provides research and development and manufacturing services to our Company. The principal terms of the MabPlex Master Service Agreement are as follows:

- MabPlex provides certain research and development and manufacturing services to our Company, including but not limited to cell culture manufacturing, synthesis of linker-payloads, ADC conjugation service, release testing service, GMP fill/finish of ADC products, and cell banking;
- with respect to specific service requests that may be identified in the future, our Company and MabPlex will enter into separate individual agreements or work orders to provide for the specific terms and conditions including service scope, service fees and other terms, subject to and in accordance with the MabPlex Master Service Agreement;
- ***pricing policy:***
 - i. service fees will be charged at rates no more favourable than rates at which our Company pays independent third parties for comparable transactions; and
 - ii. service fees will be determined by our Company and MabPlex through arm’s length negotiation with reference to a number of factors applicable to all service providers, including but not limited to the nature, complexity, and value of tasks completed by MabPlex at each stage under each work order, the market rates, quantity and sourcing of materials, the method of delivery, the fees charged for historical transactions of similar nature and the then prevailing market rates.
- the MabPlex Master Service Agreement is valid from the [REDACTED] until December 31, 2022, and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

Reasons for the transaction: As a commercial-ready biopharmaceutical company committed to the discovery, development and commercialization of innovative biologics, and with robust pipeline complemented with many early-stage drug candidates, we need various research and development and manufacturing services for biologics. As our in-house research and development and manufacturing capabilities are currently focused on meeting the research and development and manufacturing needs for telitacept, disitamab vedotin and RC28, we need to outsource some of our research and development and manufacturing requests of our non-core products to MabPlex.

CONNECTED TRANSACTIONS

MabPlex is a qualified CDMO company in China and has the relevant development and manufacturing capabilities. Given MabPlex’s experience with development and manufacturing of biologics used in the development process of telitacicept, RC88 and RC98 and with the familiarity with our drug candidates and service requests, they are in a position to continue to provide services that most appropriately suit our needs and at rates no less favorable to our Company than rates at which our Company pays independent third parties for comparable transactions.

Historical amounts: For the years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, the total amounts incurred by our Company for the services provided by MabPlex under the MabPlex Master Service Agreement were nil, RMB10,236,000 and RMB2,868,000, respectively.

Annual caps: For the years ending December 31, 2020, 2021 and 2022, the total amounts under the MabPlex Master Service Agreement shall not exceed RMB46,200,000, RMB41,700,000 and RMB29,110,000, respectively.

Basis of caps: In determining the above annual caps, our Directors have considered: (i) the historical transaction amounts paid by our Company to MabPlex; (ii) the expected volume of development and manufacturing services our Company expects to procure from MabPlex during 2020 for the materials and biologics used for the development and clinical trial of RC88 and the materials and biologics used for the research and development of RC108, RC118, RC138, RC148 and RC158; and (iii) the expected development and manufacturing services our Company expects to procure from MabPlex for the materials and biologics used for the development of RC88 and RC128 during 2021 and 2022. As we have more drug candidates progressing into development and/or clinical trial stages, the volume of services we require from MabPlex increases, as compared to such volume during the Track Record Period.

Listing Rules Implications: Since the applicable percentage ratio calculated for the purpose of Chapter 14A of the Listing Rules for the transactions under the MabPlex Master Service Agreement will be less than 5% on an annual basis, under Rule 14A.76 of the Listing Rules, the transactions under the MabPlex Master Service Agreement will be subject to the reporting, announcement and annual review requirements but will be exempt from the independent Shareholders’ approval requirement under Chapter 14A of the Listing Rules.

4. *Materials Purchase Framework Agreement*

Parties: Our Company and CelluPro.

Principal terms: Our Company has entered into a framework agreement for purchase of materials with CelloPro dated [●], 2020 (the “Materials Purchase Framework Agreement”) pursuant to which CelluPro has agreed to sell and our Company has agreed to buy from CelluPro medium products manufactured by CelluPro. The principal terms of the Materials Purchase Framework Agreement are as follows:

- CelluPro will sell to our Company and our Company will buy from CelluPro certain medium products we use in our research and development activities including but not limited to basic culture medium and feed medium;

CONNECTED TRANSACTIONS

- with respect to specific product requests that may be identified in the future, our Company and CelluPro will enter into separate individual agreements or work orders to provide for the specific terms and conditions according to the principles provided in the Materials Purchase Framework Agreement;
- **pricing policy:** fees will be charged at rates no less favourable to our Company than rates at which our Company pays independent third parties for comparable transactions and will be determined by our Company and CelluPro through arm’s length negotiation with reference to a number of factors applicable to all suppliers, including but not limited to the market price of the products, quantity and method of procurement, specifications of the products, the fees charged for historical transactions of similar nature and the then prevailing market rates;
- **term:** the Materials Purchase Framework Agreement is valid from the [REDACTED] until December 31, 2022, and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

Reasons for the transactions: As a commercial-ready biopharmaceutical company committed to the discovery, development and commercialization of innovative biologics, we need a high volume of medium products in our research and development and manufacturing activities. CelluPro is a medium manufacturing company specializing in the development, production of high-quality serum free medium for mammalian cells culture. As we have sourced medium products from CelluPro during the Track Record Period, CelluPro can provide medium products that most appropriately suit our needs.

Historical amount: For the years ended December 31, 2018 and 2019 and for the three months ended March 31, 2020, the total amounts incurred by our Company for the services provided by CelluPro under the Materials Purchase Framework Agreement were RMB2,258,000, RMB1,450,000 and RMB826,000, respectively.

Annual cap: For the three years ending December 31, 2020, 2021 and 2022, the total amounts under the Materials Purchase Framework Agreement shall not exceed RMB10,646,650, RMB14,714,000 and RMB14,893,000, respectively.

Basis of cap: In determining the above annual caps, our Directors have considered: (i) the historical amount of payments paid by our Group to CelluPro for the medium products; and (ii) the expected demand for the relevant medium products for our manufacturing activities of RC18, RC48 and RC28. As our Core Products are progressing into clinical trials and/or manufacturing stages, we need significantly more medium products, as compared to such need during the Track Record Period.

CONNECTED TRANSACTIONS

Listing Rules Implications: Since the applicable percentage ratio calculated for the purpose of Chapter 14A of the Listing Rules for the transactions under the Materials Purchase Framework Agreement will be less than 5% on an annual basis, under Rule 14A.76 of the Listing Rules, the transactions under the Materials Purchase Framework Agreement will be subject to the reporting, announcement and annual review requirements but will be exempt from the independent Shareholders’ approval requirements under Chapter 14A of the Listing Rules.

5. *MabPlex Property Lease Agreement*

Parties: Our Company and MabPlex.

Principal terms: Our Company entered into a property lease agreement dated April 22, 2020 with MabPlex (the “MabPlex Property Lease Agreement”), pursuant to which MabPlex leases from our Company manufacturing facilities comprising a non-sterilized area of 2,933.78 m² and a sterilized area of 465 m².

Pricing policy: The rentals for sterilized area and non-sterilized area are RMB46,000 per month and RMB44,100 per month, respectively. Such rentals are determined by our Company and MabPlex through arm’s length negotiation based on a number of factors including but not limited to prevailing market rent of similar property located in the vicinity and the term of the lease.

Further, the operational service charges for the sterilized and non-sterilized area are RMB128,000 and RMB58,000, respectively. Such operational service charges are determined through arm’s length negotiation by our Company and MabPlex based on a number of factors including the costs of maintenance of the operations by the Company and the prevailing market rates for such charges for similar property located in the vicinity. The Company will also charge service charges for usages of purified water, water for injection and purified steam at the rates of RMB42/ton, RMB130/ton and RMB408/ton, respectively. Such service charges are determined through arm’s length negotiation by our Company and MabPlex based on a number of factors including the costs of raw materials and for processing them.

Term: The MabPlex Property Lease Agreement is valid from May 1, 2020 to December 31, 2022, and may be renewed conditional on the fulfillment of the relevant requirements under the relevant laws, regulations and the Listing Rules.

Reasons for the transactions: Our manufacturing facilities which fulfill the relevant GMP requirements have been specifically designed for the development and production of ADCs which are not suitable for other uses due to the high toxicity of ADCs. Disitamab vedotin is the only ADC product of our Company currently, our Company has sufficient manufacturing facilities for disitamab vedotin and does not have other ADC products going into the manufacturing stage in the next 3 to 5 years. MabPlex requires such GMP-compliant facilities for their business operations and leasing out the abovementioned manufacturing facilities to MabPlex provides an additional source of income to our Company.

CONNECTED TRANSACTIONS

Historical amount: Given that the MabPlex Property Lease only began in May 2020, there is no historical payments received from MabPlex under the MabPlex Property Lease Agreement during the Track Record Period.

Annual cap: For the three years ending December 31, 2020, 2021 and 2022, the total amounts receivable by our Company from MabPlex under the MabPlex Lease Agreements shall not exceed RMB2,468,000, RMB3,772,000 and RMB3,772,000, respectively.

Basis of cap: In determining the annual caps, our Directors have considered the rental amounts and the operational service charges receivable by our Company according to the terms of the Property Lease Agreement with MabPlex, the expected usages of purified water, water for injection and purified steam by MabPlex and the pricing policy set out above.

JLL, the independent property valuer of our Company, has confirmed that, (i) the terms of the MabPlex Property Lease are at arm’s length, on normal commercial terms and reasonable for contracts of the relevant type, and (ii) the rentals of the abovementioned manufacturing facilities of a total area of 3,398.78 m² are fair and reasonable and represent the prevailing market rates for properties of similar size situated in the locality that are used for similar purposes in the PRC.

Listing Rules Implications: Given that the applicable percentage ratio calculated for the purpose of Chapter 14A of the Listing Rules for the transactions under the MabPlex Property Lease will be less than 5%, under Rule 14A.76 of the Listing Rules, the transactions under the MabPlex Property Lease will be subject to the reporting, announcement, annual review requirements but will be exempt from the independent Shareholders’ approval requirement under Chapter 14A of the Listing Rules.

INTERNAL CONTROL MEASURES FOR NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

We have established the following internal review procedures to ensure that the terms for the non-exempt continuing connected transactions we have or may have in the future are on normal commercial terms and no more favorable to the counterparties than terms available to Independent Third Parties:

- If a comparable market price is available, we shall compare the proposed product price or service fee with the market price to ensure that the proposed product price or service fee will not be higher than the selling price of product or service of a similar type or nature provided by independent third-party suppliers or providers;

CONNECTED TRANSACTIONS

- Before selecting a product supplier or services provider, our procurement department shall obtain price quotations from certain independent third-party suppliers or providers. The factors to be considered by us in conducting internal assessments include price, quality, exclusivity of product or service, and value added to us;
- If no comparable market price is available, our procurement department shall conduct arm’s length negotiation with the relevant connected persons to determine the terms in line with the relevant pricing policies based on trade cost of the product involved or value of the relevant service and the actual costs and expenses incurred;
- After arm’s length negotiation with the connected person, our procurement department will report to our senior management who will approve individual transactions as appropriate;
- Our internal audit department will regularly collect and monitor the transaction amount of continuing connected transactions to ensure timely assessment on whether the annual caps are exceeded; and
- Our independent non-executive Directors will also conduct annual review on the non-exempt continuing connected transactions to ensure that such transactions have been entered into on normal commercial terms, are fair and reasonable and conducted according to the terms of the relevant framework agreement. The auditor of our Company will also conduct annual review on the pricing and annual cap of the non-exempt continuing connected transactions.

CONFIRMATION OF DIRECTORS

Our Directors (including our independent non-executive Directors) consider that all the continuing connected transactions described under the sub-section entitled “—(B) Continuing Connected Transactions subject to the Reporting, Annual Review and Announcement Requirements but Exempt from the Independent Shareholders’ Approval Requirement” have been and will be carried out (i) in the ordinary and usual course of our business, (ii) on normal commercial terms or better and (iii) in accordance with the respective terms that are fair and reasonable and in the interests of our Company and our Shareholders as a whole.

Our Directors (including our independent non-executive Directors) are also of the view that the proposed annual caps of the continuing connected transactions described under the sub-section entitled “—(B) Continuing Connected Transactions Subject to the Reporting, Annual Review and Announcement Requirements but Exempt from the Independent Shareholders’ Approval Requirement” in this section are fair and reasonable and are in the interests of our Company and our Shareholders as a whole.

CONNECTED TRANSACTIONS

CONFIRMATION OF THE JOINT SPONSORS

The Joint Sponsors are of the view (i) that the continuing connected transactions described under the sub-section entitled “—(B) Continuing Connected Transactions subject to the Reporting, Annual Review and Announcement Requirements but Exempt from the Independent Shareholders’ Approval Requirement” in this section have been and will be entered into in the ordinary and usual course of our business, on normal commercial terms or better, and in accordance with the respective terms that are fair and reasonable and in the interests of our Company and our Shareholders as a whole; and (ii) that the proposed annual caps of such continuing connected transactions are fair and reasonable, and in the interests of our Company and our Shareholders as a whole.

WAIVER APPLICATION FOR NON-EXEMPT CONTINUING CONNECTED TRANSACTIONS

The transactions described under the sub-section entitled “—(B) Continuing Connected Transactions subject to the Reporting, Annual Review and Announcement Requirements but Exempt from the Independent Shareholders’ Approval Requirement” in this section constitute our continuing connected transactions under the Listing Rules, which are exempt from the independent Shareholders’ approval requirements but subject to the reporting, annual review, announcement requirements of the Listing Rules.

In respect of these continuing connected transactions, pursuant to Rule 14A.105 of the Listing Rules, we have applied for, and the Stock Exchange has [granted], waivers exempting us from strict compliance with the announcement requirement under Chapter 14A of the Listing Rules in respect of the continuing connected transactions as disclosed in “—(B) Continuing Connected Transactions subject to the Reporting, Annual Review and Announcement Requirements but Exempt from the Independent Shareholders’ Approval Requirement” in this section, subject to the conditions that the aggregate amounts of the continuing connected transactions for each financial year shall not exceed the relevant amounts set forth in the respective annual caps (as stated above).

SHARE CAPITAL

This section presents certain information regarding our share capital prior to and following the completion of the [REDACTED].

BEFORE THE [REDACTED]

As of the Latest Practicable Date, our registered share capital was RMB401,819,202, comprising 239,294,291 Domestic Shares and 162,524,911 Unlisted Foreign Shares, with a nominal value of RMB1.00 each.

UPON COMPLETION OF THE [REDACTED]

Assuming the [REDACTED] is not exercised, the share capital of our Company immediately after the [REDACTED] will be as follows:

Description of Shares	Number of Shares	Approximate percentage of the enlarged issued share capital after the [REDACTED]
Domestic Shares in issue ⁽¹⁾	[REDACTED]	[REDACTED]%
H Shares to be converted from Unlisted Foreign Shares ⁽²⁾	[REDACTED]	[REDACTED]%
Unlisted Foreign Shares in issue ⁽³⁾	[REDACTED]	[REDACTED]%
H Shares to be issued pursuant to the [REDACTED]	[REDACTED]	[REDACTED]%
Total	[REDACTED]	[100.00]%

Notes:

(1) These Domestic Shares are held by existing Shareholders, Yantai Rongda Venture Capital Center (Limited Partnership) (煙台榮達創業投資中心(有限合夥)), Yantai Rongshi Enterprise Management Center (Limited Partnership) (煙台榮實企業管理中心(有限合夥)), Yantai Rongyi Enterprise Management Center (煙台榮益企業管理中心(有限合夥)), Yantai Rongqian Enterprise Management Center (Limited Partnership) (煙台榮謙企業管理中心(有限合夥)), Yantai Rongjian Enterprise Management Center (煙台榮建企業管理中心(有限合夥)), Fund for the transformation of National Science and Technology Major Project (國投(上海)科技成果轉化創業投資基金企業(有限合夥)), Shenzhen Capital Group Co., Ltd. (深圳市創新投資集團有限公司), SDIC Chuanghe National Leading Fund of Emerging Industries VC (Limited Partnership) (國投創合國家新興產業創業投資引導基金(有限合夥)), Beijing Lapam Healthcare Investment Center LLP (北京龍磐健康醫療投資中心(有限合夥)), Suzhou Likang Equity Investment Center (Limited Partnership) (蘇州禮康股權投資中心(有限合夥)), Suzhou Lirui Equity Investment Center (Limited Partnership) (蘇州禮瑞股權投資中心(有限合夥)), Lu Thai Textile Co., Ltd. (魯泰紡織股份有限公司), TIBET Lapam Yijing Venture Capital Center LLP (西藏龍磐怡景創業投資中心(有限合夥)), Nanjing Huatai Healthcare Investment I LLP (南京華泰大健康一號股權投資合夥企業(有限合夥)), Shandong Jifu Jingu New Kinetic Energy Equity Investment Fund Partnership (Limited Partnership) (山東吉富金谷新動能股權投資基金合夥企業(有限合夥)), Hangzhou Chuanghe Select Venture Capital (Limited Partnership) (杭州創合精選創業投資合夥企業(有限合夥)), Weihai Luxin Fuwei Equity Investment Fund Partnership (Limited Partnership) (威海魯信福威股權投資基金合夥企業), Govtor Capital Co., Ltd. (江蘇高科技投資集團有限公司), Jiangsu International Trust Corporation Limited (江蘇省國際信託有限責任公司), Small Medium Enterprises Development Fund (Shenzhen) LLP (中小企業發展基金(深圳有限合夥)), Yan Tai Hong Da Investment Limited (煙台鴻大投資有限公司), Yantai Economic Development Investment Company (煙台市經濟發展投資公司), Shanghai Tanying Investment Partnership (Limited Partnership) (上海檀英投資合夥企業(有限合夥)), Nanjing Huatai Healthcare Investment II LLP (南京華泰大健康二號股權投資合夥企業(有限合夥)) and Nanjing Daoan Management Center GP (南京道安企業管理中心(普通合夥)). For details of their shareholdings, please refer to the section headed “History, Development and Corporate Structure” in this document.

SHARE CAPITAL

- (2) These Shares are to be converted from Unlisted Foreign Shares into H Shares and held by existing Shareholders, I-NOVA Limited, RongChang Holding Group LTD., RC-Biology Investment Ltd., PAG Growth Prosperity Holding I (HK) Limited, PAG Growth Holding IV (HK) Limited, Wholly Sunbeam Limited, Metroplus, LBC Sunshine Healthcare Fund L.P., LAV Remegen Limited, Vivo Capital Fund IX, L.P., Janchor Partners Pan-Asian Master Fund., MINTU Infrastructure Development Holdings Co., Limited (民圖基礎設施發展控股有限公司), OrbiMed Partners Master Fund Limited, OrbiMed Genesis Master Fund, L.P., Hudson Bay Master Fund LTD, Senming Capital Limited and CRF Investment Holdings Company Limited. Please see the paragraph headed “— Conversion of Our Unlisted Shares into H Shares — Conversion of Foreign Shares into H Shares” in this section.
- (3) These Unlisted Foreign Shares are held by our existing Shareholder, Dr. Fang, which will not be converted into H Shares after the completion of [REDACTED], and therefore will not be listed on the Stock Exchange. However, these Unlisted Foreign Shares may be converted into H Shares in the future, please see the paragraph headed “— Conversion of Our Unlisted Shares into H Shares” in this section.

SHARE CLASSES

Upon completion of the [REDACTED], our Company would have three classes of Shares, namely Domestic Shares, Unlisted Foreign Shares and H Shares. All three classes of Shares are ordinary shares in the share capital of our Company. H Shares may only be subscribed for and traded in Hong Kong dollars (except for H Shares under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect and can be traded in Renminbi) between legal and natural persons of Hong Kong, Macau, Taiwan or any country or jurisdiction other than the PRC and qualified domestic institutional investors of the PRC. Apart from certain qualified domestic institutional investors in the PRC, as well as certain PRC qualified investors under the Shanghai-Hong Kong Stock Connect and the Shenzhen-Hong Kong Stock Connect, H Shares generally cannot be subscribed by or traded among legal and natural persons of the PRC. Domestic Shares, on the other hand, may only be traded in Renminbi and can only be subscribed by or traded among legal and natural persons of the PRC, qualified foreign institutional investors or qualified foreign strategic investors. We have not approved any share issue plan other than the [REDACTED].

RANKING

Domestic Shares, Unlisted Foreign Shares and H Shares are regarded as different classes of Shares under the Articles of Association. The differences among all three classes of Shares and the provisions on class rights, the dispatch of notices and financial reports to shareholders, dispute resolution, registration of Shares on different registers of shareholders, the method of share transfer and appointment of dividend receiving agents are set forth in the Articles of Association and summarized in the Appendix VI to this document. Except for the differences above, our Unlisted Shares and H Shares will rank *pari passu* with each other in all other respects and, in particular, will rank equally for all dividends or distributions declared, paid or made after the date of this document. We must pay all dividends in respect of H Shares in Hong Kong dollars, all dividends in respect of Domestic Shares in Renminbi and all dividends in respect of all Unlisted Foreign Shares in foreign currency except for Renminbi. In addition to cash, dividends may be distributed in the form of Shares. However, the transfer of the Unlisted Shares is subject to such restrictions as PRC laws may impose from time to time.

SHARE CAPITAL

CONVERSION OF OUR UNLISTED SHARES INTO H SHARES

Conversion of Foreign Shares into H Shares

Following the completion of the [REDACTED] and according to the approvals issued by the CSRC on [●], 2020, the Foreign Shares held by the following individuals and entities will be converted into H Shares on a one-for-one basis and [REDACTED] on Stock Exchange for trading:

Shareholder	Number of Shares Converted to H Shares
I-NOVA Limited ⁽¹⁾	[REDACTED]
RongChang Holding Group LTD. ⁽¹⁾	[REDACTED]
PAG Growth Prosperity Holding I (HK) Limited ⁽²⁾	[REDACTED]
PAG Growth Holding IV (HK) Limited ⁽²⁾	[REDACTED]
Wholly Sunbeam Limited ⁽²⁾	[REDACTED]
RC-Biology Investment Ltd. ⁽¹⁾	[REDACTED]
Metroplus International Limited ⁽²⁾	[REDACTED]
LBC Sunshine Healthcare Fund L.P. ⁽²⁾	[REDACTED]
LAV Remegen Limited ⁽²⁾	[REDACTED]
Vivo Capital Fund IX, L.P. ⁽²⁾	[REDACTED]
Janchor Partners Pan-Asian Master Fund ⁽²⁾	[REDACTED]
MINTU Infrastructure Development Holdings Co., Limited (民圖基礎設施發展控股有限公司) ⁽²⁾	[REDACTED]
OrbiMed Partners Master Fund Limited ⁽²⁾	[REDACTED]
OrbiMed Genesis Master Fund, L.P. ⁽²⁾	[REDACTED]
Hudson Bay Master Fund LTD ⁽²⁾	[REDACTED]
Senming Capital Limited ⁽²⁾	[REDACTED]
CRF Investment Holdings Company Limited ⁽²⁾	[REDACTED]

Notes:

- (1) As these individuals and entities are core connected persons of our Company upon [REDACTED], the Shares held by them will not be counted towards the public float for the purpose of Rule 8.08 of the Listing Rule after [REDACTED].
- (2) As these entities will not be core connected persons of our Company upon [REDACTED], are not accustomed to take instructions from core connected persons in relation to the acquisition, disposal, voting or other disposition of their Shares and their acquisition of Shares were not financed directly or indirectly by core connected persons, the Shares held by them will be counted towards the public float for the purpose of Rule 8.08 of the Listing Rule after [REDACTED].

SHARE CAPITAL

Conversion of Unlisted Shares into H Shares

After the completion of the [REDACTED], we have three classes of ordinary shares, namely Domestic Shares, Unlisted Foreign Shares and H Shares. Our Domestic Shares and Unlisted Foreign Shares are Unlisted Shares which are currently not listed or traded on any stock exchange. According to the stipulations by the State Council’s securities regulatory authority and the Articles of Association, our Unlisted Shares may be converted into H Shares, and such converted shares may be listed or traded on an overseas stock exchange, provided that prior to the conversion and trading of such converted shares any requisite internal approval processes shall have been duly completed and the approval from the relevant PRC regulatory authorities, including the CSRC, shall have been obtained. In addition, such conversion, trading and listing shall in all respects comply with the regulations prescribed by the State Council’s securities regulatory authorities and the regulations, requirements and procedures prescribed by the relevant overseas stock exchange.

Approval of the Stock Exchange is required for the [REDACTED] of such converted shares on the Stock Exchange. Based on the methodology and procedures for the conversion of our Unlisted Shares into H Shares as described in this section, we can apply for the [REDACTED] of all or any portion of our Unlisted Shares on the Stock Exchange as H Shares in advance of any proposed conversion to ensure that the conversion process can be completed promptly upon notice to the Stock Exchange and delivery of shares for entry on the H Share register. As any [REDACTED] of additional Shares after our [REDACTED] on the Stock Exchange is ordinarily considered by the Stock Exchange to be a purely administrative matter, it does not require such prior application for [REDACTED] at the time of our [REDACTED] in Hong Kong.

After all the requisite approvals have been obtained, the following procedure will need to be completed in order to effect the conversion: the relevant Unlisted Shares will be withdrawn from the Domestic Share register and/or the Unlisted Foreign Share register and we will re-register such Shares on our [REDACTED] maintained in Hong Kong and instruct the [REDACTED] to issue H Share certificates. Registration on our [REDACTED] will be conditional on (a) the [REDACTED] lodging with the Stock Exchange a letter confirming the proper entry of the relevant H Shares on the [REDACTED] and the due dispatch of H Share certificates and (b) the admission of the H Shares to trade on the Stock Exchange in compliance with the Listing Rules, the General Rules of CCASS and the CCASS Operational Procedures in force from time to time. Until the converted shares are re-registered on our H Share register, such Shares would not be listed as H Shares.

No Shareholder voting by class is required for the listing and trading of the converted shares on an overseas stock exchange. Any application for [REDACTED] of the converted shares on the Stock Exchange after our initial [REDACTED] is subject to prior notification by way of announcement to inform Shareholders and the public of any proposed transfer.

In view of the above, our PRC Legal Advisor has advised us that the Articles of Association of our Company does not contradict any PRC laws and regulations in the conversion of Unlisted Shares.

SHARE CAPITAL

PUBLIC FLOAT REQUIREMENTS

Rules 8.08(1)(a) and (b) of the Listing Rules require there to be an open market in the securities for which listing is sought and for a sufficient public float of an issuer’s listed securities to be maintained. This normally means that (i) at least 25% of the issuer’s total issued share capital must at all times be held by the public; and (ii) where an issuer has one class of securities or more apart from the class of securities for which listing is sought, the total securities of the issuer held by the public (on all regulated market(s) including the Stock Exchange) at the time of listing must be at least 25% of the issuer’s total issued share capital.

Based on the information in the above tables, as 74,204,604 Unlisted Foreign Shares to be converted to H Shares (representing [REDACTED]% of the total share capital of our Company after the [REDACTED] (assuming no exercise of the [REDACTED])) are held by existing Shareholders which will not be core connected persons of our Company upon [REDACTED], such Shares will be counted towards the public float. As such, although the [REDACTED] represent less than [REDACTED]% of our total issued share capital, our Company will meet the public float requirement under the Listing Rules after the completion of the [REDACTED] (whether or not the [REDACTED] is exercised in full).

TRANSFER OF SHARES ISSUED PRIOR TO [REDACTED]

The PRC Company Law provides that in relation to the public offering of a company, the shares issued prior to the public offering shall not be transferred within a period of one year from the date on which the publicly offered shares are listed on any stock exchange. Accordingly, Shares issued by our Company prior to the [REDACTED] shall be subject to this statutory restriction and not be transferred within a period of one year from the [REDACTED].

Directors, Supervisors and senior management shall notify the Company of the Shares they hold and any changes therein. During their respective tenure of office, any Shares transferred by any of the Company’s Directors, Supervisors and senior management in any year shall not exceed 25% of the relevant individual’s total Shares in the Company. Shares held by any Director, Supervisor or senior management shall not be transferred within a period of one year from the [REDACTED].

REGISTRATION OF SHARES NOT LISTED ON THE OVERSEAS STOCK EXCHANGE

According to the Notice of Centralized Registration and Deposit of Non-overseas Listed Shares of Companies Listed on an Overseas Stock Exchange (《關於境外上市公司非境外上市股份集中登記存管有關事宜的通知》) issued by the CSRC, an overseas listed company is required to register its shares that are not listed on the overseas stock exchange with China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司) within 15 Business Days upon listing and provide a written report to the CSRC regarding the centralized registration and deposit of its unlisted shares as well as the current offering and listing of shares.

SHARE CAPITAL

CIRCUMSTANCES UNDER WHICH GENERAL MEETING AND CLASS MEETING ARE REQUIRED

For details of circumstances under which our Shareholders’ general meeting and class Shareholders’ meeting are required, please refer to the section headed “Summary of the Articles of Association” in Appendix VI to this document.

LOCK-UP PERIODS

In accordance with the PRC Company Law, the shares issued prior to any public offering of shares by a company cannot be transferred within one year from the date on which such publicly offered shares are listed and traded on the relevant stock exchange. As such, the Shares issued by our Company prior to the issue of H Shares will be subject to such statutory restriction on transfer within a period of one year from the [REDACTED].

Our Directors, Supervisors and members of the senior management of our Company shall declare their shareholdings in our Company and any changes in their shareholdings. Shares transferred by our Directors, Supervisors and members of the senior management each year during their term of office shall not exceed 25% of their total respective shareholdings in our Company. The Shares that the aforementioned persons held in our Company cannot be transferred within one year from the date on which the shares are listed and traded, nor within half a year after they leave their positions in our Company. The Articles of Association may contain other restrictions on the transfer of the Shares held by our Directors, Supervisors and members of senior management of our Company.

SUBSTANTIAL SHAREHOLDERS

So far as our Directors are aware, immediately following the completion of the [REDACTED] and without taking into account any H Shares which may be issued pursuant to the exercise of the [REDACTED], the following persons will have an interest or short position in the Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO:

Name of Shareholder	Capacity/nature of interest	Number and class of Shares to be held after the [REDACTED]	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED] (assuming no exercise of the [REDACTED])	Approximate percentage of Shareholder in the total share capital of our Company after the [REDACTED] (assuming no exercise of the [REDACTED])
Mr. Wang ⁽¹⁾	Interests of controlled corporation; interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	2.91%	[REDACTED]%	[REDACTED]%
	Interests held jointly with another person	[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	9.86%	[REDACTED]%	[REDACTED]%
Yantai Rongda Venture Capital Center (Limited Partnership) (煙台榮達創業投資中心(有限合伙)) ⁽¹⁾	Beneficial owner; interests held jointly with another person	[REDACTED] Domestic Shares	25.48%	[REDACTED]%	[REDACTED]%
		[REDACTED] Domestic Shares	11.57%	[REDACTED]%	[REDACTED]%
	Interests held jointly with another person	[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%
Yantai Rongqian Enterprise Management Center Limited Partnership) (煙台榮謙企業管理中心(有限合伙)) ⁽¹⁾	Beneficial owner	[REDACTED] Domestic Shares	4.61%	[REDACTED]%	[REDACTED]%
Yantai Rongyi Enterprise Management Center (煙台榮益企業管理中心(有限合伙)) ⁽¹⁾	Beneficial owner	[REDACTED] Domestic Shares	4.14%	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Capacity/nature of interest	Number and class of Shares to be held after the [REDACTED]	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED] (assuming no exercise of the [REDACTED])	Approximate percentage of Shareholder in the total share capital of our Company after the [REDACTED] (assuming no exercise of the [REDACTED])
RongChang Holding Group LTD. ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	9.86%	[REDACTED]%	[REDACTED]%
Dr. Fang ⁽¹⁾	Beneficial owner; interests held jointly with another person	[REDACTED] H Shares	2.91%	[REDACTED]%	[REDACTED]%
		[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
	Interests held jointly with another person	[REDACTED] H Shares	2.91%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	9.86%	[REDACTED]%	[REDACTED]%
I-NOVA Limited ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
	Beneficial owner; interests held jointly with another person	[REDACTED] H Shares	9.86%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	2.91%	[REDACTED]%	[REDACTED]%
Dr. Wang Liqiang ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Capacity/nature of interest	Number and class of Shares to be held after the [REDACTED]	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED] (assuming no exercise of the [REDACTED])	Approximate percentage of Shareholder in the total share capital of our Company after the [REDACTED] (assuming no exercise of the [REDACTED])
Mr. Lin Jian ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%
Mr. Wang Xudong ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%
Mr. Deng Yong ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%
Mr. Xiong Xiaobin ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%
Mr. Wen Qingkai ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%
Ms. Yang Minhua ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Name of Shareholder	Capacity/nature of interest	Number and class of Shares to be held after the [REDACTED]	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED] (assuming no exercise of the [REDACTED])	Approximate percentage of Shareholder in the total share capital of our Company after the [REDACTED] (assuming no exercise of the [REDACTED])
Mr. Wei Jianliang ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%
Fund for the transformation of National Science and Technology Major Project (國投(上海)科技成果轉化創業投資基金企業(有限合夥)) (“SDIC Venture”) ⁽²⁾	Beneficial owner	[REDACTED] Domestic Shares	6.16%	[REDACTED]%	[REDACTED]%
SDIC (Shanghai) Venture Capital Management Co., Ltd. (國投(上海)創業投資管理有限公司) ⁽²⁾	Interests of controlled corporation	[REDACTED] Domestic Shares	6.16%	[REDACTED]%	[REDACTED]%
SDIC Venture Capital Management Co., Ltd. (國投創業投資管理有限公司) ⁽²⁾	Interests of controlled corporation	[REDACTED] Domestic Shares	6.16%	[REDACTED]%	[REDACTED]%
China SDIC Gaoxin Industrial Investment Corp., Ltd. (中國國投高新產業投資有限公司) ⁽²⁾⁽³⁾	Interests of controlled corporation	[REDACTED] Domestic Shares	8.78%	[REDACTED]%	[REDACTED]%
State Development & Investment Corporation (國家開發投資集團有限公司) ⁽²⁾⁽³⁾	Interests of controlled corporation	[REDACTED] Domestic Shares	8.78%	[REDACTED]%	[REDACTED]%
PAG Growth Prosperity Holding I (HK) Limited (“PAG I”)	Beneficial owner	[REDACTED] H Shares	5.25%	[REDACTED]%	[REDACTED]%
PAG Growth I LP ⁽⁴⁾	Interests of controlled corporation	[REDACTED] H Shares	5.75%	[REDACTED]%	[REDACTED]%
Wholly Sunbeam Limited	Beneficial owner	[REDACTED] H Shares	3.91%	[REDACTED]%	[REDACTED]%
Mr. Zhu Hongtu (朱宏圖) ⁽⁵⁾	Interests of controlled corporation	[REDACTED] H Shares	3.91%	[REDACTED]%	[REDACTED]%
Shenzhen Capital Group Co., Ltd. (深圳市創新投資集團有限公司)	Beneficial owner	[REDACTED] Domestic Shares	3.19%	[REDACTED]%	[REDACTED]%
RC-Biology Investment Ltd.	Beneficial owner	[REDACTED] H Shares	2.69%	[REDACTED]%	[REDACTED]%

SUBSTANTIAL SHAREHOLDERS

Notes:

- (1) As of the Latest Practicable Date, each of Yantai Rongda Venture Capital Center (Limited Partnership) (煙台榮達創業投資中心(有限合夥)) (“Rongda”), Yantai Rongqian Enterprise Management Center (Limited Partnership) (煙台榮謙企業管理中心(有限合夥)) (“Rongqian”), Yantai Rongshi Enterprise Management Center (Limited Partnership) (煙台榮實企業管理中心(有限合夥)) (“Rongshi”), Yantai Rongyi Enterprise Management Center (Limited Partnership) (煙台榮益企業管理中心(有限合夥)) (“Rongyi”), Yantai Rongjian Enterprise Management Center (Limited Partnership) (煙台榮建企業管理中心(有限合夥)) (“Rongjian”) was a limited partnership established in the PRC. Each of Rongqian, Rongshi, Rongyi and Rongjian is an employee incentive platform and held [REDACTED], [REDACTED], [REDACTED] and [REDACTED] Domestic Shares in our Company, respectively. Mr. Wang is the executive partner of each of Rongda, Rongqian, Rongshi, Rongyi and Rongjian. As such, under the SFO, Mr. Wang is deemed to be interested in the equity interests held by Rongda, Rongqian, Rongshi, Rongyi and Rongjian.

Further, as of the Latest Practicable Date, RongChang Holding Group LTD. was a company incorporated in the British Virgin Islands. Mr. Wang was the sole director of RongChang Holding Group LTD. and RongChang Holding Group LTD. is accustomed to act in accordance with Mr. Wang’s instructions. As such, under the SFO, Mr. Wang is deemed to be interested in the equity interests held by RongChang Holding Group LTD.

As of the Latest Practicable Date, I-NOVA Limited was a company incorporated in the British Virgin Islands and was wholly-owned by Dr. Fang. As such, under the SFO, Dr. Fang is deemed to be interested in the equity interests held by I-NOVA Limited.

On April 16, 2020, Mr. Wang, Dr. Fang, Mr. Lin Jian, Dr. Wang Liqiang, Mr. Wang Xudong, Mr. Deng Yong, Mr. Xiong Xiaobin, Mr. Wen Qingkai, Ms. Yang Minhua, Mr. Wei Jianliang, Rongda, RongChang Holding LTD. and I-NOVA Limited entered into a concert party agreement to confirm that they have acted in concert in the management, decision-making and all major decisions of our Group. As such, each of the Concert Parties are deemed to be interested in the Shares each other is interested in.

- (2) SDIC Venture beneficially owns [REDACTED] Domestic Shares and is a limited partnership incorporated in the PRC, whose executive partner is SDIC (Shanghai) Venture Capital Management Co., Ltd. (國投(上海)創業投資管理有限公司), a wholly-owned subsidiary of SDIC Venture Capital Management Co., Ltd. (國投創業投資管理有限公司), which is owned as to 40% by China SDIC Gaoxin Industrial Investment Corp., Ltd. (中國國投高新產業投資有限公司).

China SDIC Gaoxin Industrial Investment Corp., Ltd. is a wholly-owned subsidiary of State Development & Investment Corporation (國家開發投資集團有限公司), a state-owned entity incorporated in the PRC.

As such, under the SFO, each of SDIC (Shanghai) Venture Capital Management Co., Ltd., SDIC Venture Capital Management Co., Ltd., China SDIC Gaoxin Industrial Investment Corp., Ltd. and State Development & Investment Corporation is deemed to be interested in the equity interests held by SDIC Venture.

- (3) SDIC Chuanghe beneficially owns [REDACTED] Domestic Shares and is a limited partnership incorporated in the PRC, whose executive partner is SDIC Unity Capital Co., Ltd. (國投創合基金管理有限公司).

Hangzhou Chuanghe beneficially owns [REDACTED] Domestic Shares and is a limited partnership incorporated in the PRC, whose executive partner is SDIC Unity (Hangzhou) Start-up Investment Management Co., Ltd. (國投創合(杭州)創業投資管理有限公司), a wholly-owned subsidiary of SDIC Unity Capital Co., Ltd.

SDIC Unity Capital Co., Ltd. is owned as to 40% by State Development and Hi-tech Investment Corp. (國投高科技投資有限公司), a wholly-owned subsidiary of China SDIC Gaoxin Industrial Investment Corp., Ltd. (中國國投高新產業投資有限公司). Please refer to footnote (2) for shareholding information of China SDIC Gaoxin Industrial Investment Corp., Ltd.

As such, under the SFO, each of SDIC Unity Capital Co., Ltd., State Development and Hi-tech Investment Corp. and China SDIC Gaoxin Industrial Investment Corp., Ltd. is deemed to be interested in the equity interests held by SDIC Chuanghe, and each of SDIC Unity (Hangzhou) Start-up Investment Management Co., Ltd. and SDIC Unity Capital Co., Ltd. is deemed to be interested in the equity interests held by Hangzhou Chuanghe.

SUBSTANTIAL SHAREHOLDERS

- (4) PAG I beneficially owns [REDACTED] H Shares and is wholly-owned by PAG Growth Prosperity Holding I (Cayman) Limited, which is in turn wholly-owned by PAG Growth Prosperity Holding I Limited, a wholly-owned subsidiary of PAG Growth I LP. As such, under the SFO, each of PAG Growth Prosperity Holding I (Cayman) Limited, PAG Growth Prosperity Holding I Limited and PAG Growth I LP is deemed to be interested in the equity interests held by PAG I.

PAG Growth Holding IV (HK) Limited (“PAG IV”) beneficially owns [REDACTED] H Shares and is wholly-owned by PAG Growth Holding IV (Cayman) Limited, which is in turn wholly-owned by PAG Growth Holding IV Limited, a wholly-owned subsidiary of PAG Growth I LP. As such, under the SFO, each of PAG Growth Prosperity Holding IV (Cayman) Limited, PAG Growth Prosperity Holding IV Limited and PAG Growth I LP is deemed to be interested in the equity interests held by PAG IV.

- (5) Wholly Sunbeam Limited beneficially owns [REDACTED] H Shares and is wholly-owned by Mr. Zhu Hongtu (朱宏圖). As such, under the SFO, Mr. Zhu Hongtu is deemed to be interested in the equity interests held by Wholly Sunbeam Limited.

Save as disclosed herein, our Directors are not aware of any persons who will, immediately following completion of the [REDACTED] (assuming the [REDACTED] is not exercised), without taking into account the [REDACTED] that may be taken up under the [REDACTED], have interests or short positions in Shares or underlying Shares which would fall to be disclosed under the provisions of Divisions 2 and 3 of Part XV of the SFO or, will be, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of our Company. Our Directors are not aware of any arrangement which may at a subsequent date result in a change of control of our Company.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

BOARD OF DIRECTORS

Our Board consists of nine Directors, of whom four are executive Directors, two are non-executive Directors and three are independent non-executive Directors. Our Board is responsible and has general powers for the management and conduct of our business. The table below sets out certain information in respect of the members of the Board.

The table below sets out certain information regarding our current Directors.

Name	Age	Position	Date of appointment as Director	Date of joining our Group	Roles and responsibilities
Mr. Wang Weidong (王威東)	60	Chairman and executive Director	October 30, 2013	October 30, 2013	Overall management, business, and strategy of our Group
Dr. Fang Jianmin (房健民)	58	Executive Director, chief executive officer and chief scientific officer	October 16, 2008	October 16, 2008	Overall management, business, and strategy of our Group, formulation of new drug research and development strategy of the Group, and supervision of research and development of innovative drugs with appropriate target agents
Dr. He Ruyi (何如意)	59	Executive Director, chief medical officer and head of clinical research	May 11, 2020	May 11, 2020	Management of the clinical needs, medical support, clinical pharmacology, registrational compliance, drug safety, clinical researches and statistics of our Group
Mr. Lin Jian (林健)	65	Executive Director	July 4, 2008	July 4, 2008	Overall management, business, and strategy of our Group
Dr. Wang Liqiang (王荔強)	49	Non-executive Director	May 11, 2020	May 11, 2020	Oversee Board affairs and provide strategic advice and guidance on the Group’s affairs

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Name	Age	Position	Date of appointment as Director	Date of joining our Group	Roles and responsibilities
Dr. Su Xiaodi (蘇曉迪)	34	Non-executive Director	May 11, 2020	May 11, 2020	Oversee Board affairs and provide strategic advice and guidance on the Group’s affairs
Ms. Yu Shanshan (于珊珊)	36	Independent non-executive Director	May 11, 2020	May 11, 2020	Provide independent advice and judgment to our Board
Mr. Hao Xianjing (郝先經)	54	Independent non-executive Director	May 11, 2020	May 11, 2020	Provide independent advice and judgment to our Board
Dr. Lorne Alan Babiuk	74	Independent non-executive Director	May 11, 2020	May 11, 2020	Provide independent advice and judgment to our Board

Executive Directors

Mr. Wang Weidong (王威東), aged 60, was appointed as a Director on October 30, 2013 and redesignated as an executive Director on May 22, 2020, and has been the chairman of our Board since June 21, 2019. Mr. Wang is primarily responsible for the overall management, business and strategy of our Group. He founded RC Pharma in March 1993 and has served as its chairman and legal representative since its establishment, accumulating more than 27 years of experience in the pharmaceutical industry.

Mr. Wang obtained his bachelor’s degree in Chinese medicine manufacturing at the Heilongjiang School of Commerce (黑龍江商學院) (currently known as Harbin University of Commerce (哈爾濱商業大學)) in July 1982. He is currently serving a representative on the 13th National People’s Congress in the PRC.

Mr. Wang has served as a deputy to the 13th National People’s Congress (第十三屆全國人大代表) since March 2018 and his awards and recognitions include “Outstanding Builder of Socialism with Chinese Characteristics in Non-State-Owned Sector in Shandong Province” (山東省非公有制經濟人士優秀中國特色社會主義事業建設者) jointly awarded by Shandong Provincial United Front Work Department (山東省委統戰部), Shandong Provincial Federation of Industry and Commerce (山東省工商業聯合會), Shandong Provincial Department of Industry and Information Technology (山東省工業和資訊化廳), Shandong Provincial Department of Human Resources and Social Security (山東省人力資源和社會保障廳) and Shandong Provincial Department of Market Regulation (山東省市場監管局) in July 2019,

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“2019 YEDA Distinguished Personnel” (煙台開發區功勳人物) awarded by the YEDA Management Committee Office (煙台開發區工委管委) in February 2020, and “Entrepreneurs With Outstanding Contribution” (紮根煙台開發區創業二十年特殊貢獻企業家) awarded by the YEDA Management Committee Office (煙台開發區工委管委) in February 2020 for his 20-year deep-rooted entrepreneurship contribution in YEDA.

Dr. Fang Jianmin (房健民), aged 58, was appointed as our Director, chief executive officer and chief scientific officer on October 16, 2008, and redesignated as an executive Director on May 22, 2020. Dr. Fang is a co-founder of our Company and is primarily responsible for the overall management, business and strategy of our Group. Since inception, Dr. Fang has been the key driving force in our innovation and overseen our new drug research and development from discovery, target validation, CMC development, to clinical studies. He possesses more than 20 years of experience in the research and development of biopharmaceuticals. Dr. Fang also serves as director of RemeGen Medical Research (Shanghai) Co., Ltd., RemeGen Biosciences, Inc. and RemeGen Hong Kong Limited, our wholly-owned subsidiaries.

Dr. Fang obtained his doctorate degree in Biology from Dalhousie University in Canada in May 1998 and was a post-doctoral fellow focusing on cancer research at the Department of Surgery, Harvard Medical School/Boston Children’s Hospital from 1997 to 2000.

Dr. Fang was recognized as a Taishan Scholar (泰山學者) by the Shandong Provincial People’s Government (山東省人民政府) in March 2010. He has been a member of the scientific expert committee of the National Major Scientific and Technological Project for “Major Drug Innovations” of China (“重大新藥創制”國家科技重大專項總體專家組) since December 2012 which overseen the nation’s drug innovation strategy. Dr. Fang is a professor of molecular medicine at School of Life Science and Technology at Tongji University in Shanghai, PRC. He is member of the Board of Directors of Chinese Pharmaceutical Association (中國藥學會), vice chairman of Antibody Drug Division at China Medicinal Biotechnology Association (中國醫藥生物技術協會“單克隆抗體專業委員會”) and vice chairman of Drug Innovation Division at Chinese Pharmaceutical Innovation Research and Development Association (中國醫藥創新促進會藥物研發專業委員會). He is the inventor of conbercept and owns more than 40 patents.

Dr. He Ruyi (何如意), aged 59, was appointed as a Director on May 11, 2020 and redesignated as an executive Director on May 22, 2020 and appointed as the chief medical officer and head of clinical research of our Company on May 11, 2020 and is primarily responsible for the management of the clinical needs, medical support, clinical pharmacology, registrational compliance, drug safety, clinical researches and statistics of our Group. Dr. He possesses more than 33 years of experience in medical and pharmaceutical industries in the PRC and the U.S. and nearly 20 years of unique policy-making and managerial experience at the FDA in the U.S. and the NMPA in China. He has been the chief scientist of healthcare and medicine (醫藥健康首席科學家) at SDIC Fund Management Co., Ltd. (國投招商投資管理有限公司) to advise on investment decisions in the healthcare and medicine field since October 2018. From July 2016 to October 2018, he was the chief scientist at the Center for Drug Evaluation, the China Food and Drug Administration (currently known as the National Medical

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and Pharmaceutical Administration) (國家食品藥品監督管理總局藥品審評中心), where he was responsible for improving its drug evaluation and approval process and supervising assessments related to the safety, effectiveness and quality of innovative drugs. He served in various capacities from medical officer to medical team leader and the acting deputy director in the Center for Drug Evaluation and Research at the Food and Drug Administration in the U.S. from 1999 to 2016. Dr. He was a doctor of internal medicine at Howard University Hospital and Affiliated Hospitals in Washington, District of Columbia, the U.S. between June 1996 and June 1999, and a visiting fellow at the National Institutes of Health in the U.S. between March 1988 and June 1996. He served as a doctor of internal medicine at the First Hospital of China Medical University (中國醫科大學附屬第一醫院) from July 1986 to March 1988.

Dr. He obtained his bachelor’s and master’s degrees in medicine from China Medical University (中國醫科大學) in August 1983 and July 1986, respectively, and a certification of postgraduate medical education in internal medicine from Howard University in the U.S. in June 1997. He is certified as a diplomate in internal medicine by the American Board of Internal Medicine and licensed to practise medicine and surgery in West Virginia, the U.S. since 1999 and 2015, respectively. Dr. He has served as the independent director of Suzhou Zelgen Biopharmaceuticals Co., Ltd. (蘇州澤璟生物製藥股份有限公司), a company listed on the Science and Technology Innovation Board of the Shanghai Stock Exchange (stock code: 688266), since February 2019.

Dr. He’s awards and recognitions include a Serotonin (5-HT) Receptor Against Class – AC team excellence award by the Center for Drug Evaluation and Research of the Food and Drug Administration in the U.S. in September 2012, FDA group recognitions awarded by the Food and Drug Administration in the U.S. in July and October 2013, and a leveraging collaboration award from the Food and Drug Administration in the U.S. in September 2014. Dr. He was also recognized for his outstanding service of more than 25 years in developing scientific education training activities for staff in Center for Drug Evaluation and Research of the Food and Drug Administration in the U.S. in May 2015.

Mr. Lin Jian (林健), aged 65, was appointed as a Director on July 4, 2008 and redesignated as an executive Director on May 22, 2020. He has more than 35 years of experience in the pharmaceutical industry and is primarily responsible for the overall management, business and strategy of our Group. Mr. Lin served as the chairman of our Board from July 2008 to June 2019 and was responsible for our strategic planning and development of our Group. He is also director of Ruimeijing (Beijing) Pharmaceutical Technology Co., Ltd. and RemeGen Biosciences, Inc., our wholly-owned subsidiaries.

Mr. Lin obtained his bachelor’s degree in Chinese medicine manufacturing from the Heilongjiang School of Commerce (黑龍江商學院) (currently known as Harbin University of Commerce (哈爾濱商業大學)) in January 1982.

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Non-executive Directors

Dr. Wang Liqiang (王荔強), aged 49, was appointed as a Director on May 11, 2020 and redesignated as a non-executive Director on May 22, 2020. Dr. Wang has more than 26 years of experience in the pharmaceutical industry and is primarily responsible for supervising the management of our Board. Since January 1994, Dr. Wang has served in various positions in RC Pharma, including a sales manager and vice president and the president. He currently serves as the chairman of the board and the president of RC Pharmaceutical (Zibo) Co, Ltd. (榮昌製藥(淄博)有限公司), a subsidiary of RC Pharma. In these capacities, his responsibilities primarily included production, supply and sales management, as well as business operations and overall management. Dr. Wang was also appointed as the vice chairman (副會長) of the PRC Chinese Medicine Association of Anorectal Studies (中國中醫藥研究促進會肛腸分會) in October 2019 and a member of the 3rd Council of the Pharmaceutical Chamber of Commerce of All-China Federation of Industry and Commerce (中華全國工商業聯合會醫藥業商會第三屆理事會) in August 2019.

Dr. Wang obtained his doctorate degree in business administration at the United Business Institute in Belgium in November 2019. Dr. Wang is qualified as an intermediate economist in business management (經濟專業技術資格中級經濟師工商管理專業) with the Ministry of Personnel (now known as the Ministry of Human Resources and Social Security (人力資源和社會保障部)) of the PRC since November 2000.

Dr. Wang’s awards and recognitions include top 10 emerging figures in the pharmaceutical industry in the PRC (中國醫藥行業十大新銳人物) awarded by the All-China Federation of Industry and Commerce (中華全國工商業聯合會醫藥業商會) in June 2019, 70th establishment anniversary of the PRC – Distinguished figure in the pharmaceutical industry (建國70周年•醫藥產業功勳人物) awarded by Organizing Committee of Assessment Results of Chinese Brand Influence (中國品牌影響力評價成果發佈活動組委會) in May 2019, 2017 Star Entrepreneur (2017年度明星企業家) awarded by the Management Committee of Zibo National New & Hi-tech Industrial Development Zone (淄博高新區管委會) in February 2018 and 2015 top 100 innovative individuals in PRC enterprises (2015年度中國企業百名創新人物) awarded by the Cultural Management Professional Committee of the China Culture Administration Association (中國文化管理協會企業文化管理專業委員會) in November 2015.

Dr. Su Xiaodi (蘇曉迪), aged 34, was appointed as a Director on May 11, 2020 and redesignated as a non-executive Director on May 22, 2020. She has around 6 years of experience in research and development, and investments in the biomedical industry, and is primarily responsible for supervising the management of our Board. She is currently a senior investment manager at Lilly Asia Ventures, the biomedical venture arm of Eli Lilly and Company, a company listed on the NYSE (stock code: LLY). Prior to joining our Group, she was a life science specialist at L.E.K. Consulting from September 2015 to November 2017, where she led and supported more than 15 projects focusing on pharmaceutical and medtech sectors.

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Dr. Su obtained her bachelor’s degree in biology from Fudan University in Shanghai, the PRC in July 2008 and her doctoral degree in immunology and microbial pathogenesis (免疫與微生物病原學) from Cornell University in the United States in May 2014. From June 2014 to March 2015, she was a post-doctoral fellow at Hospital for Special Surgery in New York, the United States.

Independent Non-executive Directors

Ms. Yu Shanshan (于珊珊), aged 36, was appointed as an independent Director on May 11, 2020 and redesignated as an independent non-executive Director on May 22, 2020. She is responsible for providing independent advice and judgment to our Board. Ms. Yu has more than 12 years of experience in accounting, auditing, and corporate finance. She has been an associate at China-ASEAN Capital Advisory Company Ltd. since April 2020. She was an associate at the CLSA Group from January 2018 to May 2020 and served as an analyst at BOCI Asia Limited from June 2012 to December 2017, at both she led and assisted pre-IPO financing projects, merger and acquisitions, as well as listing applications to the Stock Exchange. Ms. Yu was a senior accountant at BDO Canada LLP from September 2011 to January 2012 and a junior accountant at Fruitman Kates LLP in Toronto, Canada from December 2007 until July 2011, respectively.

Ms. Yu graduated from the University of British Columbia with a bachelor’s degree in finance in May 2005. She received a master’s degree in accounting and management from the University of Toronto in November 2007. Ms. Yu has passed the International Uniform Certified Public Accountant Qualification Examination in January 2012, and has been a member of the Chartered Professional Accountants of Canada since November 2012 and Chartered Financial Analyst since July 2016.

Mr. Hao Xianjing (郝先經), aged 54, was appointed as an independent Director on May 11, 2020 and redesignated as an independent non-executive Director on May 22, 2020. He is responsible for providing independent advice and judgment to our Board. Mr. Hao has more than 19 years of experience in accounting, auditing, and financial reporting. Mr. Hao has served as a partner and principal accountant at ShineWing Certified Public Accountants (信永中和會計師事務所) since October 2009.

Mr. Hao is currently an independent director at AVCON Information Technology Co., Ltd. (華平資訊技術股份有限公司) and at Tianguang Zhongmao Co., Ltd. (天廣中茂股份有限公司), both of which are listed on the Shenzhen Stock Exchange (stock codes: 300074 and 002509, respectively), since June 2018 and September 2019, respectively. From May 2008 to April 2014, he served as an independent director of Inspur Electronic Information Industry Co., Ltd. (浪潮電子資訊產業股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 000977).

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Hao graduated from Shandong University of Finance (山東財政學院) (currently known as Shandong University of Finance and Economics (山東財經大學)) in the PRC with a bachelor’s degree in finance in July 1989. He received a master’s degree in economics from Liaoning University (遼寧大學) in the PRC in July 1996. Mr. Hao has been a member of the Chinese Institute of Certified Public Accountants (中國註冊會計師協會) since June 1995 and a member of the China Certified Tax Agents Association (中國註冊稅務師協會) since December 2000.

Dr. Lorne Alan Babiuk, aged 74, was appointed as an independent Director on May 11, 2020 and redesignated as an independent non-executive Director on May 22, 2020. He is responsible for providing independent advice and judgment to our Board. Dr. Babiuk has more than 46 years of experience in teaching and research in immunology, pathogenesis, virology, molecular virology, and vaccinology. He was a professor of University of Saskatchewan and chief executive officer of the Vaccine and Infectious Disease Organization of the University of Saskatchewan from 1973 to 2007, and a professor of University of Alberta from 2007 to 2019. His experience was widely recognized in the field and has received the Distinguished Microbiologist Award from the Canadian College of Microbiologists in 2011, the Global Confederation of Higher Education Associations (GCHERA) World Agriculture Prize in 2016, the Canadian Association for Clinical Microbiology and Infectious Diseases (CACMID) Fitzgerald award in 2018.

Dr. Babiuk obtained his bachelor’s degree in agriculture and master’s degree in science from University of Saskatchewan in Canada in May 1967 and May 1969, respectively, and a doctorate degree in philosophy from the University of British Columbia in Canada in November 1972. He was also awarded Honorary Doctor of Science by Colorado State University in the United States, University of Guelph in Canada and University of Saskatchewan in Canada in 2007, 2008 and 2014, respectively.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SUPERVISORS

The table below sets out certain information regarding our Supervisors.

Name	Age	Position	Date of appointment as Supervisor	Date of joining our Group	Roles and responsibilities
Mr. Ren Guangke (任廣科)	46	Supervisor	May 11, 2020	May 25, 2019	Supervise the performance of our Board and members of the senior management in performing their duties to the Company
Mr. Li Yupeng (李宇鵬)	37	Supervisor	May 11, 2020	May 11, 2020	Supervise the performance of our Board and members of the senior management in performing their duties to the Company
Mr. Li Zhuanglin (李壯林)	45	Supervisor	May 11, 2020	July 1, 2011	Supervise the performance of our Board and members of the senior management in performing their duties to the Company

Mr. Ren Guangke (任廣科), aged 46, was appointed as a Supervisor on May 11, 2020, and is primarily responsible for the supervision of the performance of the Directors and members of the senior management in performing their duties to the Company. Mr. Ren has around 23 years of experience in the legal field. He joined our Company on May 25, 2019 and is primarily responsible for intellectual property matters and legal affairs of our Company. Prior to joining our Company, Mr. Ren served as the deputy general manager (副總經理) and manager of the intellectual property legal affairs department (知識產權及法務部) of RC Pharma from June 2017 to April 2019 and a president (庭長) of Shandong Yantai Intermediate People’s Court (煙台中級人民法院) to preside over and decide cases from February 2014 to May 2017.

Mr. Ren obtained his bachelor’s degree in physics from Yantai University (煙台大學) in the PRC in June 1996.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Mr. Li Yupeng (李宇鵬), aged 37, was appointed as a Supervisor on May 11, 2020, and is primarily responsible for the supervision of the performance of the Directors and members of the senior management in performing their duties to the Company. Mr. Li has around 9 years of experience in the investment management and has been the vice-president (副總裁) of SDIC Venture Capital Management Co., Ltd. (國投創業投資管理有限公司) since December 2016 and is primarily responsible for overseeing biomedical investments of our Company.

Mr. Li obtained his bachelor’s degree in computer engineering from Beijing Institute of Technology (北京理工大學) in the PRC in July 2006 and his master’s degree in finance from the Chinese Academy of Fiscal Sciences (中國財政研究院) in the PRC in July 2011.

Mr. Li Zhuanglin (李壯林), aged 45, was appointed as a Supervisor on May 11, 2020, and is primarily responsible for the supervision of the performance of the Directors and members of the senior management in performing their duties to the Company. Mr. Li has around 15 years of experience in the biomedical manufacturing field. He has been the deputy general manager (副總經理) of our Company since July 2011 and May 2019, respectively, and is primarily responsible for overseeing the commercialization and manufacturing center (商業化製造中心) of our Group. Prior to joining our Group, he was the deputy general manager (副總經理) of Shandong Simcere Pharmaceutical Co., Ltd. (山東先聲生物製藥有限公司) and supervised its manufacturing and engineering departments.

Mr. Li obtained his bachelor’s degree in microbiology (微生物學) from Yantai University (煙台大學) in the PRC in July 1997 and his master’s degree in biochemistry and molecular biology (生物化學與分子生物學) and his doctoral degree in microbiology (微生物學) from Shandong University (山東大學) in the PRC in December 2006 and June 2011, respectively.

Other Disclosure Pursuant to Rule 13.51(2) of the Listing Rules

Save as disclosed above and in this document, each of our Directors and Supervisors confirms with respect to himself or herself that he or she (1) did not hold other long positions or short positions in the Shares, underlying Shares, debentures of our Company or any associated corporation (within the meaning of Part XV of the SFO) as of the Latest Practicable Date; (2) had no other relationship with any Directors, Supervisors, senior management or substantial shareholders of our Company as of the Latest Practicable Date; (3) did not hold any other directorships in the three years prior to the Latest Practicable Date in any public companies of which the securities are listed on any securities market in Hong Kong and/or overseas; and (4) there are no other matters concerning our Director’s appointment that need to be brought to the attention of our Shareholders and the Stock Exchange or shall be disclosed pursuant to Rules 13.51(2)(h) to (v) of the Listing Rules.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

SENIOR MANAGEMENT

The table below sets out certain information regarding our senior management:

Name	Age	Position	Date of appointment as senior management	Date of joining our Group	Roles and responsibilities
Dr. Fang Jianmin (房健民)	58	Chief executive officer and chief scientific officer	October 16, 2008	October 16, 2008	Overall management, business, strategy, and technology development of our Group
Dr. Fu Daotian (傅道田)	57	President	September 2, 2019	September 2, 2019	Overall management, business, and strategy of our Group and operational management of the new drug pre-clinical research and development, processes development, quality control and pharmaceutical production of our Group
Dr. He Ruyi (何如意)	59	Chief medical officer and head of clinical research	May 11, 2020	May 11, 2020	Management of the clinical needs, medical support, clinical pharmacology, registrational compliance, drug safety, clinical researches and statistics of our Group
Mr. Wen Qingkai (温庆凯)	53	Board secretary	May 11, 2020	May 25, 2019	Supervision of financing activities, internal control and securities and listing matters of our Group
Mr. Li Jia (李嘉)	40	Chief financial officer and joint company secretary	May 11, 2020	February 3, 2020	Overseeing the overall financial management, financial matters and strategic development of our Group

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Dr. Fang Jianmin (房健民) is an executive Director, chief executive officer and chief scientific officer of our Company. Please refer to the paragraph headed “—Executive Directors” in this section for details.

Dr. Fu Daotian (傅道田), aged 57, was appointed as the president of our Company on September 2, 2019 and is primarily responsible for operational management of the new drug pre-clinical research and development, processes development, quality control, pharmaceutical production of our Group. Dr. Fu possesses more than 25 years of experience in research and development of biopharmaceuticals in the PRC and the U.S. Prior to joining our Group, he was the vice president and executive director of Livzon Pharmaceutical Group Inc. (“Livzon Pharmaceutical”), a company listed on the Stock Exchange (stock code: 1513) and in the PRC (SZSE: 000513) from March and June 2014, respectively to September 2019, where he was responsible for the strategic planning and development of research and development in biotech industry. He was the general manager of Livzon MABPharm Inc., a subsidiary of Livzon Pharmaceutical from March 2012 to September 2019, where he supervised its overall management and operation. At Livzon, he led the biologics development efforts with one successful BLA submission and multiple programs in clinical development. Dr. Fu returned to China after spending 28 years training and working in the biopharmaceutical industry in the United States. Dr. Fu had served as Vice President, Research at Genzyme Corp., one of the top five global biotech companies and was later acquired by Sanofi, a company listed on Nasdaq (stock code: SNY). At Genzyme Corp., Dr. Fu was responsible for CMC development of clinical stage programs, and was directly involved in global launching of five major biologics and clinical development of multiple research and development programs.

Dr. Fu was a guest processor of Sun Yat-Sen University (中山大學) in the PRC from 2015 to 2018, and has been an external graduate advisor of China Pharmaceutical University (中國藥科大學) in the PRC and a member of the Professional Teaching Guidance Sub-Committee under the Tertiary Education Pharmacy Teaching Guidance Committee (高等學校藥學類專業教學指導委員會) commissioned by the Ministry of Education in the PRC.

Dr. Fu obtained his bachelor’s degree in biology from Shandong University in the PRC in July 1983 and his doctorate degree in biochemistry from Iowa State University, the U.S. in May 1990.

Dr. He Ruyi (何如意) is an executive director, the chief medical officer and the head of clinical research of our Company. Please refer to the paragraph headed “—Executive Directors” in this section for details.

Mr. Wen Qingkai (溫慶凱), aged 53, was appointed as the board secretary of our Company on May 11, 2020 and is primarily responsible for overseeing financing activities, internal control and securities and listing matters of our Group. Mr. Wen has more than 16 years of experience in capital operation and corporate governance. He also currently serves as a supervisor of Heyuan Aidisi Biomedical Technology Co., Ltd. (煙台市和元艾迪斯生物醫藥科技有限公司), an investee of our Company and is responsible for supervising its board, business and operational matters. From February 2004 to May 2019, he served as the vice

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president (副總裁) in RC Pharma, and was responsible for its corporate management, internal control and information technology matters. He has been appointed as a director at Yantai MabPlex International Biomedical Co., Ltd. since November 2019.

Mr. Wen obtained his bachelor’s degree in physics at Yangzhou University in the PRC in June 1990 and master’s degree in philosophy of science and technology at Zhejiang University in the PRC in May 1995.

Mr. Li Jia (李嘉), aged 40, was appointed as the chief financial officer and joint company secretary of our Company on May 11, 2020 and is primarily responsible for overseeing the overall financial management and corporate development of our Group.

Mr. Li possesses more than 15 years of experience in investment banking and corporate finance. Prior to joining our Group, he was an executive director of Goldman Sachs, focusing on transactions in the healthcare space, the board secretary and assistant to the chairman of Hilong Holdings Ltd., a company listed on the Stock Exchange (stock code: 1623), and various investment banking positions at Morgan Stanley, China Renaissance, and Barclays Capital in Asia and the United States.

Mr. Li obtained his bachelor’s degree in business administration and a master’s degree in accountancy from University of Wisconsin-Madison in Madison, the United States in August 2003 and August 2004, respectively, and a master’s degree in business administration from University of Chicago in Illinois, the United States in June 2009.

JOINT COMPANY SECRETARIES

Mr. Li Jia (李嘉), aged 40, was appointed as a joint company secretary of our Company on May 11, 2020. Mr. Li is also a member of senior management of our Company. Please refer to “—Senior Management” in this section for his biographical details.

Ms. Tam Pak Yu, Vivien (譚栢如), was appointed as a joint company secretary of our Company on May 11, 2020. Ms. Tam serves as an assistant manager of SWCS Corporate Services Group (Hong Kong) Limited (方圓企業服務集團(香港)有限公司), a professional services provider specializing in corporate services, and has over five years of experience in corporate secretarial field. Ms. Tam has been admitted as an associate member of both The Hong Kong Institute of Chartered Secretaries and The Chartered Governance Institute in 2018.

Ms. Tam obtained a bachelor’s degree in China Studies from Hong Kong Baptist University in 2014 and a master’s degree in Professional Accounting and Corporate Governance from City University of Hong Kong in 2017.

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BOARD COMMITTEES

In accordance with the relevant PRC laws, regulations, the Articles and the corporate governance practice prescribed in the Listing Rules, we have formed three board committees, namely, the audit committee of the Board (the “Audit Committee”), the remuneration and appraisal committee of the Board (the “Remuneration and Appraisal Committee”), the nomination committee of the Board (the “Nomination Committee”), and the strategy committee of the Board (the “Strategy Committee”).

Audit Committee

Our Company has established an audit committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph C.3 and paragraph D.3 of the Corporate Governance Code as set out in Appendix 14 of the Listing Rules. The Audit Committee consists of Mr. Hao Xianjing, Ms. Yu Shanshan and Dr. Wang Liqiang. The chairman of the Audit Committee is Mr. Hao Xianjing and is our independent non-executive Director with the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing Rules. The main duties of the Audit Committee include but are not limited to:

- monitoring and evaluating the work of the external auditor;
- supervising the implementation of the internal audit system of our Company;
- being responsible for the communications among the management level of the company, the internal and external audit;
- reviewing and commenting on the financial reports of our Company;
- examining the financial reporting system, risk management and internal control systems of our Company;
- making recommendations to our Company on the appointment, reappointment and removal of the external auditor;
- performing daily management duties and implementing control on connected transactions; and
- performing such other duties determined by the Board.

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Remuneration and Appraisal Committee

Our Company has established a remuneration and appraisal committee with written terms of reference in compliance with Rule 3.25 of the Listing Rules and paragraph B.1 of the Corporate Governance Code. The Remuneration and Appraisal Committee consists of Ms. Yu Shanshan, Mr. Hao Xianjing and Mr. Lin Jian, and is chaired by Ms. Yu Shanshan. The main duties of the Remuneration and Appraisal Committee include but are not limited to:

- formulating remuneration policies for Directors and senior management in accordance with the respective scope, responsibilities and significance of Directors and senior management and remuneration levels of similar positions in other enterprises within the same industry;
- making recommendations to the Board on the establishment of a formal and transparent procedure for developing remuneration policies;
- monitoring the implementation of remuneration system of our Company for the Directors and senior management;
- assessing the fulfilment of duties of Directors and senior management of our Company and appraising their annual performance; determining or making recommendations to the Board, with delegated responsibility, the remuneration packages of individual Directors and senior management;
- reviewing and approving compensation payable to Directors and senior management for any loss or termination of office or appointment to ensure that it is consistent with contractual terms and is otherwise fair and not excessive;
- reviewing and managing the share incentive scheme(s) of our Company, including determining the scope of the eligible participants and conditions of a grant and auditing the exercise conditions; and
- performing such other duties determined by the Board.

Nomination Committee

Our Company has established a nomination committee with written terms of reference in compliance with paragraph A.5 of the Corporate Governance Code. The Nomination Committee consists of Mr. Wang Weidong, Mr. Hao Xianjing and Ms. Yu Shanshan, and is chaired by Mr. Wang Weidong. The main duties of the Nomination Committee include but are not limited to:

- making recommendation to the Board on its size and composition to complement the Company’s business operation and shareholding structure;

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- reviewing and making recommendations to the selection standard and procedure of Directors and senior management;
- identifying individuals suitably qualified to become Directors and senior management and selecting or making recommendations to the board on the selection of individuals nominated for directorships or senior management positions;
- reviewing the structure, size and composition (including the skills, knowledge and experience) of the Board at least annually and making recommendations on any proposed changes to the Board to complement our Company’s corporate strategy;
- assessing the independence of independent non-executive Directors; and
- performing such other duties determined by the Board.

Strategy Committee

Our Company has established the Strategy Committee, which consists of Dr. Fang Jianmin, Mr. Wang Weidong, Dr. He Ruyi, Dr. Su Xiaodi, Dr. Lorne Alan Babiuk and Dr. Wang Liqiang, and is chaired by Dr. Fang Jianmin. The main duties of the Strategy Committee include but are not limited to:

- researching and recommending on long-term development strategy of our Company;
- researching and recommending on significant investment and financing plans of our Company;
- researching and recommending on major capital operation and asset management project, and annual financial budget plan of our Company;
- researching and recommending on significant matters relating to the development of our Company;
- monitoring the above matters and assessing, examining and recommending on significant changes; and
- performing such other duties determined by the Board.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

CORPORATE GOVERNANCE

Board Diversity

Our Company seeks to enhance the effectiveness of the Board and to maintain high standards of corporate governance by adopting a board diversity policy. Pursuant to this policy, we intend to achieve board diversity through the consideration of a number of factors at the selection of candidates to the Board, including but not limited to gender, age, cultural and educational background, ethnicity, professional experience, skills, knowledge and length of service. The ultimate decisions of board appointments will be based on merit and the contribution which the selected candidates will bring to the Board.

Our Board consists of seven male members and two female members with two Directors of 40 years old or below, one Director of age 41 to 50 years old, four Directors of 51 to 60 years old and two Directors over 60 years old. Our Company has reviewed the membership, structure and composition of the Board, and is of the opinion that the structure of the Board is reasonable, and the experiences and skills of the Directors in various aspects and fields can enable our Company to maintain high standard of operation.

Our Nomination Committee is responsible for reviewing the diversity of the Board. After [REDACTED], our Nomination Committee will continue to monitor and evaluate the implementation of the board diversity policy from time to time to ensure its continued effectiveness and we will disclose in our corporate governance report about the implementation of the board diversity policy, including any measurable objectives set for implementing the board diversity policy and the progress on achieving these objectives on an annual basis. We will also continue to take steps to promote gender diversity at all levels of our Company.

KEY TERMS OF EMPLOYMENT CONTRACTS

We normally enter into (i) an employment contract, and (ii) a confidentiality and non-competition agreement with our senior management members and other key personnel. Below sets forth the key terms of these contracts we enter into with our senior management and other key personnel.

Term

- We normally enter into 5-year employment contracts with our senior management members or other key personnel.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Confidentiality

- *Scope of confidential information.* The employee shall keep our trade secrets and technical secrets confidential. Our trade secrets refer to information that may materially impact our competitive advantage and include but are not limited to customer information, marketing plans, procurement and pricing policies, financial information, and supply channels. Our technical secrets refer to technical information and data, and know-how that are not publicly available, and include but are not limited to biological materials, process design, manufacturing methods, testing reports, as well as any confidential information directly or indirectly provided by our Company or employees.
- *Confidentiality obligation.* The employee shall not disclose, disseminate, report, publish, transmit, transfer or otherwise make available to any third party (including our employees who are not privy to such confidential information) any confidential information of our Company and that of any third party to which we owe confidential obligations. The employee shall exercise reasonable care in observing his or her confidential obligation and shall not remove any confidential information from the premises of our Company and related companies. Upon the cessation of the employee's employment with our Company, or upon our request, the employee must return to our Company all documents, drawings, records, or any other means of record-keeping that contain our confidential information.
- *Confidential period.* The confidentiality obligation shall continue in force after the cessation of the employee's employment with our Company, until the confidential information, either, (i) is publicly disclosed by our Company, or (ii) has been rendered public without the employee's breach of obligations stated herein.
- *Employee-developed technology.* As to technical inventions, technical secrets or other trade secret information related to the Company's business completed by the employee during his/her term of office, the employee shall promptly make a statement to the Company if he/she claims that he/she shall enjoy the intellectual property rights, and the Company shall then confirm whether they are non-employee-developed technologies. If the employee has any objection to the Company's ownership of the achievements, the dispute can be settled through negotiation and litigation. If the employee fails to declare it, it is presumed that the achievements belong to employee-developed technologies, and the Company can use such achievements for production and operation or transfer them to a third party.

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

Non-competition terms

- *Non-competition obligation during employment term.* During the term of the employment with our Company, unless with our prior consent, the employee shall not engage in any business or engage in a course of employment that produces, or operates products, or provides services that are the same or similar to those offered by, our Company. The employee shall not assume any positions in, hold any interest in, nor operate on his or another's behalf, any businesses, entities, or organizations that competes with, supplies or is connected to, or has any other interest in, our Company.
- *Non-competition obligation upon expiry of employment term.* Unless otherwise agreed, the employee assume an obligation of confidentiality indefinitely after expiry of employment term with our Company until our Company announces to decrypt the secret information or such information has actually been made public.

Compensation for breach

- If the employee breaches the obligations regarding confidentiality and invention assignment, our Company shall be entitled to seek damages for all economic losses arising from the breach; if the employee breaches the non-competition covenants, our Company shall be entitled to a certain liquidated sum determined with reference to the non-competition compensation originally payable to the employee.

COMPLIANCE ADVISER

We have appointed Rainbow Capital (HK) Limited as our compliance adviser pursuant to Rules 3A.19 of the Listing Rules. Pursuant to Rule 3A.23 of the Listing Rules, the compliance adviser will advise us on the following circumstances:

- before the publication of any announcements, circulars or financial reports required by regulatory authorities or applicable laws;
- where a transaction, which might be a notifiable or connected transaction under Chapters 14 and 14A of the Listing Rules is contemplated, including share issues and share repurchases;
- where we propose to use the [REDACTED] of the [REDACTED] in a manner different from that detailed in this document or where our business activities, developments or results deviate from any forecast, estimate or other information in this document; and
- where the Stock Exchange makes an inquiry of us regarding unusual price movement and trading volume or other issues under Rule 13.10 of the Listing Rules.

The terms of the appointment shall commence on the [REDACTED] and end on the date which we distribute our annual report of our financial results for first full the financial year commencing after the [REDACTED].

DIRECTORS, SUPERVISORS AND SENIOR MANAGEMENT

COMPENSATION OF DIRECTORS AND MANAGEMENT

Our Company offers the executive Directors, Supervisors and members of senior management, who are also employees of our Company, emolument in the form of salaries, allowances, discretionary bonus and benefits in kind. Our independent non-executive Directors receive emolument based on their responsibilities (including being members or the chair of Board committees). We adopt a market and incentive-based employee emolument structure and implement a multi-layered evaluation system which focuses on performance and management goals.

The aggregate amount of remuneration paid to our Directors and Supervisors (including salaries, remuneration, pension, discretionary bonus, share-based compensation and other welfares) for the two years ended December 31, 2018 and 2019 and the three months ended March 31, 2020 were approximately RMB2.0 million, RMB3.3 million and RMB0.9 million, respectively.

It is estimated that remuneration and benefits in kind equivalent to approximately RMB38.1 million in aggregate will be paid and granted to our Directors and Supervisors by us in respect of the financial year ending December 31, 2020 under arrangements in force at the date of this document.

For the two years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, the aggregate amount of emolument paid to the five highest paid individuals of our Group (excluding Directors and Supervisors) were approximately RMB6.0 million, RMB7.0 million and RMB2.2 million, respectively.

During the Track Record Period, no remuneration was paid to, or receivable by, our Directors, Supervisors or the five highest paid individuals of our Group as an inducement to join or upon joining our Group or as a compensation for loss of office in the Track Record Period. Further, none of our Directors had waived any emolument during the same period.

Except as disclosed above, no other payments have been paid, or are payable, by our Company or any of our subsidiaries to our Directors, Supervisors or the five highest paid individuals of our Group during the Track Record Period.

For additional information on Directors’ and Supervisors’ remuneration during the Track Record Period as well as information on the highest paid individuals, please refer to Notes 8 and 9 of the Accountants’ Report in Appendix I to this document.

FINANCIAL INFORMATION

You should read the following discussion and analysis in conjunction with our audited consolidated financial information, included in the Accountants’ Report in Appendix I to this document, together with the respective accompanying notes. Our consolidated financial information has been prepared in accordance with IFRSs.

The following discussion and analysis contain forward-looking statements that reflect our current views with respect to future events and financial performance that involve risks and uncertainties. These statements are based on our assumptions and analysis made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. In evaluating our business, you should carefully consider the information provided in the section headed “Risk Factors” in this document.

OVERVIEW

We are a commercial-ready biopharmaceutical company committed to the discovery, development and commercialization of first-in-class and best-in-class biologics for the treatment of autoimmune, oncology and ophthalmology diseases with unmet medical needs in China and globally. Our vision is to become a leading player in the global biopharmaceutical industry.

We currently have no products approved for commercial sale and have not generated any revenue from product sales. We were not profitable and incurred operating losses during the Track Record Period. In full years of 2018, 2019 and the three-month period ended March 31, 2020, we had loss of RMB269.9 million, RMB430.3 million and RMB99.6 million, respectively. Substantially all of our operating losses resulted from research and development expenses, administrative expenses and finance costs.

We expect to incur an increased amount of operating expenses for at least the next several years as we further our pre-clinical research, continue the clinical development of, seek regulatory approval for and manufacturing of, our drug candidates, launch our pipeline products, and add personnel necessary to operate our business. Subsequent to the [REDACTED], we expect to incur costs associated with operating as a public company. We expect that our financial performance will fluctuate from period to period due to the development status of our drug candidates, regulatory approval timeline and commercialization of our drug candidates after approval.

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BASIS OF PREPARATION

The historical financial information of our Group has been prepared in accordance with IFRSs, which comprise all standards and interpretations approved by the International Accounting Standards Board (the “IASB”). All IFRSs effective for the accounting period commencing from January 1, 2018 to March 31, 2020, including IFRS 9 *Financial Instruments*, IFRS 15 *Revenue from Contracts with Customers* and IFRS 16 *Leases*, together with the relevant transitional provisions, have been consistently applied by our Group in the preparation of the historical financial information throughout the Track Record Period. The historical financial information has been prepared under the historical cost convention, except for equity investments designated at fair value through other comprehensive income and other financial assets which have been measured at fair value.

The adoption of IFRS 9, IFRS 15 and IFRS 16 does not have a significant impact on our financial position and performance when compared to that of IAS 39, IAS 18 and IAS 17. We performed an internal assessment of the early adoption of IFRS 9, IFRS 15 and IFRS 16 and the impacts to our Group are set forth below:

IFRS 9

IFRS 9 replaces IAS 39 and requires the recognition of impairment provisions of financial assets measured at amortized cost based on expected credit losses. Under IFRS 9, our debt financial assets are subsequently measured at fair value through other comprehensive income or amortized cost. The classification is based on two criteria: (i) our Group’s business model for managing the assets and (ii) whether the instrument’s contractual cash flows represent solely payments of principal and interest on the principal amount outstanding.

The effects of adoption of IFRS 9 have been assessed on our Group’s historical financial information and compared to the requirements of IAS 39, noted that:

- The adoption of IFRS 9 has changed the Group’s accounting for equity investments in unlisted company by replacing available-for-sale investments under IAS 39 with equity investments measured at fair value through other comprehensive income. However, these two categories are both measured at fair value, so the application would not cause a material impact on our financial position and performance.
- The adoption of IFRS 9 has changed our accounting for bills receivable by replacing loans and receivables under IAS 39 with financial assets at fair value through other comprehensive income. Our bills receivable are managed with a business model under which bills receivable are held to collect contractual cash flows or endorsed to suppliers prior to their expiry date.
- The adoption of IFRS 9 has fundamentally changed our Group’s accounting for impairment losses for financial assets by replacing IAS 39’s incurred loss approach with a forward-looking expected credit loss approach. IFRS 9 requires our Group to record an allowance for expected credit measured at amortised cost. However, most of the other receivables are expected to be collected shortly after the recognition and no history of default, so the application of IFRS 9 would not cause a material impact on our financial position and performance.

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Based on the above assessment, had IAS 39 been consistently applied throughout the Track Record Period, there would be no significant impact on our financial position and performance.

IFRS 15

IFRS 15 “Revenue from contracts with customers” replaces the previous revenue standard IAS 18 “Revenue” and related interpretation. The standard is effective for annual periods beginning on or after January 1, 2018 and earlier adoption is permitted. Our Group elected to early apply IFRS 15, which has been applied consistently throughout the Track Record Period.

Our Group derived revenue mainly from provision of contract research and pre-clinical development services to a related party. Under IFRS 15, an entity recognizes revenue when (or as) a performance obligation is satisfied, i.e. when “control” of the goods or services underlying the particular performance obligation is transferred to the customer. Based on the historical financial information, had IAS 18 been consistently applied throughout the Track Record Period, there would be no significant impact on our financial position and performance.

IFRS 16

IFRS 16 “Leases” has replaced the previous standard IAS 17 Leases and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2019 and earlier adoption is permitted. IFRS 16 has been consistently applied to the historical financial information during the Track Record Period.

The effects of the early adoption of IFRS 16 have been assessed on our historical financial information as compared to the requirements of IAS 17, which is summarized as below:

- (1) The operating lease commitments under IAS 17 were no longer disclosed as lease commitment, instead, all leases (except for short-term leases and leases of low-value assets) were recognized as a right-of-use asset and a corresponding liability under IFRS 16 at the lease commencement date. We recognized right-of-use assets of RMB10.3 million, RMB11.0 million and RMB14.7 million as of December 31, 2018, December 31, 2019 and March 31, 2020, respectively. We recognized lease liabilities of RMB4.5 million, RMB5.4 million and RMB4.4 million as of December 31, 2018, December 31, 2019 and March 31, 2020, respectively;
- (2) Under IFRS 16, each lease payment is allocated between the settlement of the principal portion of the lease liability and finance cost. The finance cost is charged to profit or loss over the lease period. The right-of-use asset is depreciated over the lease term on a straight-line basis. No material impact to the consolidated statements of profit or loss is resulted as compared to the recognition of operating lease expenses under IAS 17.

Based on the assessment, by applying IFRS 16, there are increases in both total assets and liabilities of our Group when comparing to that under IAS 17, and other than this, there is no significant impact on our Group’s financial position and financial performance. Due to the increase of the current portion of the lease liabilities, there are decreases in current ratio and quick ratio when comparing to that under IAS 17. Current ratio represents current assets divided by current liabilities as of the end of the year/period. Quick ratio represents current assets less inventories and divided by current liabilities as of the same date.

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SIGNIFICANT FACTORS AFFECTING OUR RESULTS OF OPERATIONS

Our Ability to Commercialize Our Drug Candidates

Our business and results of operations will be dependent on our receipt of regulatory approval for and successful commercialization of our drug candidates. Leveraging our strong capabilities in drug discovery, research and development, we have discovered and developed a robust pipeline of more than 10 drug candidates. Among our drug candidates, five are in clinical development stage targeting 17 indications and more than five are in IND-enabling stage. Two of our clinical-stage drug candidates, telitacicept and disitamab vedotin, are in registrational trials targeting six indications in China and the U.S. Please refer to the section headed “Business” for more details on the development of our various drug candidates.

Once our drug candidates are commercialized, our business and results of operations will be driven by the market acceptance and sales of our commercialized drugs and by our biologics production capacity to meet the commercial demand. Our commercialization strategy for our drug candidates involves building our own commercialization and distribution capabilities, seeking collaboration with leading pharmaceutical companies with relevant experience in global commercialization, and expanding our production capabilities. For more details, please refer to the paragraphs headed “Business—Our Strategies” in this document.

Our Cost Structure

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development expenses, administrative expenses, and finance costs. It also consists of our cost of sales, selling and distribution expenses and other expenses.

Research and development activities are central to our business model. In full years of 2018 and 2019 and for the three months ended March 31, 2020, our research and development expenses accounted for 73.0%, 75.1% and 70.4% of our total expenses and costs, respectively. Our research and development expenses primarily consist of:

- employee salaries, share-based compensation and other welfare for our research and development employees;
- expenses for procuring raw materials used in the research and development of our drug candidates;
- clinical trial expenses for our drug candidates, including third-party contracting costs with respect to the engagement of CROs, CRCs, clinical trial sites and principal investigators, as well as other expenses incurred in connection with our clinical trials;
- testing expenses for pre-clinical programs;

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- depreciation and amortization expenses, mainly including depreciation expenses for buildings, plant and machinery and amortization expenses for intangible assets which were used for research and development purpose;
- utilities used for research and development activities; and
- other research and development expenses, mainly including consulting fees for clinical trials, expenses for acquisition of technologies, travelling and transportation expenses in relation to research and development activities.

Our current research and development activities mainly relate to the clinical advancement of our drug candidates. We expect our research and development expenses to continue to increase for the foreseeable future as we move these drug candidates, either from pre-clinical trials to clinical trials, or further to more advanced clinical trials, and as we continue to support the clinical trials of our drug candidates as treatments for additional indications.

Our administrative expenses include (i) employee benefits expenses mainly relating to salaries, share-based compensation and other welfare for our administrative employees; (ii) consulting service expenses mainly including (a) consulting fees incurred in connection with the overseas clinical development as well as overseas sales and marketing plan for our drug candidates, and (b) expenses incurred for engaging recruiters and other agents; (iii) general office expenses mainly including hospitality expenses, office expenses, publicity expenses, travelling and transportation expenses and utilities used for administrative purposes; (iv) depreciation and amortization expenses, mainly including depreciation expenses for buildings, plant and machinery and amortization expenses for intangible assets which were used for administrative purpose; (v) [REDACTED] expenses incurred in connection with the proposed [REDACTED]; and (vi) other administrative expenses mainly including tax and surcharges, retirement costs of raw materials and other miscellaneous expenses. Our finance costs mainly include interest on borrowings from a related party and interest on bank borrowings.

We expect our cost structure to evolve as we continue to develop and expand our business. As the clinical trials of our drug candidates continue to progress and as we gradually bring assets of our product pipeline to commercialization, we expect to incur additional costs in relation to our raw materials procurement, manufacturing, sales and marketing, among other things. We also anticipate increasing legal, compliance, accounting, insurance, and investor and public relations expenses associated with being a public company in Hong Kong.

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Funding for Our Operations

During the Track Record Period, we funded our operations primarily through private equity and debt financing. Going forward, in the event of a successful commercialization of one or more of our drug candidates, we expect to fund our operations in part with revenue generated from sales of our commercialized drug products. However, with the continuing expansion of our business, we may require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. Any fluctuation in the funding for our operations will impact our cash flow plan and our results of operations.

SIGNIFICANT ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles that conform with IFRSs issued by the IASB. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

We consider an accounting policy significant if it: (i) requires management to make judgments and estimates about matters that are inherently uncertain; and (ii) is important to the understanding of our financial conditions and operating results. We believe the following accounting policies are most significant to our business operations and to an understanding of our financial conditions and results of operations, and reflect the more significant judgments and estimates used in the preparation of our consolidated financial statements. Our significant accounting policies and estimates are summarized below. Please refer to note 2.3 and note 3 of the Appendix I to this document for a detailed description of our significant accounting policies, estimates and judgments, which are important for understanding our financial condition and results of operations.

Significant Accounting Policies

Fair Value Measurement

We measure our equity investments and bills receivable at fair value at the end of each financial year/period in the Track Record Period. Fair value means the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction of selling the asset or transferring the liability takes place either in the principal market for the asset or liability, or, in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market

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must be accessible by our Group. The fair value of an asset or a liability is measured with the assumptions that market participants, when acting in their economic best interest, would adopt or accept such fair value when pricing the asset or liability.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

Our Group uses valuation techniques that are appropriate in the circumstances, for which sufficient data are available to measure fair value, and that could maximize the use of relevant observable inputs and minimize the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy as described below, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognized in the financial statements on a recurring basis, our Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Track Record Period.

Intangible Assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at the end of each of the Track Record Period.

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Patents and Licenses

Patents and licenses are stated at their costs less any impairment losses, and are amortized on the straight-line basis over their estimated useful lives of 10 years.

Research and Development Costs

All research costs are charged to profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalized and deferred only when our Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure that does not meet these criteria is expensed when incurred.

Government Grants

Government grants are recognized at their fair value where there is reasonable assurance that the grant will be received and all the attaching conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the costs, which it is intended to compensate, are expensed.

Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual instalments or deducted from the carrying amount of the asset and released to profit or loss by way of a reduced depreciation charge.

Revenue Recognition

Revenue from Contracts with Customers

Revenue from contracts with customers is recognized when control of goods or services is transferred to the customers at an amount of consideration that we expect to receive in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which our Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at the time of contract execution and is constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

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During the Track Record Period, revenue of our Group was primarily derived from research and development services to the customers. Revenue from the provision of services is recognized over the scheduled period, because the customer simultaneously receives and consumes the benefits provided by our Group.

Other income

Revenue from the sale of raw materials is recognised at the point in time when control of the asset is transferred to the customer, generally on delivery of the products.

Rental income is recognized on a time proportion basis over the lease terms. Variable lease payments that do not depend on an index or a rate are recognized as income in the accounting period in which they are incurred.

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Share-based Payments

Our Group operates a share award for the purpose of providing incentives and rewards to eligible participants who contribute to the success of our Group's operations. Employees of our Group receive remuneration in the form of share-based payments and render services as consideration for such equity instruments ("equity-settled transactions").

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value of share options and restricted shares is determined by an external valuer using Black-Scholes Option Pricing Model and discounted cash flow model, respectively. For more details, please refer to note 27 of the Appendix I to this document.

The cost of equity-settled transactions is recognized in employee benefits expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognized for equity-settled transactions at the end of each of the Track Record Period until the vesting date reflects the extent to which the vesting period has expired and our Group's best estimate of the number of equity instruments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognized as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of our Group's best estimate of the number of equity investments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

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For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognized. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognized as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognized for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. This includes any award where non-vesting conditions within the control of either our Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Significant Accounting Judgements and Estimates

Recognition of Income Taxes and Deferred Tax Assets

Determining income tax provision involves judgment on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatments of such transactions are reconsidered periodically to take into account all changes in tax legislation. Deferred tax assets are recognized in respect of deductible temporary differences and unused tax losses. As those deferred tax assets can only be recognized to the extent that it is probable that future taxable profits will be available against which the deductible temporary differences and the losses can be utilized, management's judgment is required to assess the probability of future taxable profits. Management's assessment is revised as necessary and additional deferred tax assets are recognized if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

Impairment of Non-financial Assets (other than Goodwill)

Our Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each of the Track Record Period. Indefinite life intangible assets are tested for impairment annually and at other times when such an indicator exists. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is

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the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Useful Lives and Residual Values of Property, Plant and Equipment

In determining the useful lives and residual values of items of property, plant and equipment, our Group has to consider various factors, including technical or commercial obsolescence arising from changes or improvements in production, or from a change in the market demand for the product or service output of the asset, expected usage of the asset, expected physical wear and tear, the care and maintenance of the asset and the legal or similar limits on the use of the asset. The estimation of the useful lives of the assets is based on the experience of our Group with similar assets that are used in a similar way.

Additional depreciation is recognized if the estimated useful lives and/or the residual values of items of property, plant and equipment are different from the previous estimation. Useful lives and residual values are reviewed at the end of year during the Track Record Period based on changes in circumstances.

Write-down of Inventories to Net Realisable Value

Write-down of inventories to net realisable value is made for those identified obsolete and slow-moving inventories and inventories with a carrying amount higher than the net realisable value. The assessment of the provision required involves management’s judgement and estimates on which are influenced by assumptions concerning future sales and usage and judgements in determining the appropriate level of inventory provisions against identified surplus or obsolete items. Where the actual outcome or expectation in future is different from the original estimate, such differences will have impact on the carrying amounts of inventories and the write-down/write-back of inventories in the period in which such estimate has been changed.

Fair Value of Unlisted Equity Investments

The unlisted equity investments have been valued based on the expected cash flows discounted at current rates applicable for items with similar terms and risk characteristics. This valuation requires our Group to make estimates on expected future cash flows, credit risk, volatility and discount rates and thus involves uncertainty. The fair value of our unlisted equity investments as of December 31, 2018, December 31, 2019 and March 31, 2020 were RMB10.0 million, RMB11.4 million and RMB11.4 million, respectively. For more details, please refer to note 16 of the Appendix I to this document.

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DESCRIPTION OF SELECTED COMPONENTS OF STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME ITEMS

The following table sets forth selected components of our consolidated statements of profit or loss and other comprehensive income items for the periods indicated:

	Year Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Revenue	11,321	–	–	–
Cost of sales	(8,932)	–	–	–
Gross profit	2,389	–	–	–
Other income and gains	15,377	38,481	2,551	7,316
Selling and distribution expenses	–	(621)	–	(1,306)
Administrative expenses	(29,125)	(68,434)	(8,420)	(20,336)
Research and development costs	(216,438)	(352,066)	(69,137)	(75,210)
Impairment losses on financial assets, net	(196)	134	–	(79)
Other expenses	(1,900)	(3,985)	(325)	(1,008)
Finance costs	(40,055)	(43,789)	(12,430)	(8,970)
Loss before tax	(269,948)	(430,280)	(87,761)	(99,593)
Income tax expenses	–	–	–	–
Loss for the year/period	<u>(269,948)</u>	<u>(430,280)</u>	<u>(87,761)</u>	<u>(99,593)</u>
Attributable to:				
Owners of the parent	<u>(269,948)</u>	<u>(430,280)</u>	<u>(87,761)</u>	<u>(99,593)</u>
Other comprehensive income/(loss)				
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	72	(62)	(12)	21
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:				
Equity investments designated at fair value through other comprehensive income:				
Changes in fair value	2,076	1,425	–	–
Other comprehensive income/(loss) for the year/period, net of tax	<u>2,148</u>	<u>1,363</u>	<u>(12)</u>	<u>21</u>
Total comprehensive loss for the year/period	<u>(267,800)</u>	<u>(428,917)</u>	<u>(87,773)</u>	<u>(99,572)</u>
Attributable to:				
Owners of the parent	<u>(267,800)</u>	<u>(428,917)</u>	<u>(87,773)</u>	<u>(99,572)</u>

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Revenue

During the Track Record Period, all of our revenue was generated from the provision of contract research and pre-clinical development services to Rongchang Pharmaceuticals (Zibo), Ltd. (“Rongchang Zibo”), our related party. Rongchang Zibo engaged us to provide research and pre-clinical development services for the development of certain biologics in 2018. During the Track Record Period, as we did not obtain regulatory approval for the commercial sale of any of our drug candidates, we have not generated any revenue from sales of any drug candidate. With our pipeline drug candidates expected to be launched into the market and generate sales in the near future upon regulatory approval, our sources of revenue are expected to become more diversified.

The following table summarizes the components of our revenue in absolute amounts and as percentages of the total revenue for the periods indicated:

	Year Ended December 31,				Three Months Ended March 31,			
	2018		2019		2019		2020	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%	<i>RMB'000</i>	%
	<i>(Unaudited)</i>							
Rendering of services	11,321	100.0	-	-	-	-	-	-
	11,321	100.0	-	-	-	-	-	-

Cost of Sales

During the Track Record Period, our cost of sales was primarily related to the provision of contract research and pre-clinical development services to Rongchang Zibo. Our cost of sales is primarily comprised of costs of raw materials and other consumables, employee benefits expenses and others. Costs of raw materials and consumables are primarily incurred for raw materials and consumables used for providing our contract research services to Rongchang Zibo. Employee benefits expenses under cost of sales primarily include salaries and other welfare for R&D employees involved in our provision of contract research and pre-clinical development services to Rongchang Zibo. Others mainly include the following costs in connection with our provision of services: depreciation expenses for our buildings and equipment, utilities and other miscellaneous expenses.

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The following table summarizes a breakdown of our other income and gains in absolute amounts and as percentages of the total other income and gains for the periods indicated:

	Year Ended December 31,				Three Months Ended March 31,			
	2018		2019		2019		2020	
	RMB'000	%	RMB'000	%	RMB'000	%	RMB'000	%
	<i>(Unaudited)</i>							
Government grants	11,704	76.1	33,471	87.0	1,918	75.2	5,858	80.1
Rental income	–	–	2,452	6.4	544	21.3	425	5.8
Sales of materials	1,518	9.9	1,610	4.2	2	0.1	20	0.3
Gain on disposal of equipment	1,658	10.8	–	–	15	0.6	–	–
Others	497	3.2	948	2.4	72	2.8	1,013	13.8
	15,377	100.0	38,481	100.0	2,551	100.0	7,316	100.0

Selling and Distribution Expenses

During the Track Record Period, our selling and distribution expenses mainly consisted of employee benefits expenses and market development expenses. Employee benefits expenses primarily include salaries, share-based compensation and other welfare for our sales and marketing employees. Market development expenses mainly include travelling and transportation expenses, sponsoring fees for industry conventions, and hospitality expenses in relation to our selling and distribution activities. Other selling and distribution expenses mainly include rental fees, office consumable expenses and other miscellaneous expenses in relation to our selling and distribution activities. As we established our sales and marketing department in July 2019, we did not incur any selling and distribution expenses in or before 2018.

The following table sets forth a breakdown of our selling and distribution expenses in absolute amounts and as percentages of the total selling and distribution expenses for the periods indicated:

	Year Ended December 31,				Three Months Ended March 31,			
	2018		2019		2019		2020	
	RMB'000	%	RMB'000	%	RMB'000	%	RMB'000	%
	<i>(Unaudited)</i>							
Employee benefits expenses	–	–	359	57.8	–	–	899	68.8
Market development expenses	–	–	103	16.6	–	–	392	30.0
Others	–	–	159	25.6	–	–	15	1.2
	–	–	621	100.0	–	–	1,306	100.0

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Administrative Expenses

During the Track Record Period, our administrative expenses consisted of (i) employee benefits expenses mainly relating to salaries, share-based compensation and other welfare for our administrative employees; (ii) consulting service expenses mainly including (a) consulting fees incurred in connection with the overseas clinical development as well as overseas sales and marketing plan for our drug candidates, and (b) expenses incurred for engaging recruiters and other agents; (iii) general office expenses mainly including hospitality expenses, office expenses, publicity expenses, travelling and transportation expenses and utilities used for administrative purposes; (iv) depreciation and amortization expenses, mainly including depreciation expenses for buildings, plant and machinery and amortization expenses for intangible assets which were used for administrative purpose; (v) [REDACTED] expenses incurred in connection with the proposed [REDACTED]; and (vi) other administrative expenses mainly including tax and surcharges, retirement costs of raw materials and other miscellaneous expenses.

The following table sets forth a breakdown of our administrative expenses in absolute amounts and as percentages of the total administrative expenses for the periods indicated:

	Year Ended December 31,				Three Months Ended March 31,			
	2018		2019		2019		2020	
	RMB'000	%	RMB'000	%	RMB'000	%	RMB'000	%
	<i>(Unaudited)</i>							
Employee benefits expenses	17,484	60.0	30,102	44.0	4,440	52.7	10,234	50.3
Consulting service expenses	3,789	13.0	12,135	17.7	494	5.9	3,459	17.0
General office expenses	4,377	15.0	13,018	19.0	1,154	13.7	3,331	16.4
Depreciation and amortization expenses	2,271	7.8	5,553	8.1	1,862	22.1	1,702	8.4
[REDACTED] expenses	–	–	1,641	2.4	–	–	674	3.3
Others	1,204	4.2	5,985	8.8	470	5.6	936	4.6
	29,125	100.0	68,434	100.0	8,420	100.0	20,336	100.0

Research and Development Expenses

During the Track Record Period, our research and development expenses consisted of (i) employee benefits expenses mainly relating to salaries, share-based compensation and other welfare for our R&D employees, (ii) expenses for procuring raw materials used in the research and development of our drug candidates, (iii) clinical trial expenses for our drug candidates, including third-party contracting costs with respect to the engagement of CROs, CRCs, clinical trial sites and principal investigators, as well as other expenses incurred in connection with our clinical trials, (iv) testing expenses for pre-clinical programs, (v) depreciation and amortization expenses, mainly including depreciation expenses for buildings, plant and machinery and amortization expenses for intangible assets which were used for research and development purpose; (vi) utilities used for research and development activities, and (vii) other research and development expenses which mainly included consulting fees for clinical trials, expenses for acquisition of technologies, travelling and transportation expenses in relation to research and development activities, and other miscellaneous expenses.

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The following table below sets forth a breakdown of our research and development expenses in absolute amounts and as percentages of the total research and development expenses for the periods indicated:

	Year Ended December 31,				Three Months Ended March 31,			
	2018		2019		2019		2020	
	RMB'000	%	RMB'000	%	RMB'000	%	RMB'000	%
	<i>(Unaudited)</i>							
Employee benefits expenses	68,776	31.8	109,189	31.0	24,723	35.8	26,922	35.8
Raw material expenses	48,062	22.2	71,570	20.3	19,178	27.7	22,105	29.4
Clinical trial expenses	31,939	14.8	36,352	10.3	4,289	6.2	4,633	6.2
Testing expenses	17,603	8.1	38,258	10.9	5,100	7.4	2,367	3.1
Depreciation and amortization expenses	20,135	9.3	36,179	10.3	7,829	11.3	8,670	11.5
Utilities	11,664	5.4	16,393	4.7	3,969	5.7	4,343	5.8
Others	18,259	8.4	44,125	12.5	4,049	5.9	6,170	8.2
	216,438	100.0	352,066	100.0	69,137	100.0	75,210	100.0

The following table below sets forth a breakdown of our research and development expenses by each product in absolute amounts and as percentages of the total research and development expenses:

	Year Ended December 31,				Three Months Ended March 31,			
	2018		2019		2019		2020	
	RMB'000	%	RMB'000	%	RMB'000	%	RMB'000	%
	<i>(Unaudited)</i>							
RC18	66,786	30.9	117,034	33.2	24,249	35.1	28,181	37.5
RC28	6,100	2.8	15,880	4.5	1,024	1.5	2,239	3.0
RC48	100,171	46.3	122,713	34.9	23,186	33.5	23,625	31.4
RC88	13,569	6.3	18,779	5.3	4,849	7.0	2,510	3.3
RC98	8,791	4.1	23,123	6.6	9,575	13.8	1,560	2.1
RC108	10,053	4.6	27,956	7.9	2,158	3.1	8,107	10.8
RC118	2,326	1.1	6,043	1.7	425	0.6	3,338	4.4
Other drug candidates ⁽¹⁾	8,642	3.9	20,538	5.9	3,671	5.4	5,650	7.5
	216,438	100.0	352,066	100.0	69,137	100.0	75,210	100.0

Note:

- (1) Other drug candidates include our in-house-developed, IND-enabling drug candidates, as well as some other drug candidates that are currently under research and development.

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Net Impairment Losses on Financial Assets

We recorded net impairment losses on financial assets in relation to our other receivables. For more details of the impairment of our other receivables, please refer to the paragraphs headed “—Discussion of Certain Selected Items from the Consolidated Statements of Financial Position—Prepayments, Other Receivables and Other Assets” in this section.

Other Expenses

During the Track Record Period, our other expenses primarily consisted of (i) rental related expenses relating to the leases of our facilities including a cold storage warehouse to related parties; (ii) expenses incurred for sales of materials to our related parties, and (iii) other expenses incurred for our provision of testing services to related parties and donation to a charity organization. The following table sets forth a breakdown of our other expenses for the periods indicated:

	Year Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Rental related expenses	–	1,809	316	418
Expenses for sales of materials	1,518	899	2	20
Others	382	1,277	7	570
	1,900	3,985	325	1,008

Finance Costs

During the Track Record Period, our finance costs consisted of interest on borrowings from a related party, interest on bank borrowings and interest on lease liabilities during the Track Record Period. The table below sets forth a breakdown of our finance costs for the periods indicated:

	Year Ended December 31,		Three Months Ended March 31,	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Interest on borrowings from a related party	39,791	41,649	12,346	8,012
Interest on bank borrowings	–	1,811	–	892
Interest on lease liabilities	264	329	84	66
	40,055	43,789	12,430	8,970

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During the Track Record Period, interest on borrowings from a related party mainly related to our borrowings from RC Pharma. We borrowed RMB380.9 million, RMB584.1 million, RMB111.0 million and RMB134.8 million from RC Pharma in 2018, 2019 and the three-month periods ended March 31, 2019 and March 31, 2020, respectively. These borrowings are unsecured and payable on demand. The applicable interest rates are determined in accordance with the prevailing market borrowing rates. In 2018 and 2019 and the three-month period ended March 31, 2020, the applicable annual interest rate for the borrowings from RC Pharma was approximately 6.3%, 6.0% and 6.0%, respectively. Please refer to the paragraphs headed “—Indebtedness” in this section for more details.

Interest on bank borrowings mainly related to seven short-term bank loans with an aggregate drawdown amount of RMB206.0 million, including four short-term bank loans with an aggregate drawdown amount of RMB146 million in the year ended December 31, 2019, each with an effective interest rate of approximately 5.5% or 6.3% per annum, and three short-term bank loans with an aggregate drawdown amount of RMB60 million in the three months ended March 31, 2020, each with an effective interest rate of approximately 6.3% per annum. For more details of the bank loans, please refer to the paragraphs headed “—Indebtedness” in this section.

Income Tax Expense

China

The provision for the mainland China current income tax is based on the statutory rate of 25% of the assessable profits of our Group as determined in accordance with the PRC Corporate Income Tax Law which was approved and became effective on January 1, 2008.

Hong Kong

Our subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% on any estimated assessable profits arising in Hong Kong during the Track Record Period. No provision for Hong Kong profits tax has been made as our Group has no assessable profits derived from or earned in Hong Kong during the Track Record Period.

United States

Our U.S. subsidiary is subject to statutory U.S. federal corporate income tax at a rate of 21% on any estimated assessable profits arising in the U.S. during the Track Record Period. Our U.S. subsidiary files tax returns in California and thus is also subject to the state income tax in California at a rate of 8.84% on any estimated assessable profits arising in the U.S. during the Track Record Period.

During the Track Record Period, we recorded no income tax expense. This is due to the fact that our costs and expenses were significantly higher than our taxable income for those periods. Our Directors confirm that during the Track Record Period, we had made all the required tax filings and had paid all outstanding tax liabilities with the relevant tax authorities in the relevant jurisdictions and we are not aware of any outstanding or potential disputes with such tax authorities.

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PERIOD TO PERIOD COMPARISON OF RESULTS OF OPERATIONS

Three Months Ended March 31, 2019 Compared with Three Months Ended March 31, 2020

Other Income and Gains

Our other income and gains increased from RMB2.6 million for the three months ended March 31, 2019 to RMB7.3 million for the three months ended March 31, 2020, primarily due to an increase in government grants of RMB3.9 million, mainly in relation to (a) government grants of RMB1.5 million to compensate us for expenses incurred in our research activities relating to the large-scale preparation technology of RC48, (b) a one-off government grant of RMB0.8 million as technology innovation development fund to compensate and encourage our research and development activities, and (c) government grants of RMB0.5 million to compensate our research and development activities in relation to our clinical trials of RC18 with respect to RA and SLE.

Selling and Distribution Expenses

Our selling and distribution expenses increased from nil million for the three months ended March 31, 2019 to RMB1.3 million for the three months ended March 31, 2020, primarily as we established our sales and marketing department and initiated market development activities in preparation for commercialization of our products in July 2019.

Administrative Expenses

Administrative expenses increased from RMB8.4 million for the three months ended March 31, 2019 to RMB20.3 million for the three months ended March 31, 2020, primarily due to (i) an increase in employee benefits expenses of RMB5.8 million mainly due to an increase in the number of administrative employees as a result of our Reorganization in 2019, as well as an increase in their salaries and share-based compensation. For more details of the Reorganization, please refer to the paragraphs headed “History, Development and Corporate Structure – Reorganization” in this document; (ii) an increase in consulting service expenses of RMB3.0 million mainly due to consulting fees incurred in relation to the overseas clinical trial development as well as overseas sales and marketing plan for our drug candidates including RC18 and RC48; (iii) an increase in general office expenses of RMB2.2 million mainly due to increases in hospitality expenses, office expenses, publicity expenses and travelling and transportation expenses, mainly as a result of the increase in the number of our administrative employees as well as our continuous efforts to grow our business, and (iv) an increase in [REDACTED] expenses of RMB0.7 million incurred in connection with our proposed [REDACTED].

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Research and Development Expenses

Research and development expenses increased from RMB69.1 million for the three months ended March 31, 2019 to RMB75.2 million for the three months ended March 31, 2020, primarily due to (i) an increase in raw material expenses of RMB2.9 million mainly due to the continuous development of drug candidates, (ii) an increase in employee benefits expenses of RMB2.2 million mainly due to an increase in the number of research and development employees, as well as an increase in their salaries and share-based compensation, and (iii) an increase in others of RMB2.1 million mainly due to an increase in office expenses and an increase in repair and maintenance expenses; such increase was partially offset by a decrease in testing expenses of RMB2.7 million mainly due to decreased testing for pre-clinical programs as a result of the COVID-19 outbreak in 2020.

Net Impairment Losses on Financial Assets

Our net impairment losses on financial assets increased from nil for the three months ended March 31, 2019 to RMB79,000 for the three months ended March 31, 2020, mainly due to impairment losses relating to our other receivables.

Other Expenses

Other expenses increased from RMB0.3 million for the three months ended March 31, 2019 to RMB1.0 million for the three months ended March 31, 2020, primarily due to our donation of RMB550,000 to a charity organization.

Finance Costs

Our finance costs decreased from RMB12.4 million for the three months ended March 31, 2019 to RMB9.0 million for the three months ended March 31, 2020, primarily due to a decrease in interest expenses on borrowings from a related party of RMB4.3 million as (i) RC Pharma converted a portion of its loans to us in an amount of RMB600.0 million as consideration to subscribe for the increased registered capital of our Company in July 2019, and (ii) we repaid the principal of borrowings in an amount of RMB207.2 million to RC Pharma in the first quarter of 2020.

Loss for the Period

Based on the reasons described above, our loss for the period increased from RMB87.8 million for the three months ended March 31, 2019 to RMB99.6 million for the three months ended March 31, 2020.

Other Comprehensive Income/(Loss) for the Period, Net of Tax

We recorded other comprehensive loss of RMB12,000 for the three months ended March 31, 2019 and other comprehensive income of RMB21,000 for the three months ended March 31, 2020, primarily due to exchange differences on translation of foreign operations.

Total Comprehensive Loss for the Period

Based on the reasons described above, the total comprehensive loss for the period increased from RMB87.8 million for the three months ended March 31, 2019 to RMB99.6 million for the three months ended March 31, 2020.

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Year ended December 31, 2018 Compared to the Year ended December 31, 2019

Revenue

Our revenue decreased from RMB11.3 million in 2018 to nil in 2019, mainly as Rongchang Zibo ceased the development of the relevant biologics and, as a result, we ceased offering contract research and pre-clinical development services to Rongchang Zibo in 2019.

Cost of Sales

Our cost of sales decreased from RMB8.9 million in 2018 to nil in 2019, primarily as we ceased offering contract research and pre-clinical development services to Rongchang Zibo in 2019.

Gross Profit and Gross Profit Margin

As a result of the changes in our revenue and cost of sales described above, our gross profit decreased from RMB2.4 million in 2018 to nil in 2019. Our gross profit margin decreased from 21.1% in 2018 to nil in 2019.

Other Income and Gains

Our other income and gains increased from RMB15.4 million in 2018 to RMB38.5 million in 2019, primarily attributable to (i) an increase in government grants of RMB21.8 million, mainly in relation to (a) a one-off government grant of RMB11.7 million from the Department of Science & Technology of Shandong Province (山東省科學技術廳) as compensation and encouragement for our research and development activities, and (b) a government grant of RMB8.1 million to compensate our research and development activities for our clinical trials of RC18 with respect to RA and SLE; and (ii) an increase in rental income of RMB2.5 million mainly due to leases of our facilities including a cold storage warehouse to our related parties in 2019.

Selling and Distribution Expenses

Our selling and distribution expenses increased from nil in 2018 to RMB621,000 in 2019, primarily as we established our sales and marketing department and initiated market development activities in preparation for commercialization of our products in July 2019.

Administrative Expenses

Administrative expenses increased from RMB29.1 million in 2018 to RMB68.4 million in 2019, mainly attributable to (i) an increase in employee benefits expenses of RMB12.6 million primarily due to an increase in the number of administrative employees mainly as a result of our Reorganization in 2019, as well as an increase in their salaries and share-based compensation. For more details of the Reorganization, please refer to the paragraphs headed

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“History, Development and Corporate Structure – Reorganization” in this document; (ii) an increase in consulting service expenses of RMB8.3 million, primarily due to an increase in consulting fees incurred in connection with the overseas clinical trial development as well as overseas sales and marketing plan for our drug candidates, and an increase in consulting fees for engaging technical experts in relation to the product registration and commercial sales plan for our drug candidates; (iii) an increase in general office expenses of RMB8.6 million, primarily due to increases in travelling and transportation expenses, office expenses, publicity expenses and hospitality expenses, mainly as a result of the increase in the number of our administrative employees as well as our continuous efforts to grow our business; and (iv) an increase in [REDACTED] expenses of RMB1.6 million incurred in connection with our proposed [REDACTED].

Research and Development Expenses

Research and development expenses increased from RMB216.4 million in 2018 to RMB352.1 million in 2019, mainly attributable to (i) an increase in employee benefits expenses of RMB40.4 million primarily due to an increase in the number of research and development employees as well as an increase in their salaries and share-based compensation; (ii) an increase in raw material expenses of RMB23.5 million due to the continuous development of drug candidates, (iii) an increase in testing expenses of RMB20.7 million, mainly due to the clinical trial advancement of our drug candidates, and particularly in relation to (a) clinical testing of telitacept and disitamab vedotin, which led to an increase in telitacept’s and disitamab vedotin’s testing expenses of RMB6.4 million and RMB8.1 million, respectively, and (b) an increase in the testing expenses of RMB5.7 million for RC108 in relation to its pre-clinical programs in 2019; (iv) an increase in depreciation and amortization expenses of RMB16.0 million mainly due to our construction of new building and purchase of equipment for research and development purpose, (v) an increase in others of RMB25.9 million mainly in relation to increases in consulting fees for clinical trials and expenses incurred for acquisition of technologies, which were in line with our continuous development of drug candidates.

Net Impairment Losses on Financial Assets

We recorded net impairment losses on financial assets of RMB196,000 in 2018, while we reversed the impairment losses of RMB134,000 in 2019, mainly due to our collection of other receivables in 2019.

Other Expenses

Other expenses increased from RMB1.9 million in 2018 to RMB4.0 million in 2019, primarily attributable to an increase in rental related expenses (mainly including depreciation expenses and utilities) of RMB1.8 million in relation to our leases of facilities including a cold storage warehouse to related parties in 2019.

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Finance Costs

Our finance costs increased from RMB40.1 million in 2018 to RMB43.8 million in 2019, primarily due to (i) an increase in interest on borrowings from a related party of RMB1.9 million, mainly due to increased amount of our borrowings from RC Pharma in 2019, and (ii) an increase in interest on bank borrowings of RMB1.8 million, mainly as we obtained four short-term bank loans in an aggregate drawdown amount of RMB146.0 million in 2019, each with an effective interest rate of approximately 5.5% or 6.3% per annum.

Loss for the Year

Based on the reasons described above, our loss for the year increased from RMB269.9 million in 2018 to RMB430.3 million in 2019.

Other Comprehensive Income/(Loss) for the Period, Net of Tax

Our other comprehensive income of RMB2.1 million in 2018 mainly due to the changes in fair value in relation to our equity investments in MabPlex, while our other comprehensive income of RMB1.4 million in 2019 mainly due to the changes in fair value in relation to our equity investments in Heyuan Addis. Please refer to the paragraphs headed “– Discussion of Certain Selected Items from the Consolidated Statements of Financial Position – Equity Investments Designated at Fair Value through Other Comprehensive Income” in this section.

Total Comprehensive Loss for the Year

Based on the reasons described above, the total comprehensive loss for the year increased from RMB267.8 million in 2018 to RMB428.9 million in 2019.

DISCUSSION OF CERTAIN SELECTED ITEMS FROM THE CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

The following table sets forth selected information from our consolidated statements of financial position as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Total non-current assets	466,208	551,737	647,080
Total current assets	64,884	137,574	498,455
Total assets	531,092	689,311	1,145,535
Total non-current liabilities	32,331	64,327	59,295
Total current liabilities	996,939	856,953	680,024
Net current liabilities	932,055	719,379	181,569
Total liabilities	1,029,270	921,280	739,319
Net (liabilities)/assets	(498,178)	(231,969)	406,216
Equity			
Equity attributable to owners of the parent			
Paid-in capital	70,000	168,654	182,645
Reserves	(568,178)	(400,623)	223,571
Total (deficit)/equity	(498,178)	(231,969)	406,216

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The following table sets forth our current assets and current liabilities as of the dates indicated:

	As at December 31,		As at March 31,	As at April 30.
	2018	2019	2020	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>
Current assets				
Inventories	29,671	31,247	33,297	33,448
Bills receivable	10,969	1,058	–	–
Prepayments, other receivables and other assets	19,175	29,858	154,299	55,730
Pledged deposits	–	40,866	23,256	22,204
Cash and cash equivalents	5,069	34,545	287,603	290,206
Total current assets	64,884	137,574	498,455	401,588
Current liabilities				
Trade and bills payables	16,745	67,697	57,521	54,949
Other payables and accruals	972,201	720,602	614,341	596,861
Interest-bearing bank borrowings	–	60,000	–	–
Lease liabilities	1,131	1,602	1,189	1,244
Deferred income	6,862	7,052	6,973	6,942
Total current liabilities	996,939	856,953	680,024	659,996
Net current liabilities	932,055	719,379	181,569	258,408

We recorded net liabilities of RMB498.2 million and RMB232.0 million as of December 31, 2018 and 2019, respectively, and recorded net current liabilities of RMB932.1 million, RMB719.4 million, RMB181.6 million and RMB258.4 million as of December 31, 2018 and 2019, March 31, 2020 and April 30, 2020, respectively, mainly attributable to our borrowings and interest payables to RC Pharma in an amount of RMB858.3 million, RMB588.1 million, RMB523.7 million and RMB494.4 million under current liabilities as of December 31, 2018 and 2019, March 31, 2020 and April 30, 2020, respectively. For more details, please refer to the paragraphs headed “—Indebtedness” in this section. We plan to repay the borrowings from RC Pharma by using a portion of net [REDACTED] from the [REDACTED]. For more details, please refer to the section headed “Future Plan and Use of [REDACTED]” in this document. As a result, we expect to improve our liquidity position in the future.

Property, Plant and Equipment

Our property, plant and equipment primarily consist of buildings, plant and machinery, office equipment and others, motor vehicles and construction in progress. Our property, plant and equipment increased from RMB387.7 million as of December 31, 2018 to RMB459.7 million as of December 31, 2019, primarily due to an increase in plant and machinery, as well as the construction in progress mainly including the construction of our manufacturing facilities, partially offset by depreciation during such period. Our property, plant and

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equipment increased from RMB459.7 million as of December 31, 2019 to RMB469.8 million as of March 31, 2020, primarily due to the increase in construction in progress in relation to the preparation works for the construction of our new manufacturing facilities, partially offset by depreciation during such period. As of December 31, 2019, certain of our Group’s buildings and the corresponding land use rights with net carrying amounts of approximately RMB86.0 million and approximately RMB2.4 million were pledged to secure the short-term loan with a principal amount of RMB60.0 million from Yantai Bank. Furthermore, as of December 31, 2019 and March 31, 2020, certain of our Group’s buildings with net carrying amounts of approximately RMB63.5 million and approximately RMB145.9 million were pledged to obtain the banking facilities of RMB26.0 million and RMB109.3 million, respectively. The corresponding land use rights of the aforementioned buildings with net carrying amounts of approximately RMB3.2 million and approximately RMB5.5 million were also pledged for such banking facilities, respectively.

Right-of-use Assets

Our right-of-use assets are primarily related to our leased land use rights, buildings, and plant and machinery used in our operations. Our right-of-use assets increased from RMB10.3 million as of December 31, 2018 to RMB11.0 million as of December 31, 2019, mainly due to an increase in machinery of RMB0.7 million leased from Yeda Incubation. Our right-of-use assets increased from RMB11.0 million as of December 31, 2019 to RMB14.7 million as of March 31, 2020, mainly due to an increase in land use rights of RMB4.8 million as a result of our acquisition of the land use right for a land parcel from MabPlex for the construction of our new manufacturing facility.

Other Intangible Assets

Our other intangible assets include patents and licenses related to our business operations. The net carrying amount of our intangible assets decreased from RMB2.9 million as of December 31, 2018 to RMB2.1 million as of December 31, 2019, and further decreased to RMB1.9 million as of March 31, 2020, mainly as a result of the amortization.

Equity Investments Designated at Fair Value through Other Comprehensive Income

Our equity investments designated at fair value through other comprehensive income amounted to RMB10.0 million, RMB11.4 million and RMB11.4 million as of December 31, 2018, December 31, 2019 and March 31, 2020, respectively, mainly relating to our equity investment in Yantai Heyuan Addis Biomedical Technology, Ltd. (烟台市和元艾迪斯生物醫藥科技有限公司) (“Heyuan Addis”). We acquired approximately 10.5% equity interests in Heyuan Addis in 2018 with a total consideration of RMB10.0 million, mainly as our Directors believe that Heyuan Addis has advanced technologies in ADC and thus could have potentials in cooperating and achieving business synergy with us. Such equity investment was irrevocably designated at fair value through other comprehensive income mainly as we consider such investment to be strategic in nature and is not held for trading. As of the Latest Practicable Date, we held approximately 8.7% equity interests in Heyuan Addis mainly due to an increase in the registered capital of Heyuan Addis in 2019.

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The following table sets forth details of our equity investments designated at fair value through other comprehensive income as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Heyuan Addis	10,023	11,448	11,448

Our equity investments designated at fair value through other comprehensive income increased from RMB10.0 million as of December 31, 2018 to RMB11.4 million as of December 31, 2019, mainly due to an increase in the fair value of our equity investments in Heyuan Addis based on the appraisal value assessed by a third-party valuer. Our equity investments designated at fair value through other comprehensive income remained stable at RMB11.4 million as of December 31, 2019 and RMB11.4 million as of March 31, 2020.

Furthermore, we held 10% equity interests in MabPlex International Ltd. (“MabPlex”) as of January 1, 2018. We sold all of our equity interests in MabPlex with a consideration of RMB15.0 million based on the appraisal value assessed by a third-party valuer, to Yantai Zeng Rui Corporate Management Center (Limited Partnership) (煙台增瑞企業管理中心(有限合夥)) which is a related party, on June 13, 2018, mainly as our Directors believed such investment no longer coincided with our investment strategy.

Other Non-Current Assets

Other non-current assets mainly include prepayments for property, plant and equipment. The following table sets forth details of our other non-current assets as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Prepayments for property, plant and equipment	24,193	19,825	75,217
Valued-added tax recoverable	31,076	47,548	44,567
Prepayments for land lease	–	–	29,290
Long-term prepayments	–	63	55
	55,269	67,436	149,129

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Prepayments for property, plant and equipment represents the advanced payments we paid to suppliers for the construction of property and plant and purchase of equipment. Value-added tax recoverable recorded under other non-current assets represents our value-added tax (VAT) input tax credit that cannot be refunded by the competent authority within one year and would be utilized to deduct our VAT output tax in the future. Such VAT input tax credit is resulted from the difference between our VAT input tax (arising from our purchase of property, plant and equipment, as well as raw materials and other consumables) and our VAT output tax (arising from sales of equipment and materials). Prepayments for land lease represents our deposit for acquiring the land use rights for the construction of our new manufacturing facility.

Other non-current assets increased from RMB55.3 million as of December 31, 2018 to RMB67.4 million as of December 31, 2019, mainly due to an increase in value-added tax recoverable of RMB16.5 million as we purchased more raw materials and made more payments in 2019; such increase was partially offset by a decrease in advance payments for property, plant and equipment of RMB4.4 million as we gradually received the underlying equipment. Other non-current assets increased from RMB67.4 million as of December 31, 2019 to RMB149.1 million as of March 31, 2020, mainly due to an increase in prepayments for land lease of RMB29.3 million relating to deposit for acquiring the land use rights for the construction of our new manufacturing facility, and an increase in advance payment for property, plant and equipment of RMB55.4 million as a result of advance payments made for the preparation works for the construction of our new manufacturing facilities, as well as for the purchase of certain research and development equipment.

Inventories

Our inventories consist of raw materials and low-value consumption materials purchased for our drug research and development.

The following table sets forth our inventories as of the dates indicated:

	As at December 31,		As at March 31,
	2018	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	28,620	29,876	31,899
Low-value consumption materials	1,051	1,371	1,398
	29,671	31,247	33,297

The balance of our inventories increased from RMB29.7 million as of December 31, 2018 to RMB31.2 million as of December 31, 2019, and further increased to RMB33.3 million as of March 31, 2020, primarily due to increases in raw materials as we purchased more raw materials to be used in the commercial-scale production of our drug candidates.

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We regularly monitor our inventory to reduce the risk of overstocking. Our Directors confirm that our inventory control system and policies have been effective and we had not experienced any material shortage in supply or overstock of inventory during the Track Record Period and up to the Latest Practicable Date.

Bills Receivable

Our bills receivable amounted to RMB11.0 million, RMB1.1 million and nil as of December 31, 2018, December 31, 2019 and March 31, 2020, respectively. Our bills receivable mainly relate to our Bill Transfer Arrangements for the settlement of the payables to some of our suppliers in the ordinary course of business. The Bill Transfer Arrangements have been terminated since March 31, 2019. For more details, please refer to the paragraphs headed “–Indebtedness” in this section and “Business – Legal Proceedings and Compliance – Compliance” in this document.

Our bills receivable decreased significantly from RMB11.0 million as of December 31, 2018 to RMB1.1 million as of December 31, 2019, and further decreased to nil as of March 31, 2020, mainly attributable to our termination of the Bill Transfer Arrangements since March 31, 2019.

Prepayments, Other Receivables and Other Assets

Prepayments, other receivables and other assets mainly include cash in transit, value-added tax recoverable, prepayments, due from other related parties, deposits and other receivables. The following tables set forth the breakdown of prepayments, other receivables and other assets as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Cash in transit	–	–	109,819
Value-added tax recoverable	–	16,786	12,362
Prepayments	14,674	10,156	22,292
Due from other related parties	3,764	64	2,812
Deposits and other receivables	959	2,940	7,181
	19,397	29,946	154,466
Impairment allowance	(222)	(88)	(167)
	19,175	29,858	154,299

Cash in transit represents the amount of capital invested by LBC Sunshine, a Pre-[REDACTED] Investor, in a total amount of US\$15.5 million which has not been transferred to the bank account of our Group as of March 31, 2020 due to the ongoing approval process by the State Administration of Foreign Exchange. The investment amount from LBC Sunshine was subsequently transferred to our bank account in April 2020. For more details of

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the investment made by LBC Sunshine, please refer to the paragraphs headed “History, Development and Corporate Structure—Pre-[REDACTED] Investments—2020 Subscription” in this document. Value-added tax recoverable recorded under current assets represents our value-added tax (VAT) input tax credit that can be refunded by the competent authority within one year. Our VAT input tax credit is resulted from the difference between our VAT input tax (arising from our purchase of property, plant and equipment, as well as raw materials and other consumables) and our VAT output tax (arising from sales of equipment and materials). Prepayments mainly relate to our purchase of raw materials and consumables, as well as our prepayments for pre-clinical and clinical research and development services. Due from other related parties mainly relates to our sales of research and development equipment to MabPlex. Deposits and other receivables mainly relate to payment of social insurance contributions and housing provident fund contributions on behalf of employees, as well as capitalized [REDACTED] expenses.

Our prepayments, other receivables and other assets increased from RMB19.2 million as of December 31, 2018 to RMB29.9 million as of December 31, 2019, mainly due to an increase in value-added tax recoverable of RMB16.8 million as we purchased more raw materials and made more payments in 2019. Such increase was partially offset by a decrease in prepayments of RMB4.5 million mainly as we received and accepted the underlying raw materials as well as the research and development services in 2019.

Our prepayments, other receivables and other assets increased from RMB29.9 million as of December 31, 2019 to RMB154.3 million as of March 31, 2020, mainly due to (i) an increase in capital contribution from LBC Sunshine of RMB109.8 million, and (ii) an increase in prepayments of RMB12.1 million, mainly due to an increase in prepayments of RMB6.5 million for the purchase of materials for production purpose as well as an increase in research and development related prepayments of RMB5.3 million.

The following table sets forth the movements in the loss allowance for impairment of other receivables as of the dates indicated:

	As at December 31,		As at March 31,
	2018	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At the beginning of the year/period	26	222	88
Impairment losses, net	196	(134)	79
At the end of the year/period	222	88	167

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Cash and Cash Equivalents and Pledged Deposits

Our cash and cash equivalents primarily consist of cash and bank balances, while our pledged deposits mainly include cash deposits pledged for bills payable and wages of migrant workers. As of December 31, 2018, December 31, 2019 and March 31, 2020, nil, RMB40.9 million and RMB22.6 million of cash deposits were pledged for bills payable, respectively. The amount of cash deposits was equivalent to the amount of bills payable during the Track Record Period.

The following table sets forth the breakdown of our cash and cash equivalents and pledged deposits as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	2020
			<i>RMB'000</i>
Cash and bank balances	5,069	75,411	310,859
Less: Pledged for bills payable	–	(40,866)	(22,642)
Pledged for wages of migrant workers	–	–	(614)
	<u>5,069</u>	<u>34,545</u>	<u>287,603</u>
Cash and cash equivalents	<u>5,069</u>	<u>34,545</u>	<u>287,603</u>

Our cash and bank balances increased significantly from RMB5.1 million as of December 31, 2018 to RMB75.4 million as of December 31, 2019, mainly due to the subscription of our registered capital by PAG with a total consideration of RMB90.0 million in December 2019, as well as our receipt of government grants during 2019. For more details of the subscription of registered capital of our Company by PAG, please refer to the paragraphs headed “History, Development and Corporate Structure—Pre-[REDACTED] Investments—2019 Subscription” in this document.

Our cash and bank balances increased significantly from RMB75.4 million as of December 31, 2019 to RMB310.9 million as of March 31, 2020, mainly due to subscription for the increased registered capital of RMB13,991,040 of our Company by Pre-[REDACTED] Investors at a total consideration of US\$105,355,440 in March 2020. For more details, please refer to the paragraphs headed “History, Development and Corporate Structure—Pre-[REDACTED] Investments—2020 Subscription” in this document.

The following table sets forth the breakdown of our cash and cash equivalents denominated in RMB and USD as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	2020
			<i>RMB'000</i>
Denominated in RMB	4,305	34,295	285,285
Denominated in USD	764	250	2,318
	<u>5,069</u>	<u>34,545</u>	<u>287,603</u>
	<u>5,069</u>	<u>34,545</u>	<u>287,603</u>

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Trade and Bills Payables

Trade and bills payables mainly include payables in connection with our purchase of raw materials, consumables, and services from suppliers. Our trade and bills payables are non-interest-bearing and are normally settled on terms of one to three months. The following table sets forth a breakdown of trade and bill payables as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	2020
Trade payables	16,745	27,102	35,149
Bills payables	–	40,595	22,372
	16,745	67,697	57,521

Our trade and bills payables increased from RMB16.7 million as of December 31, 2018 to RMB67.7 million as of December 31, 2019, mainly due to an increase in the bills payables of RMB40.6 million and an increase in the trade payables of RMB10.4 million, primarily as we purchased more raw materials, consumables and services from suppliers for the development of our drug candidates, and with respect to the increase in bills payables, mainly as we used bank acceptance bills more frequently for these transactions in 2019.

Our trade and bills payables decreased from RMB67.7 million as of December 31, 2019 to RMB57.5 million as of March 31, 2020, mainly due to a decrease in the bills payables of RMB18.2 million, mainly as we reduced the use of bank acceptance bills for transactions with suppliers, which was partially offset by an increase in the trade payables of RMB8.0 million, primarily as we purchased more raw materials, consumables and services from suppliers for the development of our drug candidates.

The following table sets forth an aging analysis of our trade and bills payables based on the invoice date as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	2020
Within 3 months	15,188	46,209	37,201
3 to 6 months	5	21,417	20,225
6 months to 1 year	–	54	52
Over 1 year	1,552	17	43
	16,745	67,697	57,521

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Other Payables and Accruals

Our other payables and accruals primarily consist of payables for purchase of property, plant and equipment, payroll payable, other tax payables, accruals, due to related parties and other payables. The table below sets forth the details of our other payables and accruals as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Payables for purchase of property, plant and equipment	52,624	47,751	37,646
Payroll payable	14,680	28,091	24,093
Other payables	890	26,616	2,653
Other tax payables	498	1,087	848
Accruals	848	1,196	908
Due to related parties	902,591	615,857	548,180
Due to key management personnel	70	4	13
	972,201	720,602	614,341

Payables for purchase of property, plant and equipment are mainly related to payables in relation to construction in progress and purchase of machinery. Payroll payable mainly includes salary and other welfare payables to employees. Other payables are non-interest-bearing and repayable on demand, and are primarily consisted of payables in relation to government grants that we received as a R&D project leader which were payable to our R&D collaborators. We received such government grants from the Development Center for Medical Science & Technology of the National Health Commission (國家衛生健康委醫藥衛生科技發展研究中心) mainly for the development of ADC drug and relevant key technologies with our R&D collaborators. Other tax payables mainly include payables in relation to withholding individual income tax for employees and property tax. Accruals mainly consist of accrued travelling and transportation expenses, office expenses and sponsoring fees for industry conventions. Due to related parties mainly includes (i) the balance of borrowings and interest payables due to RC Pharma in an amount of RMB858.3 million, RMB588.1 million and RMB523.7 million as at December 31, 2018, December 31, 2019 and March 31, 2020, respectively, and (ii) other payables due to related parties in relation to payables for general administrative services provided by RC Pharma. Please refer to the paragraphs headed “—Related Party Transactions” in this section and note 31 of Appendix I to this document for further information with respect to various transactions and amounts due to and due from related parties.

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Our other payables and accruals decreased from RMB972.2 million as of December 31, 2018 to RMB720.6 million as of December 31, 2019, primarily attributable to (i) the decrease in due to related parties of RMB286.7 million, as RC Pharma converted a portion of its loans to us in an amount of RMB600.0 million as consideration to subscribe for the increased registered capital of our Company in July 2019. For more details of such debt to equity conversion, please refer to the paragraphs headed “History, Development and Corporate Structure—Corporate Development—Subsequent Capital Increase and Equity Transfer” in this document; and (ii) a decrease in payables for purchase of property, plant and equipment of RMB4.9 million, mainly as we gradually made the relevant payments for such purchase. Such decrease was partially offset by (i) an increase in other payables of RMB25.7 million mainly as we received the government grants on behalf of all research project participants in December 2019, a portion of which was payable to our R&D collaborators, and (ii) an increase in payroll payable of RMB13.4 million, primarily due to an increase in the number of employees as well as an increase in their salaries in 2019.

Other payables and accruals decreased from RMB720.6 million as of December 31, 2019 to RMB614.3 million as of March 31, 2020, primarily attributable to (i) a decrease in due to related parties of RMB67.7 million mainly as we repaid the principal of borrowings in an amount of RMB207.2 million to RC Pharma in the first quarter of 2020, (ii) a decrease in other payables of RMB24.0 million, mainly as we transferred the government grants to our R&D collaborators in the first quarter of 2020, (iii) a decrease in payables for purchase of property, plant and equipment of RMB10.1 million mainly as we gradually made the relevant payments for such purchase, and (iv) a decrease in payroll payable of RMB4.0 million mainly as we fully paid the bonus for the year of 2019 to employees in the first quarter of 2020.

Interest-bearing Bank borrowings

Our interest-bearing bank borrowings amounted to nil, RMB60.0 million and nil as at December 31, 2018, December 31, 2019 and March 31, 2020, respectively. The outstanding balance of the bank loan as of December 31, 2019 was related to a one-year bank loan with a principal amount of RMB60.0 million and an effective interest rate of approximately 6.3% per annum. This one-year bank loan was granted under an overall credit line of RMB70.0 million made available by Yantai Bank to our Company. This bank loan was secured by the mortgage of one of our buildings and the corresponding land use rights with net carrying amounts of RMB86.0 million and RMB2.4 million, respectively, and was also guaranteed by the Chairman of the Board, Mr. Weidong Wang, as of December 31, 2019. We have fully repaid the loan in the principal amount of RMB60.0 million in the first quarter of 2020, and thus the relevant personal guarantee provided by Mr. Weidong Wang for this bank loan has been fully released in March 2020.

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Deferred Income

Our deferred income consists of current and non-current government grants received but not yet recognized as income. The following table sets forth the breakdown of our deferred income as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	2020
			<i>RMB'000</i>
<i>Government grants:</i>			
Current	6,862	7,052	6,973
Non-current	28,951	60,565	56,047
	35,813	67,617	63,020

Our deferred income increased from RMB35.8 million as of December 31, 2018 to RMB67.6 million as of December 31, 2019, primarily in relation to (i) a one-off government grant of RMB11.7 million as compensation and encouragement for our research and development activities, and (ii) government grant of RMB8.1 million to compensate our research and development activities relating to our clinical trials of RC18 with respect to RA and SLE. Our deferred income decreased from RMB67.6 million as of December 31, 2019 to RMB63.0 million as of March 31, 2020, primarily due to amortization of government grants related to relevant assets.

KEY FINANCIAL RATIOS

The table below sets forth the key financial ratios of our Group as at the dates indicated:

	As at December 31,		As at
	2018	2019	March 31,
	%	%	2020
			%
Current ratio ⁽¹⁾	6.5	16.1	73.3
Quick ratio ⁽²⁾	3.5	12.4	68.4
	3.5	12.4	68.4

Notes:

- (1) Current ratio represents current assets divided by current liabilities as of the same date.
- (2) Quick ratio represents current assets less inventories and divided by current liabilities as of the same date.

Current ratio increased from 6.5% as of December 31, 2018 to 16.1% as of December 31, 2019, while the quick ratio increased from 3.5% as of December 31, 2018 to 12.4% as of December 31, 2019, mainly due to (i) a decrease in other payables and accruals of RMB251.6 million, primarily attributable to the decrease in due to related parties of RMB286.7 million, as RC Pharma converted a portion of its loans to us in an amount of RMB600.0 million as

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consideration to subscribe for the increased registered capital of our Company in July 2019; and (ii) an increase in pledged deposits of RMB40.9 million and an increase in cash and cash equivalents of RMB29.5 million.

Current ratio increased from 16.1% as at December 31, 2019 to 73.3% as at March 31, 2020, while the quick ratio increased from 12.4% as at December 31, 2019 to 68.4% as at March 31, 2020, mainly due to (i) an increase in prepayments, other receivables and other assets of RMB124.4 million, mainly attributable to an increase in cash in transit from LBC Sunshine of RMB109.8 million; (ii) an increase in cash and cash equivalents of RMB253.1 million mainly due to subscription for the increased registered capital of RMB13,991,040 of our Company by Pre-[REDACTED] Investors at a total consideration of US\$105,355,440 in March 2020; (iii) a decrease in other payables and accruals of RMB106.3 million, primarily due to a decrease in due to related parties of RMB67.7 million mainly as we repaid the principal of borrowings in an amount of RMB207.2 million to RC Pharma in the first quarter of 2020; and (iv) a decrease in interest-bearing bank borrowings of RMB60.0 million as we repaid the bank loan.

Our current ratio and quick ratio were relatively low during the Track Record Period, mainly as we recorded the balance of borrowings and interest payables due to RC Pharma in an amount of RMB858.3 million, RMB588.1 million and RMB523.7 million under current liabilities as at December 31, 2018, December 31, 2019 and March 31, 2020, respectively, because such loan was payable on demand, which led to relatively large amount of current liabilities during the Track Record Period. If the balance of borrowings and interest payables due to RC Pharma in an amount of RMB523.7 million were excluded in calculating the current liabilities as of March 31, 2020, the current assets of our Group as of March 31, 2020 would be sufficient to cover the other current liabilities as of the same date. We plan to repay the borrowings from RC Pharma by using a portion of net [REDACTED] from the [REDACTED]. For more details, please refer to the section headed “Future Plan and Use of [REDACTED]” in this document.

LIQUIDITY AND CAPITAL RESOURCES

Our primary uses of cash are to fund the development of our drug candidates, our clinical trials, our payment for the construction of research and manufacturing facilities and for the purchase of equipment, administrative expenses and other recurring expenses. Our net cash used in operating activities was RMB128.0 million, RMB282.7 million, RMB58.1 million and RMB117.9 million in 2018 and 2019, and the three-month period ended March 31, 2019 and 2020, respectively, primarily due to the significant research and development expenses and administrative expenses we incurred during the Track Record Period without generating any revenue from sales of our drug candidates. Our operating cash flow will continue to be affected by our research and development expenses. During the Track Record Period and up to the Latest Practicable Date, we primarily funded our working capital requirements through proceeds from private equity and debt financing. Our management closely monitors uses of cash and cash balances and strives to maintain a healthy liquidity for our operations. Going forward, we believe our liquidity requirements will be satisfied by a combination of net [REDACTED] from the [REDACTED], bank borrowings and government grants. As of March 31, 2020, our cash and cash equivalents amounted to RMB287.6 million.

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Cash Flows

The following table sets forth our cash flows for the periods indicated:

	Year ended December 31,		Three months ended March 31,	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Cash outflow from operating activities before movements in working capital	(205,850)	(338,438)	(64,866)	(77,205)
Changes in working capital	77,801	55,545	6,806	(40,894)
Interest received	21	147	3	239
Net cash flows used in operating activities	(128,028)	(282,746)	(58,057)	(117,860)
Net cash flows used in investing activities	(77,172)	(95,100)	(19,519)	(121,926)
Net cash flows from financing activities	206,289	407,322	77,904	493,539
Net increase in cash and cash equivalents	1,089	29,476	328	253,753
Cash and cash equivalents at end of the year/period	<u>5,069</u>	<u>34,545</u>	<u>5,397</u>	<u>287,603</u>

Net Cash Flows Used in Operating Activities

For the three months ended March 31, 2020, our net cash used in operating activities was RMB117.9 million, which was primarily attributable to our net loss before tax of RMB99.6 million, adjusted for non-cash and non-operating items. Positive adjustments primarily include finance costs of RMB9.0 million, depreciation of property, plant and equipment of RMB11.6 million and share-based payment expenses of RMB1.9 million. The amount was then further adjusted negatively by a decrease in other payables and accruals of RMB31.7 million, an increase in prepayments, other receivables and other assets of RMB14.6 million.

In 2019, our net cash used in operating activities was RMB282.7 million, which was primarily attributable to our net loss before tax of RMB430.3 million, adjusted for non-cash and non-operating items. Positive adjustments primarily include finance costs of RMB43.8 million, depreciation of property, plant and equipment of RMB40.2 million, and share-based payment expenses of RMB5.1 million. The amount was then further adjusted positively by a decrease in bills receivable of RMB20.8 million, an increase in trade and bills payables of RMB19.0 million, an increase in other payables and accruals of RMB23.5 million and an increase in deferred income in respect of government grants related to income of RMB29.8 million; partially offset by an increase in prepayments, other receivables and other assets of RMB10.7 million and an increase in other non-current assets of RMB16.6 million.

In 2018, our net cash used in operating activities was RMB128.0 million, which was primarily attributable to our net loss before tax of RMB269.9 million, adjusted for non-cash and non-operating items. Positive adjustments primarily include finance costs of RMB40.1

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million, depreciation of property, plant and equipment of RMB20.5 million, and share-based payment expenses of RMB3.0 million. The amount was then adjusted positively by an increase in other payables and accruals of RMB38.5 million, a decrease in bills receivable of RMB31.9 million and a decrease in prepayments, other receivables and other assets of RMB42.5 million; partially offset by an increase in other non-current assets of RMB31.1 million, an increase in inventories of RMB7.8 million and a decrease in deferred income in respect of government grants related to income of RMB4.6 million.

Net Cash Flows Used in Investing Activities

For the three months ended March 31, 2020, our net cash used in investing activities was RMB121.9 million, primarily as a result of purchases of items of property, plant and equipment of RMB100.1 million and purchase of items of land lease of RMB34.1 million, and partially offset by a decrease in pledged deposits of RMB12.3 million.

In 2019, our net cash used in investing activities was RMB95.1 million, primarily as a result of purchases of items of property, plant and equipment of RMB65.2 million mainly relating to our construction of manufacturing facilities, among others, and an increase in pledged deposits of RMB32.1 million, and partially offset by receipt of government grants for property, plant and equipment of RMB2.0 million.

In 2018, our net cash used in investing activities was RMB77.2 million, primarily as a result of purchases of items of property, plant and equipment of RMB83.7 million as well as purchase of an equity investment designated at fair value through other comprehensive income of RMB10.0 million, and partially offset by proceeds from disposal of another equity investment designated at fair value through other comprehensive income of RMB15.0 million.

Net Cash Flows from Financing Activities

For the three months ended March 31, 2020, our net cash generated from financing activities was RMB493.5 million, mainly attributable to capital contributions from Pre-[REDACTED] Investors of RMB627.3 million, new borrowings from a related party of RMB134.8 million and new bank borrowings of RMB60.0 million, and partially offset by repayment of borrowings to RC Pharma of RMB207.2 million and repayment of bank borrowings of RMB120.0 million.

In 2019, our net cash generated from financing activities was RMB407.3 million, mainly attributable to new borrowings from a related party of RMB557.0 million, new bank borrowings of RMB146.0 million and capital contributions from a shareholder of RMB90.0 million, and partially offset by repayment of borrowings to RC Pharma of RMB209.1 million, interest payment of RMB89.0 million and repayment of bank borrowings of RMB86.0 million.

In 2018, our net cash generated from financing activities was RMB206.3 million, mainly attributable to new borrowings from RC Pharma of RMB294.1 million, and partially offset by repayment of borrowings to RC Pharma of RMB86.8 million.

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CASH OPERATING COSTS

The following table sets forth our cash* operating costs for the periods indicated:

	Year ended December 31,		Three Months ended March 31,	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>	<i>(unaudited)</i>
Costs Relating to Research and Development of Our Core Product Candidates				
Clinical trial costs	36,136	41,644	6,666	8,270
Raw material costs	39,500	43,925	8,841	12,655
Testing expenses	9,930	21,629	3,606	4,856
Salaries and benefits	46,228	81,481	18,390	24,435
Others	13,504	64,602	4,736	4,250
Subtotal	145,298	253,281	42,239	54,466
Costs Relating to Research and Development of Our Other Product Candidates				
Clinical trial costs	–	1,120	–	922
Raw material costs	15,013	32,400	9,559	4,614
Testing expenses	9,247	13,200	4,571	3,260
Salaries and benefits	7,859	15,833	4,311	6,852
Others	4,306	19,574	4,737	9,255
Subtotal	36,425	82,127	23,178	24,903
Workforce Employment Cost⁽¹⁾	8,790	21,334	5,186	9,269
Direct Production Cost⁽²⁾	–	–	–	–
Non-income Taxes, Royalties and Other Governmental Charges⁽³⁾	950	1,678	235	843
Contingency Allowances	–	–	–	–
Product Marketing	–	411	–	1,081
Others⁽⁴⁾	19,427	32,152	3,927	10,054
Total	210,890	390,983	74,765	100,616

Notes:

* Our cash operating costs set forth in this table include our operating expenses paid in cash and bank acceptance bills.

- (1) Workforce employment cost represents total non-research and development personnel costs mainly including salaries and benefits.
- (2) We had not commenced product manufacturing as of the Latest Practicable Date.
- (3) Royalties and other governmental charges mainly include taxes and other surcharges.
- (4) Others mainly include administrative expenses (other than employee benefits expenses), and with respect to 2018, also include cost of sales in relation to our provision of contract research and pre-clinical development services to Rongchang Zibo.

WORKING CAPITAL CONFIRMATION

The Directors are of the opinion that, taking into account of the financial resources available to us, including cash and cash equivalents, available credit facilities, the estimated net [REDACTED] from the [REDACTED] and government grants, we have sufficient working capital to cover at least 125% of our costs, including research and development costs, business development and marketing expenses, and administrative and operating costs for at least the next 12 months from the date of this document. Based on the review of financial documents and other due diligence documents, discussion with the Directors and the Directors' confirmation, the Joint Sponsors concur with the Directors' view.

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INDEBTEDNESS

Borrowings

The following table sets forth the breakdown of our borrowings as at the dates indicated:

	As at December 31,		As at	As at
	2018	2019	March 31,	April 30,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>
Principal of the interest-bearing bank borrowings ⁽¹⁾	–	60,000	–	–
Principal and interests of borrowings from a related party	858,288	588,082	523,661	494,445
	858,288	648,082	523,661	494,445

Note:

(1) There was no interests payable of the bank borrowings as of the dates indicated.

Interest-bearing bank borrowings

As of December 31, 2018, December 31, 2019, March 31, 2020 and April 30, 2020, the outstanding amount of our bank borrowings was nil, RMB60.0 million, nil and nil, respectively. The outstanding amount of the bank loan as of December 31, 2019 was related to a one-year bank loan with a principal amount of RMB60.0 million and an effective interest rate of approximately 6.3% per annum. This bank loan was secured by the mortgage of one of our buildings and the corresponding land use rights with net carrying amounts of RMB86.0 million and RMB2.4 million, respectively, and was also guaranteed by the Chairman of the Board, Mr. Weidong Wang, as of December 31, 2019. We have fully repaid the loan in the principal amount of RMB60.0 million in the first quarter of 2020, and thus the relevant personal guarantees provided by Mr. Weidong Wang for this bank loan has been fully released in March 2020.

Our bank borrowing agreements contain standard terms, conditions and covenants that are customary for commercial bank loans. Our Directors confirm that we had not experienced any difficulty in obtaining bank loans and other borrowings, default in payment of bank borrowings or breach of covenants during the Track Record Period and up to the Latest Practicable Date, other than the deviation from intended use of loan proceeds for certain of our bank loans as discussed below. As of the Latest Practicable Date, we had unutilized banking facilities of RMB630.0 million which were granted by Yantai Bank upon its approval for drawdowns.

Borrowings from a related party

As of December 31, 2018, December 31, 2019, March 31, 2020 and April 30, 2020, the outstanding principal and interests of our borrowings due to RC Pharma amounted to RMB858.3 million, RMB588.1 million, RMB523.7 million and RMB494.4 million,

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respectively. We borrowed loans from RC Pharma in form of cash and bank acceptance bills in a total amount of RMB380.9 million, RMB584.1 million and RMB134.8 million in 2018, 2019 and the three-month periods ended March 31, 2020, respectively. These borrowings are unsecured and payable on demand. The applicable interest rates are determined in accordance with the prevailing market borrowing rates. In 2018 and 2019, and the three-month periods ended March 31, 2020, the applicable annual interest rate for the borrowings from RC Pharma was approximately 6.3%, 6.0% and 6.0%, respectively. We plan to repay the borrowings from RC Pharma by using a portion of net [REDACTED] from the [REDACTED]. For more details, please refer to the section headed “Future Plan and Use of [REDACTED]” in this document.

Bill Transfer Arrangements and deviation of intended use of loan proceeds

We have entered into certain bill transfer arrangements to obtain bank acceptance bills of RMB86.8 million and RMB25.6 million from RC Pharma in 2018 and 2019, respectively (the “Bill Transfer Arrangements”). Upon becoming aware of such non-compliance and the advice of our professional advisors, our Company has ceased conducting such Bill Transfer Arrangements since March 31, 2019.

Further, our Company has made drawdowns by entering into four loan contracts to draw down an aggregate amount of RMB146 million for the year ended December 31, 2019, and three loan contracts to draw down an aggregate amount of RMB60 million for the three months ended March 31, 2020. Instead of using the Loans in accordance with the pre-agreed usages in the Loan Contracts, we used them for different purposes including settlements with MabPlex, settlement of related party loans and payables owed to RC Pharma and other general working capital uses. Upon becoming aware of the non-compliance and with the advice of our professional advisors, our Company has ceased the Bank Loan Transfer Arrangements since March 1, 2020 and has fully repaid all of the Loans under the Bank Loan Transfer Arrangements by March 13, 2020.

For more details of the Bill Transfer Arrangements and the deviation of intended use of loan proceeds, please refer to the paragraphs headed “Business – Legal Proceedings and Compliance – Compliance” in this document.

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Lease Liabilities

The following table sets forth the lease liabilities of our Group as of the dates indicated:

	As at December 31,		As at March 31,	As at April 30,
	2018	2019	2020	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>
Current portion	1,131	1,602	1,189	1,244
Non-current portion	3,380	3,762	3,248	3,193
	4,511	5,364	4,437	4,437

Except as discussed in “Discussion of Certain Selected Items from the Consolidated Statements of Financial Position—Interest-bearing bank borrowings” and “—Indebtedness” in this section, we had no outstanding indebtedness or any loan capital issued and outstanding or agreed to be issued, bank overdrafts, loans or similar indebtedness, liabilities under acceptances (other than normal trade bills), acceptance credits, debentures, mortgages, charges, finance leases or hire purchase commitments, guarantees or other contingent liabilities or any covenant in connection therewith as of April 30, 2020, being our indebtedness statement date. After due and careful consideration, our Directors confirm that there had been no material adverse change in our indebtedness since April 30, 2020 and up to the Latest Practicable Date.

CAPITAL EXPENDITURES

We regularly incur capital expenditures to purchase and maintain our property, plant and equipment in order to enhance our development capabilities and expand our business operations. Historically, we have funded our capital expenditures mainly through private equity and debt financing. The following table sets forth our capital expenditures for the periods indicated:

	Year ended December 31,		Three Months ended March 31,	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
				<i>(Unaudited)</i>
Purchase of items of property, plant and equipment	83,722	65,209	21,158	100,112
Purchase of items of land lease	–	–	–	34,072
	83,722	65,209	21,158	134,184

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We expect to incur capital expenditures of approximately RMB485.6 million in 2020. The expected capital expenditures are primarily for the construction of our new manufacturing facility and for the acquisition of research and development equipment. We plan to fund our planned capital expenditures through net [REDACTED] from the [REDACTED] and bank borrowings. We may adjust our capital expenditures for any given period according to our development plans or in light of market conditions and other factors we believe to be appropriate.

CONTRACTUAL OBLIGATIONS

Capital Commitments

As of December 31, 2018, December 31, 2019 and March 31, 2020, we had capital commitments contracted for but not yet provided of RMB25.0 million, RMB653.8 million and RMB761.7 million primarily in connection with (i) contracts entered into with contractors for the construction of our new manufacturing facilities, and (ii) contracts entered into with suppliers for the purchase of equipment and materials. The following table sets forth our capital commitments as at the date indicated:

	As at December 31,		As at
	2018	2019	March 31,
	RMB'000	RMB'000	2020
			RMB'000
<i>Contracted, but not provided for:</i>			
Purchases of items of property, plant and equipment	25,020	653,810	761,694

CONTINGENT LIABILITIES

As at December 31, 2018, our Group provided a credit guarantee for RC Pharma with respect to its bank loan of RMB36.0 million, which was released on August 6, 2019. As at December 31, 2019 and March 31, 2020, our Group did not have any contingent liabilities.

OFF-BALANCE SHEET COMMITMENTS AND ARRANGEMENTS

As of the Latest Practicable Date, we had not entered into any off-balance sheet transactions.

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RELATED PARTY TRANSACTIONS

During the Track Record Period, we had the following transactions with the following related parties that had material transaction amounts or balances with us:

(a) Our Group had the following transactions with related parties during the Track Record Period:

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Sales of materials				
Yantai Dasike Biotechnology Co., Ltd. (煙台達思科生物科技有限 公司)	-	1	-	-
Yantai Rongchang Biomedical Industry Technology Research Institute Co., Ltd. (煙台榮昌生物醫藥產業技 術研究院有限公司)	-	-	-	1
MabPlex	13	1,451	1	-
CelluPro	1,505	155	-	19
Yeda Incubation	-	1	1	-
	<u>1,518</u>	<u>1,608</u>	<u>2</u>	<u>20</u>
Rendering of services				
Rongchang Zibo	11,321	-	-	-
MabPlex	-	474	-	-
CelluPro	372	215	-	17
	<u>11,693</u>	<u>689</u>	<u>-</u>	<u>17</u>
Rental income				
MabPlex	-	2,449	544	408
Lida	-	3	-	17
	<u>-</u>	<u>2,452</u>	<u>544</u>	<u>425</u>
Sales of equipment				
MabPlex	1,177	-	-	-
CelluPro	122	194	-	-
	<u>1,299</u>	<u>194</u>	<u>-</u>	<u>-</u>

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	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Purchases of materials				
MabPlex	–	–	–	41
CelluPro	2,258	1,450	–	826
Yeda Incubation	–	2	–	–
	2,258	1,452	–	867
	2,258	1,452	–	867
Purchases of services⁽¹⁾				
Shanghai Kangkang Medical Technology Center (上海康康醫藥科 技中心)	–	390	–	1,209
MabPlex	–	10,236	–	2,868
RC Pharma	15,103	21,619	4,557	5,681
Yeda Incubation	57	–	–	–
	15,160	32,245	4,557	9,758
	15,160	32,245	4,557	9,758
Purchases of equipment				
MabPlex	1,194	–	–	–
RC Pharma	292	–	–	–
Yeda Incubation	–	685	–	–
	1,486	685	–	–
	1,486	685	–	–
Purchases of land use right				
MabPlex	–	–	–	4,589
	–	–	–	4,589
	–	–	–	4,589
Rental expenses				
MabPlex	–	512	–	–
Yeda Incubation	665	388	180	257
	665	900	180	257
	665	900	180	257
Interest expenses on borrowings				
RC Pharma	39,791	41,649	12,392	8,012
	39,791	41,649	12,392	8,012
	39,791	41,649	12,392	8,012
Borrowings from a related party				
RC Pharma	380,875	584,054	110,969	134,753
	380,875	584,054	110,969	134,753
	380,875	584,054	110,969	134,753
Repayment of interest expenses				
RC Pharma	–	86,860	–	–
	–	86,860	–	–
	–	86,860	–	–

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	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
			<i>(Unaudited)</i>	
Repayment of borrowings				
RC Pharma	86,788	209,050	7,039	207,186
Repayment of lease liabilities				
Yeda Incubation	–	1,824	–	364
Interest expenses on lease liabilities				
Yeda Incubation	230	281	74	61

Note:

- (1) During the Track Record Period, we mainly purchased contract development and manufacturing services from Shanghai Kangkang Medical Technology Center, MabPlex and Yeda Incubation. We also purchased general administrative services from RC Pharma. For more details of the general administrative services provided by RC Pharma, please refer to the paragraphs headed “Connected Transactions—Our Continuing Connected Transactions” in this document.

(b) Outstanding balances with related parties:

	As at December 31,		As at March 31,
	2018	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade and bills payables			
MabPlex	1,540	–	41
CelluPro	2,619	1,577	2,403
Rongchang Zibo	–	8,930	8,930
	4,159	10,507	11,374
Prepayments, other receivables and other assets			
MabPlex	1,366	–	2,800
CelluPro	2,283	–	12
Yeda Incubation	115	64	–
	3,764	64	2,812

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	As at December 31,		As at
	2018	2019	March 31,
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Other payables and accruals			
Dr. Fang Jianmin	70	–	–
Dr. Fu Daotian	–	4	13
Yeda Incubation	721	2,392	686
MabPlex	2,962	10,275	971
RC Pharma	897,956	603,184	546,517
Lida	648	6	6
Beijing Rongchang Medical Research Institute Ltd. (北京榮昌藥物研究院有 限公司)	304	–	–
	902,661	615,861	548,193
Lease liabilities			
Yeda Incubation	4,040	4,734	4,437
	4,040	4,734	4,437

Our outstanding balances due from and due to the related parties as of December 31, 2018, December 31, 2019 and March 31, 2020 were trade in nature, unsecured, interest-free and have no fixed terms of repayment, except for the outstanding principal and interests amount due to RC Pharma with an interest at approximately 6.3%, 6.0% and 6.0% per annum as of December 31, 2018, December 31, 2019 and March 31, 2020, respectively. For more details of our financing arrangement with RC Pharma during the Track Record Period, please refer to the paragraphs headed “—Indebtedness” in this section. As of March 31, 2020 and April 30, 2020, the outstanding balance of principal and interests from RC Pharma amounted to RMB523.7 million and RMB494.4 million, respectively. We plan to repay the borrowings from RC Pharma by using a portion of net [REDACTED] from the [REDACTED]. For more details, please refer to the section headed “Future Plan and Use of [REDACTED]” in this document.

It is the view of our Directors that each of the above transactions (i) was conducted in the ordinary and usual course of business and on normal commercial terms between the relevant parties, and (ii) does not distort our Track Record Period results or make our historical results not reflective of future performance.

MARKET RISK DISCLOSURE

Our Group’s principal financial instruments mainly comprise cash and bank balances and interest-bearing borrowings. The main purpose of these financial instruments is to raise finance for our Group’s operations. Our Group has various other financial assets and liabilities such as bills receivables, other receivables, trade and bills payables and other payables, which arise directly from its operations.

The main risks arising from our Group’s financial instruments are foreign currency risk, credit risk and liquidity risk. The directors review and agree policies for managing each of these risks and they are summarized below. For more details, please refer to note 34 to Appendix I in this document.

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Currency risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between RMB and other currencies in which we conduct business may affect our financial condition and results of operations.

The following table demonstrates the sensitivity at the end of each of the Track Record Period to a reasonably possible change in foreign currency exchange rate, with all other variables held constant, of our loss before tax (due to changes in the fair values of monetary assets and liabilities) and our equity.

	<u>Increase/(decrease) in the rate of foreign currency</u>	<u>Increase/(decrease) in loss before tax</u>	<u>Increase/(decrease) in equity</u>
	%	RMB'000	RMB'000
December 31, 2018			
If RMB weakens against USD	5	(38)	(38)
If RMB strengthens against USD	(5)	38	38
December 31, 2019			
If RMB weakens against USD	5	(12)	(12)
If RMB strengthens against USD	(5)	12	12
March 31, 2020			
If RMB weakens against USD	5	(791)	(791)
If RMB strengthens against USD	(5)	791	791

Credit risk

Our Group trades only with recognized and creditworthy parties. Receivable balances are monitored on an ongoing basis and our Group’s exposure to bad debts is not significant. The credit risk of our Group’s other financial assets, which comprise cash and cash equivalents, pledged deposits and financial assets included in prepayments, other receivables and other assets, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments.

For other receivables and other assets, management makes periodic collective assessment as well as individual assessment on the recoverability of other receivables based on historical settlement records and past experience. Our Directors believe that there is no material credit risk inherent in our Group’s outstanding balance of other receivables.

As at the end of the each of the Track Record Period, cash and cash equivalents were deposited in financial institutions in high quality without significant credit risk.

Liquidity risk

Our Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of our Group to finance the operations and mitigate the effects of fluctuations in cash flows.

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The maturity profile of our Group’s financial liabilities as at the end of each of the Track Record Period, based on the contractual undiscounted payments, is as follows:

As at December 31, 2018					
	On demand	Within one year	One to five years	Over five years	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade and bills payables	–	16,745	–	–	16,745
Financial liabilities included in other payables and accruals	957,023	–	–	–	957,023
Lease liabilities	–	1,345	3,737	–	5,082
	957,023	18,090	3,737	–	978,850
	957,023	18,090	3,737	–	978,850
As at December 31, 2019					
	On demand	Within one year	One to five years	Over five years	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade and bills payables	–	67,697	–	–	67,697
Financial liabilities included in other payables and accruals	691,424	–	–	–	691,424
Interest-bearing bank borrowings	–	60,000	–	–	60,000
Lease liabilities	–	1,851	4,087	–	5,938
	691,424	129,548	4,087	–	825,059
	691,424	129,548	4,087	–	825,059
As at March 31, 2020					
	On demand	Within one year	One to five years	Over five years	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade and bills payables	–	57,521	–	–	57,521
Financial liabilities included in other payables and accruals	589,400	–	–	–	589,400
Lease liabilities	–	1,366	3,549	–	4,915
	589,400	58,887	3,549	–	651,836
	589,400	58,887	3,549	–	651,836

Capital management

The primary objectives of our Group’s capital management are to safeguard our Group’s ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximize shareholders’ value.

Our Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, our Group may return capital to shareholders or issue new shares. Our Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Track Record Period.

FINANCIAL INFORMATION

DIVIDEND

No dividend have been declared or paid by entities comprising our Group. We currently expect to retain all future earnings for use in operation and expansion of our business, and do not have any dividend policy to declare or pay any dividends in the foreseeable future. The declaration and payment of any dividends in the future will be determined by our board of directors and subject to our Articles of Association and the PRC Company Law, and will depend on a number of factors, including the successful commercialization of our drugs as well as our earnings, capital requirements, overall financial condition and contractual restrictions. No dividend shall be declared or payable except out of our profits and reserves lawfully available for distribution. As confirmed by our PRC Legal Advisor, according to the PRC law, any future net profit that we make will have to be first applied to make up for our historically accumulated losses, after which we will be obliged to allocate 10% of our net profit to our statutory common reserve fund until such fund has reached more than 50% of our registered capital. We will therefore only be able to declare dividends after (i) all our historically accumulated losses have been made up for; and (ii) we have allocated sufficient net profit to our statutory common reserve fund as described above.

DISTRIBUTABLE RESERVES

As of March 31, 2020, we did not have any distributable reserves.

[REDACTED] EXPENSE

[REDACTED] expenses to be borne by us are estimated to be approximately HK\$[REDACTED] (including [REDACTED] commission, assuming an [REDACTED] of HK\$[REDACTED] per Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per Share), assuming no Shares are issued pursuant to the [REDACTED]. In 2018, 2019 and the three-month period ended March 31, 2020, the [REDACTED] expenses charged to profit or loss were [REDACTED], RMB[REDACTED] (approximately HK\$[REDACTED]) and RMB[REDACTED] (approximately HK\$[REDACTED]), respectively, and the issue costs capitalized to deferred issue costs were [REDACTED], RMB[REDACTED] (approximately HK\$[REDACTED]) and RMB[REDACTED] (approximately HK\$[REDACTED]), respectively. After March 31, 2020, we estimate that additional [REDACTED] expenses of approximately HK\$[REDACTED] will be incurred by our Company, approximately HK\$[REDACTED] of which is expected to be charged to our consolidated statements of profit or loss, approximately HK\$[REDACTED] of which is expected to be capitalized, and approximately HK\$[REDACTED] of which is expected to be recognized directly as a deduction from equity upon the [REDACTED]. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

UNAUDITED PRO FORMA STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited pro forma statement of adjusted consolidated net tangible assets of our Group prepared in accordance with Rule 4.29 of the Listing Rules is set out below to illustrate the effect of the [REDACTED] on the consolidated net tangible assets of our Group attributable to our owners as at March 31, 2020 as if the [REDACTED] had taken place on such date.

FINANCIAL INFORMATION

This unaudited pro forma statement of adjusted consolidated net tangible assets has been prepared for illustrative purposes only and because of its hypothetical nature, it may not give a true and fair picture of the consolidated net tangible assets of our Group attributable to our owners as at March 31, 2020 or at any further dates following the [REDACTED].

Audited consolidated net tangible assets attributable to owners of the parent as at 31 March 2020	Estimated net [REDACTED] from the [REDACTED]	Unaudited pro forma adjusted consolidated net tangible assets	Unaudited pro forma adjusted consolidated net tangible assets per Share		
<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB</i>	<i>HK\$</i>	
<i>(Note 1)</i>	<i>(Note 2)</i>		<i>(Note 3)</i>	<i>(Note 4)</i>	
Based on an [REDACTED] of HK\$[REDACTED] per Share	404,283	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Based on an [REDACTED] of HK\$[REDACTED] per Share	404,283	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Based on an [REDACTED] of

HK\$[REDACTED] per Share 404,283 [REDACTED] [REDACTED] [REDACTED] [REDACTED]

Based on an [REDACTED] of

HK\$[REDACTED] per Share 404,283 [REDACTED] [REDACTED] [REDACTED] [REDACTED]

Notes:

- (1) The consolidated net tangible assets attributable to owners of the parent as at 31 March 2020 is arrived at after deducting intangible assets of RMB1,933,000 from the audited net assets attributable to owners of the parent of RMB406,216,000 as at 31 March 2020, as shown in the Accountants’ Report, the text of which is set out in Appendix I to this document.
- (2) The estimated net [REDACTED] from the [REDACTED] are based on estimated low end and high end [REDACTED] of HK\$[REDACTED] or HK\$[REDACTED] per Share after deduction of the [REDACTED] fees and other related expenses payable by our Company and do not take into account any share which may be sold and offered upon exercise of the [REDACTED].
- (3) The unaudited pro forma adjusted consolidated net tangible assets per Share is arrived at after adjustments referred to in the preceding paragraphs and on the basis that [REDACTED] Shares are in issue assuming the [REDACTED] has been completed on 31 March 2020.
- (4) The unaudited pro forma adjusted consolidated net tangible assets per Share are converted into Hong Kong dollars at an exchange rate of RMB0.9181 to HK\$1.00.
- (5) No adjustment has been made to the unaudited pro forma adjusted consolidated net tangible assets to reflect any trading results or other transactions of the Group entered into subsequent to 31 March 2020.

NO MATERIAL ADVERSE CHANGE

Our Directors confirm that, save as disclosed in the paragraphs headed “Summary—Recent Development” and the COVID-19 outbreak as stated below in this document, there has been no material adverse change in our financial, operational or trading position or prospects since March 31, 2020 and up to the date of this document and there is no event since March 31, 2020 which would materially affect the information shown in our consolidated financial statements included in the Accountants’ Report in Appendix I to this document.

FINANCIAL INFORMATION

IMPACT OF THE COVID-19 OUTBREAK

In December 2019, a novel strain of coronavirus causing coronavirus disease 2019 (COVID-19), was reported in Wuhan, China. The spread of COVID-19 subsequently evolved into a global pandemic and continues to affect China, where we manage our business and are conducting pre-clinical studies and clinical trials, as well as the U.S., Europe and other countries, where we intend to carry out our global clinical development plan. The outbreak of COVID-19 since the end of 2019 has not caused any early termination of our clinical trials or necessitated removal of any patients enrolled in our clinical trials. We have employed various measures to mitigate any impact the COVID-19 outbreak may have on our ongoing clinical trials in China, including cooperating with clinical trial sites to offer personal protection equipment such as masks to our enrolled patients, engaging frequent communications with our principal investigators to identify and address any issues that may arise. Although we experienced minor delays in the patient enrollment process and data entry for certain of our clinical trials in China at the beginning of the COVID-19 outbreak, since then the situation has improved due to the enhanced containment policies implemented by the PRC government and the gradual control of the COVID-19 outbreak in China. As of the Latest Practicable Date, we had resumed the normal patient enrollment and data entry for our clinical trials in China. With respect to our global clinical development plan, (a) we expect to initiate global Phase III clinical trials of telitacept for SLE in the first half of 2021 to cover multiple jurisdictions, including the United States, Europe and other countries, and (b) we expect to initiate a Phase II trial of disitamab vedotin in UC in the U.S. in the first quarter of 2021, while to initiate a bridging trial in GC patients in the first half of 2021 in the U.S. to seek expedited approval. We are currently conducting preparation works for the aforementioned clinical trials, and had not initiated the patient enrollment process for these clinical trials as of the Latest Practicable Date. We currently do not expect a delay in the aforementioned global clinical development plan of telitacept and disitamab vedotin. We expect the situation to continue to improve with the sustained implementation of containment policies for the COVID-19 outbreak, and we do not expect it to have any material long-term impact on our clinical trials or our overall clinical development plans. Based on the foregoing, we currently expect that our ongoing clinical trials will not be significantly affected by the outbreak of COVID-19.

We believe that the COVID-19 outbreak will not significantly affect our ability to carry out our obligations under existing contracts or disrupt any supply chains that we currently rely upon. As of the Latest Practicable Date, our top five suppliers in 2019 and other major domestic suppliers had all resumed normal operations, and none of our overseas suppliers had reported any disruption to their business operations as a result of COVID-19.

We have resumed our normal operations since February 9, 2020 in accordance with applicable regulations. As of the Latest Practicable Date, we had no suspected or confirmed COVID-19 cases on our premises or among our employees. To prevent any spread of COVID-19 in our offices and production facilities, we have adopted a thorough disease prevention scheme to protect our employees from the spread of COVID-19. The measures we have implemented include, among others, regularly sterilizing and ventilating our offices and production facilities, checking the body temperature of our employees daily, keeping track of the travel history and health conditions of employees, and providing face masks and disinfectant to employees attending our offices and facilities.

FINANCIAL INFORMATION

Our Directors believe that, based on information available as of the date of this document, while the extent to which the COVID-19 outbreak will affect our operations cannot be predicted at this stage, the outbreak of COVID-19 would not result in a material impact on our business operations because (i) we currently expect that our clinical trials will not be significantly affected by the outbreak of COVID-19; (ii) none of our major customers and suppliers is located in Hubei Province (the epicenter in China before the outbreak was contained) or any other regions under government lockdown; (iii) our supply chain has not experienced any material disruption since the outbreak of COVID-19; (iv) none of our headquarters, offices and other facilities are located in Hubei province or any other region under government lockdown; (v) we have resumed our normal operations since February 9, 2020; (vi) substantially all of our employees reside outside of locations under government lockdown; and (vii) the PRC government has brought down the new reporting COVID-19 infection cases to low digit numbers as of the Latest Practicable Date.

It is uncertain when and whether COVID-19 could be contained globally. The above analyses are made by our management based on currently available information concerning COVID-19. We cannot guarantee you, however, that the COVID-19 outbreak will not further escalate or have a material adverse effect on our results of operations, financial position or prospects. For example, with the ongoing COVID-19 outbreak around the world, we cannot assure you that our global clinical development plan covering multiple jurisdictions including the United States, Europe and/or other countries, will not be adversely affected. If the COVID-19 continues to spread in the United States, Europe and/or other countries, we may need to adjust or even postpone our current global clinical development plan. For more details, please refer to the paragraphs headed “Risk Factors—Risks relating to Our Operations—We may be subject to natural disasters, acts of war or terrorism or other factors beyond our control” in this document. We are constantly monitoring the COVID-19 outbreak situation as well as various regulatory and administrative measures adopted by local governments to prevent and control the pandemic. We will continue to monitor and evaluate any impact of the COVID-19 outbreak on us and adjust our precautionary measures according to the latest developments of the outbreak.

DISCLOSURE UNDER RULES 13.13 TO 13.19 OF THE LISTING RULES

Our Directors have confirmed that, as of the Latest Practicable Date, there was no circumstance that would give rise to a disclosure requirement under Rules 13.13 to 13.19 of the Listing Rules.

FUTURE PLANS AND USE OF [REDACTED]

FUTURE PLANS

For a detailed description of our future plans, please refer to the paragraph headed “Business—Our Strategies” in this document.

USE OF [REDACTED]

We estimate that the aggregate net [REDACTED] to our Company from the [REDACTED] (after deducting [REDACTED] commissions and other estimated expenses in connection with the [REDACTED] paid and payable by us taking into account any additional discretionary incentive fee and assuming that the [REDACTED] is not exercised and an [REDACTED] of HK\$[REDACTED] per H Share, being the mid-point of the indicative [REDACTED] range of HK\$[REDACTED] to HK\$[REDACTED] per H Share) will be approximately US\$[REDACTED] (HK\$[REDACTED]). We currently intend to apply such net [REDACTED] we will receive from this [REDACTED] for the following purposes:

- (a) approximately 45.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used primarily for the clinical development and commercialization (subject to regulatory approval) of the following drug candidates:
 - (i) approximately 10.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the ongoing and planned clinical trials, preparation for registration filings, launch and, subject to regulatory approval, commercialization (including sales and marketing) of telitacicept (RC18), including (a) in China: to cover expenses relating to the ongoing and planned clinical trials, registration filings and commercialization (including sales and marketing) of telitacicept for the treatment of SLE in China, and the ongoing and planned clinical trials of telitacicept for the treatment of NMOSD, RA, IgAN, SS, MG and MS in China; and (b) outside of China: to cover a portion of expenses relating to the global multi-center Phase III clinical trials of telitacicept for the treatment of SLE in the U.S., Europe and other countries;
 - (ii) approximately 15.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the ongoing and planned clinical trials and preparation for potential registration filings of disitamab vedotin (RC48), including (a) in China: to cover expenses relating to the ongoing and planned clinical trials and preparation for potential registration filings of disitamab vedotin for the treatment of HER2 over-expressing locally advanced or metastatic GC, HER2 over-expressing locally advanced or metastatic UC, HER2 low-expressing locally advanced or metastatic BC and other HER2-positive indications (including HER2 over-expressing or HER2 mutated advanced NSCLC and HER2 over-expressing advanced BTC after the failure of 1L chemotherapy) in China; and (b) outside of China: to cover a portion of expenses relating to the ongoing and planned clinical trials and preparation for potential registration filings of disitamab vedotin for the treatment of HER2 over-expressing locally advanced or metastatic GC and HER2 over-expressing locally advanced or metastatic UC outside of China;

FUTURE PLANS AND USE OF [REDACTED]

- (iii) approximately 5.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the ongoing and planned clinical trials of RC28 for the treatment of wet AMD, DME and DR in China;
- (iv) approximately 15.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the development of RC88 and RC98, as well as our early-stage drug discovery and development, including (a) the ongoing and planned clinical trials of RC88 for the treatment of advanced solid tumors in China; (b) the ongoing and planned clinical trials of RC98 both as a monotherapy and in combination with other therapies for the treatment of advanced solid tumors in China; and (c) the early-stage drug discovery and development, including preclinical and clinical development of our other pipeline assets, discovery and development of new drug candidates, and the expansion of our R&D center in the U.S.
- (b) approximately 25.0%, or US\$[REDACTED] (HK\$[REDACTED]), will be used to fund the construction of our new manufacturing facility to expand our commercial manufacturing capacity, of which a majority will be used for the construction of the buildings and for the procurement of new machineries, instruments and equipment.
- (c) approximately 15.0%, or US\$[REDACTED] (HK\$[REDACTED]) will be used to repay the borrowings from RC Pharma. As of the Latest Practicable Date, the total amount of the principal and interest of our borrowings from RC Pharma amounted to RMB417.0 million with an annual interest rate of approximately 6.0%. Our borrowings from RC Pharma were used for general corporate and working capital purposes. The borrowings from RC Pharma are unsecured and payable on demand. For more details, please refer to the paragraphs headed “Financial Information – Indebtedness – Borrowings from a related party” in this document.
- (d) approximately 15.0%, or US\$[REDACTED] (HK\$[REDACTED]) will be used for our general corporate and working capital purposes. We execute an adaptive clinical development strategy which means that we may from time to time evaluate and adjust our priority and allocation of funds for different drug candidates depending on the results and status of their clinical development. Therefore, we may allocate more funds to a particular drug candidate out of such portion of net proceeds if such drug candidate has greater clinical progress than currently expected or requires more funding than originally anticipated.

If the [REDACTED] is exercised in full, the net [REDACTED] of the [REDACTED] would increase to approximately US\$[REDACTED] (HK\$[REDACTED]) (based on the mid-point [REDACTED] of HK\$[REDACTED] per H Share). We intend to apply the additional net [REDACTED] to the above uses in the proportions stated above.

FUTURE PLANS AND USE OF [REDACTED]

The allocation of the [REDACTED] used for the above will be adjusted in the event that the [REDACTED] is fixed at a higher or lower level compared to the mid-point of the estimated [REDACTED] range. If the [REDACTED] is fixed at HK\$[REDACTED] per H Share, being the high end of the stated [REDACTED] range, our net [REDACTED] will (i) assuming the [REDACTED] is not exercised, be increased by approximately US\$[REDACTED] (HK\$[REDACTED]), or (ii) assuming the [REDACTED] is exercised in full, be increased by approximately US\$[REDACTED] (HK\$[REDACTED]). In such circumstances, we currently intend to use such additional [REDACTED] to increase the net [REDACTED] applied for the same purposes as set out above on a pro rata basis. If the [REDACTED] is fixed at HK\$[REDACTED] per H Share, being the low end of the stated [REDACTED] range, our net [REDACTED] will (i) assuming the [REDACTED] is not exercised, be decreased by approximately US\$[REDACTED] (HK\$ [REDACTED]), or (ii) assuming the [REDACTED] is exercised in full, be decreased by approximately US\$[REDACTED] (HK\$[REDACTED]). In such circumstances, we currently intend to reduce the net [REDACTED] applied for the same purposes as set out above on a pro rata basis.

To the extent that our net [REDACTED] are not sufficient to fund the purposes set out above, we intend to fund the balance through a variety of means, including cash generated from operations, bank loans and other borrowings.

To the extent that the net [REDACTED] from the [REDACTED] are not immediately used for the purposes described above and to the extent permitted by the relevant laws and regulations, they will be placed in short-term demand deposits with banks in Hong Kong or China and/or through money market instruments.

We will issue an appropriate announcement if there is any material change to the above proposed use of [REDACTED].

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

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[REDACTED]

STRUCTURE OF THE [REDACTED]

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[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

STRUCTURE OF THE [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

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HOW TO APPLY FOR [REDACTED]

[REDACTED]

HOW TO APPLY FOR [REDACTED]

[REDACTED]

APPENDIX I

ACCOUNTANTS’ REPORT

The following is the text of a report, prepared for inclusion in this document, received from the Company’s reporting accountants, Ernst & Young, Certified Public Accountants, Hong Kong.



22/F, CITIC Tower
1 Tim Mei Avenue
Central, Hong Kong

The Directors
RemeGen Co., Ltd.
Morgan Stanley Asia Limited
Huatai Financial Holdings (Hong Kong) Limited
J.P. Morgan Securities (Far East) Limited

Dear Sirs,

We report on the historical financial information of RemeGen Co., Ltd. (the “Company”) and its subsidiaries (together, the “Group”) set out on pages I-4 to I-74, which comprises the consolidated statements of profit or loss, the consolidated statements of comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows of the Group for each of the years ended 31 December 2018 and 2019, and the three months ended 31 March 2020 (the “Relevant Periods”), and the consolidated statements of financial position of the Group and the statements of financial position of the Company as at 31 December 2018 and 2019 and 31 March 2020 and a summary of significant accounting policies and other explanatory information (together, the “Historical Financial Information”). The Historical Financial Information set out on pages I-4 to I-74 forms an integral part of this report, which has been prepared for inclusion in the document of the Company dated [●] (the “Document”) in connection with the initial [REDACTED] of the shares of the Company on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”).

DIRECTORS’ RESPONSIBILITY FOR THE HISTORICAL FINANCIAL INFORMATION

The directors of the Company are responsible for the preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information, and for such internal control as the directors of the Company determine is necessary to enable the preparation of the Historical Financial Information that is free from material misstatement, whether due to fraud or error.

APPENDIX I

ACCOUNTANTS’ REPORT

REPORTING ACCOUNTANTS’ RESPONSIBILITY

Our responsibility is to express an opinion on the Historical Financial Information and to report our opinion to you. We conducted our work in accordance with Hong Kong Standard on Investment Circular Reporting Engagements 200 *Accountants’ Reports on Historical Financial Information in Investment Circulars* issued by the Hong Kong Institute of Certified Public Accountants (“HKICPA”). This standard requires that we comply with ethical standards and plan and perform our work to obtain reasonable assurance about whether the Historical Financial Information is free from material misstatement.

Our work involved performing procedures to obtain evidence about the amounts and disclosures in the Historical Financial Information. The procedures selected depend on the reporting accountants’ judgement, including the assessment of risks of material misstatement of the Historical Financial Information, whether due to fraud or error. In making those risk assessments, the reporting accountants consider internal control relevant to the entity’s preparation of the Historical Financial Information that gives a true and fair view in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information in order to design procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity’s internal control. Our work also included evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors of the Company, as well as evaluating the overall presentation of the Historical Financial Information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

OPINION

In our opinion, the Historical Financial Information gives, for the purposes of the accountants’ report, a true and fair view of the financial position of the Group and the Company as at 31 December 2018 and 2019 and 31 March 2020 and of the financial performance and cash flows of the Group for each of the Relevant Periods in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

Review of interim comparative financial information

We have reviewed the interim comparative financial information of the Group which comprises the consolidated statements of profit or loss, the consolidated statements of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows of the Group for the three months ended 31 March 2019 and other explanatory information (the “Interim Comparative Financial Information”).

APPENDIX I

ACCOUNTANTS' REPORT

The directors of the Company are responsible for the preparation of the Interim Comparative Financial Information in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information. Our responsibility is to express a conclusion on the Interim Comparative Financial Information based on our review. We conducted our review in accordance with Hong Kong Standard on Review Engagements 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity* issued by the HKICPA. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Hong Kong Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion. Based on our review, nothing has come to our attention that causes us to believe that the Interim Comparative Financial Information, for the purposes of the accountants' report, is not prepared, in all material respects, in accordance with the basis of preparation set out in note 2.1 to the Historical Financial Information.

Report on matters under the Rules Governing the Listing of Securities on the Stock Exchange and the Companies (Winding Up and Miscellaneous Provisions) Ordinance

Adjustments

In preparing the Historical Financial Information, no adjustments to the Underlying Financial Statements as defined on page 4 have been made.

Dividends

We refer to note 11 to the Historical Financial Information which states that no dividends have been paid by the Company in respect of the Relevant Periods.

Yours faithfully,

Ernst & Young

Certified Public Accountants

Hong Kong

[●] 2020

APPENDIX I

ACCOUNTANTS’ REPORT

I HISTORICAL FINANCIAL INFORMATION

Preparation of Historical Financial Information

Set out below is the Historical Financial Information which forms an integral part of this accountants’ report.

The financial statements of the Group for the Relevant Periods, on which the Historical Financial Information is based, were audited by Ernst & Young in accordance with Hong Kong Standards on Auditing (“HKASs”) issued by the Hong Kong Institute of Certified Public Accountants (the “HKICPA”) (the “Underlying Financial Statements”).

The Historical Financial Information is presented in Renminbi (“RMB”) and all values are rounded to the nearest thousand (RMB’000) except when otherwise indicated.

Consolidated Statements of Profit or Loss

	<i>Notes</i>	Year ended 31 December		Three months ended 31 March	
		2018	2019	2019	2020
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
				<i>(Unaudited)</i>	
REVENUE	5	11,321	–	–	–
Cost of sales		(8,932)	–	–	–
Gross profit		2,389	–	–	–
Other income and gains	5	15,377	38,481	2,551	7,316
Selling and distribution expenses		–	(621)	–	(1,306)
Administrative expenses		(29,125)	(68,434)	(8,420)	(20,336)
Research and development costs		(216,438)	(352,066)	(69,137)	(75,210)
Impairment losses on financial assets, net		(196)	134	–	(79)
Other expenses		(1,900)	(3,985)	(325)	(1,008)
Finance costs	6	(40,055)	(43,789)	(12,430)	(8,970)
LOSS BEFORE TAX	7	(269,948)	(430,280)	(87,761)	(99,593)
Income tax expense	10	–	–	–	–
LOSS FOR THE YEAR/ PERIOD		<u>(269,948)</u>	<u>(430,280)</u>	<u>(87,761)</u>	<u>(99,593)</u>
Attributable to: Owners of the parent		<u>(269,948)</u>	<u>(430,280)</u>	<u>(87,761)</u>	<u>(99,593)</u>
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT					
Basic and diluted (RMB)	12	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>

APPENDIX I

ACCOUNTANTS’ REPORT

Consolidated Statements of Comprehensive Income

	Year ended		Three months ended	
	31 December		31 March	
	2018	2019	2019	2020
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(Unaudited)</i>	
LOSS FOR THE YEAR/PERIOD	<u>(269,948)</u>	<u>(430,280)</u>	<u>(87,761)</u>	<u>(99,593)</u>
OTHER COMPREHENSIVE INCOME/(LOSS)				
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:				
Exchange differences on translation of foreign operations	<u>72</u>	<u>(62)</u>	<u>(12)</u>	<u>21</u>
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:				
Equity investments designated at fair value through other comprehensive income:				
Changes in fair value	<u>2,076</u>	<u>1,425</u>	<u>–</u>	<u>–</u>
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR/PERIOD, NET OF TAX	<u>2,148</u>	<u>1,363</u>	<u>(12)</u>	<u>21</u>
TOTAL COMPREHENSIVE LOSS FOR THE YEAR/PERIOD	<u>(267,800)</u>	<u>(428,917)</u>	<u>(87,773)</u>	<u>(99,572)</u>
Attributable to:				
Owners of the parent	<u>(267,800)</u>	<u>(428,917)</u>	<u>(87,773)</u>	<u>(99,572)</u>

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ACCOUNTANTS’ REPORT

Consolidated Statements of Financial Position

	<i>Notes</i>	As at 31 December		As at
		2018	2019	31 March
		<i>RMB’000</i>	<i>RMB’000</i>	2020
				<i>RMB’000</i>
NON-CURRENT ASSETS				
Property, plant and equipment	13	387,663	459,713	469,829
Right-of-use assets	14	10,320	11,007	14,741
Other intangible assets	15	2,933	2,133	1,933
Equity investments designated at fair value through other comprehensive income	16	10,023	11,448	11,448
Other non-current assets	17	55,269	67,436	149,129
Total non-current assets		466,208	551,737	647,080
CURRENT ASSETS				
Inventories	18	29,671	31,247	33,297
Bills receivable		10,969	1,058	–
Prepayments, other receivables and other assets	19	19,175	29,858	154,299
Pledged deposits	20	–	40,866	23,256
Cash and cash equivalents	20	5,069	34,545	287,603
Total current assets		64,884	137,574	498,455
CURRENT LIABILITIES				
Trade and bills payables	21	16,745	67,697	57,521
Other payables and accruals	22	972,201	720,602	614,341
Interest-bearing bank borrowings	23	–	60,000	–
Lease liabilities	14	1,131	1,602	1,189
Deferred income	24	6,862	7,052	6,973
Total current liabilities		996,939	856,953	680,024
NET CURRENT LIABILITIES		(932,055)	(719,379)	(181,569)
TOTAL ASSETS LESS CURRENT LIABILITIES		(465,847)	(167,642)	465,511
NON-CURRENT LIABILITIES				
Lease liabilities	14	3,380	3,762	3,248
Deferred income	24	28,951	60,565	56,047
Total non-current liabilities		32,331	64,327	59,295
Net (liabilities)/assets		(498,178)	(231,969)	406,216
EQUITY				
Equity attributable to owners of the parent				
Paid-in capital	25	70,000	168,654	182,645
Reserves	26	(568,178)	(400,623)	223,571
Total (deficit)/equity		(498,178)	(231,969)	406,216

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ACCOUNTANTS’ REPORT

Consolidated Statements of Changes in Equity

Year ended 31 December 2018

	Attributable to owners of the parent						
	Paid-in capital	Capital reserve*	Other reserve*	Fair value reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total deficit
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
At 1 January 2018	70,000	127	1,356	(2,053)	34	(302,865)	(233,401)
Loss for the year	-	-	-	-	-	(269,948)	(269,948)
Other comprehensive income for the year:							
Changes in fair value of equity investments at fair value through other comprehensive income, net of tax	-	-	-	2,076	-	-	2,076
Exchange differences related to foreign operations	-	-	-	-	72	-	72
Total comprehensive loss for the year	-	-	-	2,076	72	(269,948)	(267,800)
Share-based payments (note 27)	-	-	3,023	-	-	-	3,023
At 31 December 2018	<u>70,000</u>	<u>127</u>	<u>4,379</u>	<u>23</u>	<u>106</u>	<u>(572,813)</u>	<u>(498,178)</u>

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Year ended 31 December 2019

	Attributable to owners of the parent						
	Paid-in capital	Capital reserve*	Other reserve*	Fair value reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total deficit
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
At 31 December 2018 and 1 January 2019	70,000	127	4,379	23	106	(572,813)	(498,178)
Loss for the year	-	-	-	-	-	(430,280)	(430,280)
Other comprehensive income for the year:							
Changes in fair value of equity investments at fair value through other comprehensive income, net of tax	-	-	-	1,425	-	-	1,425
Exchange differences related to foreign operations	-	-	-	-	(62)	-	(62)
Total comprehensive loss for the year	-	-	-	1,425	(62)	(430,280)	(428,917)
Debt to equity conversion (note 25 and note 26)	95,913	504,087	-	-	-	-	600,000
Capital contribution from shareholders (note 25 and note 26)	2,741	87,259	-	-	-	-	90,000
Share-based payments (note 27)	-	-	5,126	-	-	-	5,126
At 31 December 2019	<u>168,654</u>	<u>591,473</u>	<u>9,505</u>	<u>1,448</u>	<u>44</u>	<u>(1,003,093)</u>	<u>(231,969)</u>

For the three months ended 31 March 2020

	Attributable to owners of the parent						
	Paid-in capital	Capital reserve*	Other reserve*	Fair value reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total equity
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
At 31 December 2019 and 1 January 2020	168,654	591,473	9,505	1,448	44	(1,003,093)	(231,969)
Loss for the period	-	-	-	-	-	(99,593)	(99,593)
Other comprehensive income for the period:							
Exchange differences related to foreign operations	-	-	-	-	21	-	21

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ACCOUNTANTS’ REPORT

	Attributable to owners of the parent						
	Paid-in capital	Capital reserve*	Other reserve*	Fair value reserve*	Exchange fluctuation reserve*	Accumulated losses*	Total equity
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
Total comprehensive loss for the period	-	-	-	-	21	(99,593)	(99,572)
Capital contribution from shareholders (note 25 and note 26)	13,991	721,835	-	-	-	-	735,826
Share-based payments (note 27)	-	-	1,931	-	-	-	1,931
At 31 March 2020	<u>182,645</u>	<u>1,313,308</u>	<u>11,436</u>	<u>1,448</u>	<u>65</u>	<u>(1,102,686)</u>	<u>406,216</u>

For the three months ended 31 March 2019

	Attributable to owners of the parent						
	Paid-in capital	Capital reserve	Other reserve	Fair value reserve	Exchange fluctuation reserve	Accumulated losses	Total deficit
	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000	RMB’000
At 31 December 2018 and 1 January 2019	70,000	127	4,379	23	106	(572,813)	(498,178)
Loss for the period	-	-	-	-	-	(87,761)	(87,761)
Other comprehensive income for the period:							
Exchange differences related to foreign operations	-	-	-	-	(12)	-	(12)
Total comprehensive loss for the period	-	-	-	-	(12)	(87,761)	(87,773)
Share-based payments (note 27)	-	-	756	-	-	-	756
At 31 March 2019 (Unaudited)	<u>70,000</u>	<u>127</u>	<u>5,135</u>	<u>23</u>	<u>94</u>	<u>(660,574)</u>	<u>(585,195)</u>

* These reserve accounts comprise the consolidated reserves of minus RMB568,178,000, minus RMB400,623,000 and RMB223,571,000 in the consolidated statements of financial position as at 31 December 2018 and 2019 and 31 March 2020, respectively.

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Consolidated Statements of Cash Flows

	<i>Notes</i>	Year ended		Three months ended	
		31 December		31 March	
		2018	2019	2019	2020
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
				<i>(Unaudited)</i>	
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss before tax		(269,948)	(430,280)	(87,761)	(99,593)
Adjustments for:					
Finance costs	6	40,055	43,789	12,430	8,970
Bank interest income	5	(21)	(147)	(3)	(239)
Gain upon early termination of leases		–	–	–	(5)
Depreciation of property, plant and equipment	7, 13	20,542	40,203	9,165	11,598
Depreciation of right of use assets	7, 14	803	1,769	369	471
Amortisation of other intangible assets	7, 15	1,294	800	200	200
Amortisation of long-term prepayment	7	–	28	–	12
Loss/(gain) on disposal of items of property, plant and equipment	7	(1,658)	340	(15)	6
Share-based payment expenses	27	3,023	5,126	756	1,931
Foreign exchange differences, net		60	(66)	(7)	(556)
		(205,850)	(338,438)	(64,866)	(77,205)
Increase in inventories		(7,802)	(1,576)	(329)	(2,050)
Decrease in bills receivable		31,863	20,802	17,880	1,058
Decrease/(increase) in prepayments, other receivables and other assets		42,475	(10,683)	(8,828)	(14,622)
(Increase)/decrease in other non-current assets		(31,076)	(16,563)	(6,784)	2,981
Increase/(decrease) in trade and bills payables		8,454	19,006	(2,812)	2,696
Increase/(decrease) in other payables and accruals		38,513	23,481	5,397	(31,735)
(Increase)/decrease in pledged deposits		–	(8,742)	–	5,352
(Decrease)/increase in deferred income in respect of government grants related to income		(4,626)	29,820	2,282	(4,574)
Cash used in operations		(128,049)	(282,893)	(58,060)	(118,099)
Interest received		21	147	3	239
Net cash flows used in operating activities		(128,028)	(282,746)	(58,057)	(117,860)

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ACCOUNTANTS’ REPORT

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(Unaudited)</i>	
CASH FLOWS FROM				
INVESTING ACTIVITIES				
Purchases of items of property, plant and equipment	(83,722)	(65,209)	(21,158)	(100,112)
Purchase of items of land lease	–	–	–	(34,072)
Proceeds from disposal of items of property, plant and equipment	–	199	–	–
Receipts of government grants related to assets	1,550	2,034	1,639	–
Purchase of an equity investment designated at fair value through other comprehensive income	(10,000)	–	–	–
Proceeds from disposal of an equity investment designated at fair value through other comprehensive income	15,000	–	–	–
(Increase)/decrease in pledged deposits	–	(32,124)	–	12,258
Net cash flows used in investing activities	<u>(77,172)</u>	<u>(95,100)</u>	<u>(19,519)</u>	<u>(121,926)</u>

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ACCOUNTANTS’ REPORT

	<i>Notes</i>	Year ended		Three months ended	
		31 December		31 March	
		2018	2019	2019	2020
		<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
<i>(Unaudited)</i>					
CASH FLOWS FROM FINANCING ACTIVITIES					
New bank borrowings		–	146,000	–	60,000
Repayment of bank borrowings		–	(86,000)	–	(120,000)
New borrowings from a related party		294,106	556,975	85,348	134,753
Repayment of borrowings to a related party		(86,788)	(209,050)	(7,039)	(207,186)
Capital contributions from shareholders		–	90,000	–	627,275
Interest paid		(264)	(89,000)	(84)	(958)
Principal portion of lease payments		(765)	(1,603)	(321)	(345)
Net cash flows from financing activities		206,289	407,322	77,904	493,539
NET INCREASE IN CASH AND CASH EQUIVALENTS					
Cash and cash equivalents at beginning of year/period		1,089	29,476	328	253,753
Effect of foreign exchange rate changes, net		3,980	5,069	5,069	34,545
		–	–	–	(695)
CASH AND CASH EQUIVALENTS AT END OF YEAR/PERIOD	<i>20</i>	<u>5,069</u>	<u>34,545</u>	<u>5,397</u>	<u>287,603</u>
ANALYSIS OF BALANCES OF CASH AND CASH EQUIVALENTS					
Cash and bank balances	<i>20</i>	5,069	75,411	5,397	310,859
Less: pledged deposits	<i>20</i>	–	(40,866)	–	(23,256)
Cash and cash equivalents as stated in the consolidated statements of cash flows		<u>5,069</u>	<u>34,545</u>	<u>5,397</u>	<u>287,603</u>

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ACCOUNTANTS’ REPORT

Statements of Financial Position of the Company

		As at 31 December		As at
	<i>Notes</i>	2018	2019	31 March
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
NON-CURRENT ASSETS				
Property, plant and equipment	<i>13</i>	387,411	459,444	469,556
Right-of-use assets	<i>14</i>	10,320	11,007	14,741
Other intangible assets	<i>15</i>	2,933	2,133	1,933
Investments in subsidiaries		30,891	21,786	23,173
Equity investments designated at fair value through other comprehensive income	<i>16</i>	10,023	11,448	11,448
Other non-current assets	<i>17</i>	55,269	67,436	149,129
Total non-current assets		496,847	573,254	669,980
CURRENT ASSETS				
Inventories	<i>18</i>	29,671	31,247	33,297
Bills receivable		10,969	1,058	–
Prepayments, other receivables and other assets	<i>19</i>	19,175	29,859	154,188
Pledged deposits	<i>20</i>	–	40,866	23,256
Cash and cash equivalents	<i>20</i>	4,299	33,295	286,592
Total current assets		64,114	136,325	497,333
CURRENT LIABILITIES				
Trade and bills payables	<i>21</i>	16,745	67,697	57,521
Other payables and accruals	<i>22</i>	986,937	720,291	614,704
Interest-bearing bank borrowings	<i>23</i>	–	60,000	–
Lease liabilities	<i>14</i>	1,131	1,602	1,189
Deferred income	<i>24</i>	6,862	7,052	6,973
Total current liabilities		1,011,675	856,642	680,387

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ACCOUNTANTS’ REPORT

	<i>Notes</i>	As at 31 December		As at
		2018	2019	31 March
		<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
NET CURRENT LIABILITIES		<u>(947,561)</u>	<u>(720,317)</u>	<u>(183,054)</u>
TOTAL ASSETS LESS CURRENT LIABILITIES		<u>(450,714)</u>	<u>(147,063)</u>	<u>486,926</u>
NON-CURRENT LIABILITIES				
Lease liabilities	14	3,380	3,762	3,248
Deferred income	24	<u>28,951</u>	<u>60,565</u>	<u>56,047</u>
Total non-current liabilities		<u>32,331</u>	<u>64,327</u>	<u>59,295</u>
Net (liabilities)/assets		<u><u>(483,045)</u></u>	<u><u>(211,390)</u></u>	<u><u>427,631</u></u>
EQUITY				
Equity attributable to owners of the parent				
Paid-in capital	25	70,000	168,654	182,645
Reserves	26	<u>(553,045)</u>	<u>(380,044)</u>	<u>244,986</u>
Total (deficit)/equity		<u><u>(483,045)</u></u>	<u><u>(211,390)</u></u>	<u><u>427,631</u></u>

APPENDIX I

ACCOUNTANTS’ REPORT

II NOTES TO THE HISTORICAL FINANCIAL INFORMATION

1. CORPORATE INFORMATION

RemeGen Co., Ltd. (the “Company”) was incorporated in the People’s Republic of China (“PRC”) on 4 July 2008 as a limited liability company. On 12 May 2020, the Company was converted into a joint stock company with limited liability under the Company Law of the PRC. The registered office of the Company is located at 58 Middle Beijing Road, Yantai Economic and Technological Development Zone, Shandong Province, PRC.

During the Relevant Periods, the Company and its subsidiaries (together, the “Group”) were principally engaged in the research and development of biological products.

As at the date of this report, the Company had direct interests in its subsidiaries, all of which are private limited liability companies, the particulars of which are as follows:

Name ^(d)	Place and date of registration/ incorporation and place of operations	Nominal value of issued ordinary/ registered paid-in capital	Percentage of equity attributable to the Company		Principal activities
			Direct		
RemeGen Biosciences, Inc. (previously known as “RC Biotechnologies, Inc.”) (note (a) and note (c))	Delaware, United States of America (“USA”) 18 April 2011	1,500 common shares	100%		Research and development, registration and business development
Ruimeijing (Beijing) Pharmaceutical Technology Co., Ltd. (瑞美京(北京)醫藥科技有限公司)* (note (a))	Beijing, PRC 14 August 2019	RMB 1,000,000	100%		Research and development
RemeGen Hong Kong Limited (note (b))	Hong Kong 26 September 2019	United States dollars (“USD”) 4,000,000	100%		Research and development and business development
RemeGen Medical Research (Shanghai) Co., Ltd. (榮昌生物醫藥研究(上海)有限公司) (note (c))	Shanghai, PRC 20 May 2020	RMB 8,000,000	100%		Research and development

* The English name of this subsidiary represented the best efforts made by the management of the Company to translate the Chinese name as it does not have an official English name registered in the PRC.

Notes:

- (a) No audited financial statements have been prepared for these entities since the dates of incorporation, as these entities were not subject to any statutory audit requirements under the relevant rules and regulations in their jurisdiction of incorporation.
- (b) No audited financial statements have been prepared for this entity for the period from the date of incorporation to 31 December 2019, as the entity had no operating activities and no financial statements during the Relevant Periods. The registered capital of this entity was unpaid as at 31 March 2020. Subsequent to 31 March 2020, the registered capital of this entity amounting of HKD979,000 was paid up.
- (c) The registered capital of RemeGen Biosciences, Inc. amounting of USD3,400,000 was paid up as at 31 March 2020. Subsequent to 31 March 2020, the registered capital of RemeGen Biosciences, Inc. amounting of USD200,000 was paid up. None of RemeGen Medical Research (Shanghai) Co., Ltd.’s registered capital was paid as at 31 March 2020. Subsequent to 31 March 2020, the registered capital of this entity amounting of RMB2,000,000 was paid up.
- (d) Yantai Tongyi Pharmaceuticals, Ltd. (“Tongyi”) was established on 15 April 2013 in Yantai, the PRC with registered capital of RMB15,000,000. Tongyi was a wholly-owned subsidiary of the Group and no substantial business operated since it had been established. The application for deregistration of Tongyi was officially approved by the Market Supervision Authority of Yantai Economic and Technological Development Zone on 26 August 2019.

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ACCOUNTANTS’ REPORT

2.1 BASIS OF PREPARATION

The Historical Financial Information has been prepared in accordance with International Financial Reporting Standards (“IFRSs”), which comprise all standards and interpretations approved by the International Accounting Standards Board (“IASB”). All IFRSs effective for the accounting period commencing from 1 January 2018 to 31 March 2020, including IFRS 9 *Financial Instruments*, IFRS 15 *Revenue from Contracts with Customers* and IFRS 16 *Leases*, together with the relevant transitional provisions, have been early adopted by the Group in the preparation of the Historical Financial Information throughout the Relevant Periods and in the period covered by the Interim Comparative Financial Information.

The Historical Financial Information has been prepared under the historical cost convention, except for equity investments designated at fair value through other comprehensive income and other financial assets which have been measured at fair value.

The Group incurred losses continually during the Relevant Periods due to the pre-revenue stage of its drug research and development businesses. In addition, as at 31 March 2020, the Group had current liabilities exceeded its current assets by RMB181,569,000. The Group has been taking various measures to obtain sufficient financing for the Group to operate as a going concern, which included an agreement with a related party that it will not demand repayment of the Group’s balance of RMB523,661,000 due to it as at 31 March 2020 before the date of completion of the Company’s [REDACTED] on the Stock Exchange. In addition, the Group obtained new banking facilities of RMB630 million in June 2020, which replaced the then unused banking facilities of RMB143 million.

In light of the above measures of the Group and after taking into account the Group’s operating cash flow needs and capital expenditure spending in the foreseeable future, the Directors are of the opinion that the Group shall be able to meet with its liabilities and expenses as and when they fall due in the foreseeable future. Hence the preparation of the Historical Financial Information under the going concern basis by the Directors is appropriate.

Basis of consolidation

The Historical Financial Information includes the financial information of the Company and its subsidiaries for the Relevant Periods. A subsidiary is an entity (including a structured entity), directly or indirectly, controlled by the Company. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee (i.e., existing rights that give the Group the current ability to direct the relevant activities of the investee).

When the Company has, directly or indirectly, less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

- (a) the contractual arrangement with the other vote holders of the investee;
- (b) rights arising from other contractual arrangements; and
- (c) the Group’s voting rights and potential voting rights.

The financial information of the subsidiaries are prepared for the same reporting period as the Company, using consistent accounting policies. The results of subsidiaries are consolidated from the date on which the Group obtains control, and continue to be consolidated until the date that such control ceases.

Profit or loss and each component of other comprehensive income are attributed to the owners of the parent of the Group. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control described above. A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

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If the Group loses control over a subsidiary, it derecognises (i) the assets (including goodwill) and liabilities of the subsidiary, (ii) the carrying amount of any non-controlling interest and (iii) the cumulative translation differences recorded in equity; and recognises (i) the fair value of the consideration received, (ii) the fair value of any investment retained and (iii) any resulting surplus or deficit in profit or loss. The Group’s share of components previously recognised in other comprehensive income is reclassified to profit or loss or retained profits, as appropriate, on the same basis as would be required if the Group had directly disposed of the related assets or liabilities.

2.2 ISSUED BUT NOT YET EFFECTIVE INTERNATIONAL FINANCIAL REPORTING STANDARDS

The Group has not applied the following new and revised IFRSs, that have been issued but are not yet effective, in the Historical Financial Information.

IFRS 17	<i>Insurance Contracts</i> ¹
Amendments to IFRS 10 and IAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ²
Amendments to IAS 1	<i>Classification of Liabilities as Current or Non-current</i> ³

¹ Effective for annual periods beginning on or after 1 January 2021

² No mandatory effective date yet determined but available for adoption

³ Effective for annual periods beginning on or after 1 January 2022

These issued but not yet effective IFRSs are not expected to have any significant impact on the Group’s Historical Financial Information, except as described below.

Amendments to IAS 1 clarify that the classification of liabilities as current or non-current should be based on rights that are in existence at the end of the reporting period and align the wording in all affected paragraphs to refer to the “right” to defer settlement by at least twelve months and make explicit that only rights in place “at the end of the reporting period” should affect the classification of a liability. The amendments also clarify that classification is unaffected by expectations about whether an entity will exercise its right to defer settlement of a liability, and make clear that settlement refers to the transfer to the counterparty of cash, equity investments, other assets or services.

2.3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Fair value measurement

The Group measures its equity investments and bills receivable at fair value at the end of each of the Relevant Periods. Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either in the principal market for the asset or liability, or in the absence of a principal market, in the most advantageous market for the asset or liability. The principal or the most advantageous market must be accessible by the Group. The fair value of an asset or a liability is measured using the assumptions that market participants would use when pricing the asset or liability, assuming that market participants act in their economic best interest.

A fair value measurement of a non-financial asset takes into account a market participant’s ability to generate economic benefits by using the asset in its highest and best use or by selling it to another market participant that would use the asset in its highest and best use.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

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All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – based on quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is observable, either directly or indirectly
- Level 3 – based on valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reassessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each of the Relevant Periods.

Impairment of non-financial assets

Where an indication of impairment exists, or when annual impairment testing for an asset is required (other than inventories, financial assets and other non-current assets), the asset’s recoverable amount is estimated. An asset’s recoverable amount is the higher of the asset’s or cash-generating unit’s value in use and its fair value less costs of disposal, and is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets, in which case the recoverable amount is determined for the cash-generating unit to which the asset belongs.

An impairment loss is recognised only if the carrying amount of an asset exceeds its recoverable amount. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. An impairment loss is charged to profit or loss in the period in which it arises in those expense categories consistent with the function of the impaired asset.

An assessment is made at the end of each of the Relevant Periods as to whether there is an indication that previously recognised impairment losses may no longer exist or may have decreased. If such an indication exists, the recoverable amount is estimated. A previously recognised impairment loss of an asset other than goodwill is reversed only if there has been a change in the estimates used to determine the recoverable amount of that asset, but not to an amount higher than the carrying amount that would have been determined (net of any depreciation/amortisation) had no impairment loss been recognised for the asset in prior years. A reversal of such an impairment loss is credited to profit or loss in the period in which it arises.

Related parties

A party is considered to be related to the Group if:

- (a) the party is a person or a close member of that person’s family and that person
 - (i) has control or joint control over the Group;
 - (ii) has significant influence over the Group; or
 - (iii) is a member of the key management personnel of the Group or of a parent of the Group; or
- (b) the party is an entity where any of the following conditions applies:
 - (i) the entity and the Group are members of the same group;
 - (ii) one entity is an associate or joint venture of the other entity (or of a parent, subsidiary or fellow subsidiary of the other entity);
 - (iii) the entity and the Group are joint ventures of the same third party;
 - (iv) one entity is a joint venture of a third entity and the other entity is an associate of the third entity;

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- (v) the entity is a post-employment benefit plan for the benefit of employees of either the Group or an entity related to the Group;
- (vi) the entity is controlled or jointly controlled by a person identified in (a);
- (vii) a person identified in (a)(i) has significant influence over the entity or is a member of the key management personnel of the entity (or of a parent of the entity); and
- (viii) the entity, or any member of a group of which it is a part, provides key management personnel services to the Group or to the parent of the Group.

Property, plant and equipment and depreciation

Property, plant and equipment, other than construction in progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property, plant and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property, plant and equipment have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalised in the carrying amount of the asset as a replacement. Where significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognises such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on the straight-line basis to write off the cost of each item of property, plant and equipment to its residual value over its estimated useful life. The principal annual rates used for this purpose are as follows:

Buildings	2%-10%
Plant and machinery	10%-19%
Office equipment and others	10%-19%
Motor vehicles	12%-19%

Where parts of an item of property, plant and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately. Residual values, useful lives and the depreciation methods are reviewed, and adjusted if appropriate, at least at the end of each of the Relevant Periods.

An item of property, plant and equipment including any significant part initially recognised is derecognised upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss on disposal or retirement recognised in profit or loss in the year the asset is derecognised is the difference between the net sales proceeds and the carrying amount of the relevant asset.

Construction in progress represents buildings, plant and machinery, and office equipment and others under construction, which is stated at cost less any impairment losses, and is not depreciated. Cost comprises the direct costs of construction during the period of construction. Construction in progress is reclassified to the appropriate category of property, plant and equipment when completed and ready for use.

Intangible assets (other than goodwill)

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives are subsequently amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortisation period and the amortisation method for an intangible asset with a finite useful life are reviewed at least at the end of each of the Relevant Periods.

Patents and licences

Patents and licences are stated at cost less any impairment losses and are amortised on the straight-line basis over their estimated useful lives of 10 years.

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Research and development costs

All research costs are charged to profit or loss as incurred.

Expenditure incurred on projects to develop new products is capitalised and deferred only when the Group can demonstrate the technical feasibility of completing the intangible asset so that it will be available for use or sale, its intention to complete and its ability to use or sell the asset, how the asset will generate future economic benefits, the availability of resources to complete the project and the ability to measure reliably the expenditure during the development. Product development expenditure which does not meet these criteria is expensed when incurred.

Leases

The Group assesses at contract inception whether a contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognises lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

(a) Right-of-use assets

Right-of-use assets are recognised at the commencement date of the lease (that is the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Group is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognised right-of-use assets are depreciated on a straight-line basis over the shorter of their estimated useful lives and the lease terms as follows:

Land use rights	50 years
Buildings	2 to 3 years
Plant and machinery	5 years

If ownership of the leased asset transfers to the Group by the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

(b) Lease liabilities

Lease liabilities at the commencement date of the lease are recognised at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating a lease, if the lease term reflects the Group exercising the option to terminate. The variable lease payments that do not depend on an index or a rate are recognised as an expense in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

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(c) Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases (that is those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the recognition exemption for leases of low-value assets to leases of office equipment that is considered to be of low value. Lease payments on short-term leases and leases of low-value assets are recognised as an expense on a straight-line basis over the lease term.

The Group as a lessor

When the Group acts as a lessor, it classifies at lease inception (or when there is a lease modification) each of its leases as either an operating lease or a finance lease.

Leases in which the Group does not transfer substantially all the risks and rewards incidental to ownership of an asset are classified as operating leases. When a contract contains lease and non-lease components, the Group allocates the consideration in the contract to each component on a relative stand-alone selling price basis. Rental income is accounted for on a straight-line basis over the lease terms and is included in revenue in profit or loss due to its operating nature. Initial direct costs incurred in negotiating and arranging an operating lease are added to the carrying amount of the leased asset and recognised over the lease term on the same basis as rental income. Contingent rents are recognised as revenue in the period in which they are earned.

Leases that transfer substantially all the risks and rewards incidental to ownership of an underlying asset to the lessee, are accounted for as finance leases.

Investments and other financial assets

Initial recognition and measurement

Financial assets are classified, at initial recognition, as subsequently measured at amortised cost, fair value through other comprehensive income, and fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset’s contractual cash flow characteristics and the Group’s business model for managing them. With the exception of trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient of not adjusting the effect of a significant financing component, the Group initially measures a financial asset at its fair value, plus in the case of a financial asset not at fair value through profit or loss, transaction costs. Trade receivables that do not contain a significant financing component or for which the Group has applied the practical expedient are measured at the transaction price determined under IFRS 15 in accordance with the policies set out for “Revenue recognition” below.

In order for a financial asset to be classified and measured at amortised cost or fair value through other comprehensive income, it needs to give rise to cash flows that are solely payments of principal and interest (“SPPI”) on the principal amount outstanding. Financial assets with cash flows that are not SPPI are classified and measured at fair value through profit or loss, irrespective of the business model.

The Group’s business model for managing financial assets refers to how it manages its financial assets in order to generate cash flows. The business model determines whether cash flows will result from collecting contractual cash flows, selling the financial assets, or both. Financial assets classified and measured at amortised cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows, while financial assets classified and measured at fair value through other comprehensive income are held within a business model with the objective of both holding to collect contractual cash flows and selling. Financial assets which are not held within the aforementioned business models are classified and measured at fair value through profit or loss.

All regular way purchases and sales of financial assets are recognised on the trade date, that is, the date that the Group commits to purchase or sell the asset. Regular way purchases or sales are purchases or sales of financial assets that require delivery of assets within the period generally established by regulation or convention in the marketplace.

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Subsequent measurement

The subsequent measurement of financial assets depends on their classification as follows:

Financial assets at amortised cost (debt instruments)

Financial assets at amortised cost are subsequently measured using the effective interest method and are subject to impairment. Gains and losses are recognised in profit or loss when the asset is derecognised, modified or impaired.

Financial assets at fair value through other comprehensive income (debt instruments)

For debt investments at fair value through other comprehensive income, interest income, foreign exchange revaluation and impairment losses or reversals are recognised in profit or loss and computed in the same manner as for financial assets measured at amortised cost. The remaining fair value changes are recognised in other comprehensive income. Upon derecognition, the cumulative fair value change recognised in other comprehensive income is recycled to profit or loss.

Financial assets at fair value through other comprehensive income (equity investments)

Upon initial recognition, the Group can elect to classify irrevocably its equity investments as equity investments designated at fair value through other comprehensive income when they meet the definition of equity under IAS 32 *Financial Instruments: Presentation* and are not held for trading. The classification is determined on an instrument-by-instrument basis.

Gains and losses on these financial assets are never recycled to profit or loss. Dividends are recognised as other income in profit or loss when the right of payment has been established, it is probable that the economic benefits associated with the dividend will flow to the Group and the amount of the dividend can be measured reliably, except when the Group benefits from such proceeds as a recovery of part of the cost of the financial asset, in which case, such gains are recorded in other comprehensive income. Equity investments designated at fair value through other comprehensive income are not subject to impairment assessment.

Derecognition of financial assets

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognised (i.e., removed from the Group’s consolidated statement of financial position) when:

- the rights to receive cash flows from the asset have expired; or
- the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a “pass-through” arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset, but has transferred control of the asset.

When the Group has transferred its rights to receive cash flows from an asset or has entered into a pass-through arrangement, it evaluates if, and to what extent, it has retained the risk and rewards of ownership of the asset. When it has neither transferred nor retained substantially all the risks and rewards of the asset nor transferred control of the asset, the Group continues to recognise the transferred asset to the extent of the Group’s continuing involvement. In that case, the Group also recognises an associated liability. The transferred asset and the associated liability are measured on a basis that reflects the rights and obligations that the Group has retained.

Continuing involvement that takes the form of a guarantee over the transferred asset is measured at the lower of the original carrying amount of the asset and the maximum amount of consideration that the Group could be required to repay.

Impairment of financial assets

The Group recognises an allowance for expected credit losses (“ECLs”) for all debt instruments not held at fair value through profit or loss. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

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General approach

ECLs are recognised in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next 12 months (a 12-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

At the end of each of the Relevant Periods, the Group assesses whether the credit risk on a financial instrument has increased significantly since initial recognition. When making the assessment, the Group compares the risk of a default occurring on the financial instrument as at the end of each of the Relevant Periods with the risk of a default occurring on the financial instrument as at the date of initial recognition and considers reasonable and supportable information that is available without undue cost or effort, including historical and forward-looking information.

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

Financial assets at amortised cost are subject to impairment under the general approach and they are classified within the following stages for measurement of ECLs except for trade receivables which apply the simplified approach as detailed below.

- | | | |
|---------|---|--|
| Stage 1 | – | Financial instruments for which credit risk has not increased significantly since initial recognition and for which the loss allowance is measured at an amount equal to 12-month ECLs |
| Stage 2 | – | Financial instruments for which credit risk has increased significantly since initial recognition but that are not credit-impaired financial assets and for which the loss allowance is measured at an amount equal to lifetime ECLs |
| Stage 3 | – | Financial assets that are credit-impaired at the end of each of the Relevant Periods (but that are not purchased or originated credit-impaired) and for which the loss allowance is measured at an amount equal to lifetime ECLs |

Simplified approach

For trade receivables that do not contain a significant financing component or when the Group applies the practical expedient of not adjusting the effect of a significant financing component, the Group applies the simplified approach in calculating ECLs. Under the simplified approach, the Group does not track changes in credit risk, but instead recognises a loss allowance based on lifetime ECLs at the end of each of the Relevant Periods. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment.

Financial liabilities

Initial recognition and measurement

Financial liabilities are classified, at initial recognition, as loans and borrowings, or payables as appropriate.

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group’s financial liabilities include trade and other payables, financial liabilities included in other payables and accruals, interest-bearing bank borrowings and lease liabilities.

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Subsequent measurement

The subsequent measurement of financial liabilities depends on their classification as follows:

Financial liabilities at amortised cost (loans and borrowings)

After initial recognition, interest-bearing bank borrowings are subsequently measured at amortised cost, using the effective interest method unless the effect of discounting would be immaterial, in which case they are stated at cost. Gains and losses are recognised in profit or loss when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Amortised cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the effective interest rate. The effective interest rate amortisation is included in finance costs in the statement of profit or loss.

Derecognition of financial liabilities

A financial liability is derecognised when the obligation under the liability is discharged or cancelled, or expires.

When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as a derecognition of the original liability and a recognition of a new liability, and the difference between the respective carrying amounts is recognised in profit or loss.

Offsetting of financial instruments

Financial assets and financial liabilities are offset and the net amount is reported in the statement of financial position if there is a currently enforceable legal right to offset the recognised amounts and there is an intention to settle on a net basis, or to realise the asset and settle the liabilities simultaneously.

Inventories

Inventories are stated at the lower of cost and net realisable value. Cost is determined on the weighted average basis. Net realisable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal.

Cash and cash equivalents

For the purpose of the consolidated statement of cash flows, cash and cash equivalents comprise cash at banks, are subject to an insignificant risk of changes in value and form an integral part of the Group’s cash management.

For the purpose of the consolidated statement of financial position, cash and cash equivalents comprise cash at banks, which are not restricted as to use.

Provisions

A provision is recognised when a present obligation (legal or constructive) has arisen as a result of a past event and it is probable that a future outflow of resources will be required to settle the obligation, provided that a reliable estimate can be made of the amount of the obligation.

When the effect of discounting is material, the amount recognised for a provision is the present value at the end of each of the Relevant Periods of the future expenditures expected to be required to settle the obligation. The increase in the discounted present value amount arising from the passage of time is included in finance costs in profit or loss.

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Income tax

Income tax comprises current and deferred tax. Income tax relating to items recognised outside profit or loss is recognised outside profit or loss, either in other comprehensive income or directly in equity.

Current tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods, taking into consideration interpretations and practices prevailing in the country in which the Group operates.

Deferred tax is provided, using the liability method, on all temporary differences at the end of each of the Relevant Periods between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred tax liabilities are recognised for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of an asset or liability in a transaction that is not a business consolidation and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of taxable temporary differences associated with investments in subsidiaries, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognised for all deductible temporary differences, and the carry-forward of unused tax credits and any unused tax losses. Deferred tax assets are recognised to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carryforward of unused tax credits and unused tax losses can be utilised, except:

- when the deferred tax asset relating to the deductible temporary differences arises from the initial recognition of an asset or liability in a transaction that is not a business consolidation and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; and
- in respect of deductible temporary differences associated with investments in subsidiaries, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilised.

The carrying amount of deferred tax assets is reviewed at the end of each of the Relevant Periods and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilised. Unrecognised deferred tax assets are reassessed at the end of each of the Relevant Periods and are recognised to the extent that it has become probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of each of the Relevant Periods.

Deferred tax assets and deferred tax liabilities are offset if and only if the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred liabilities relate to income taxes levied by the same taxation authority on either the same taxable entity or different taxable entities which intend either to settle current tax liabilities and assets on a net basis, or to realise the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

Government grants

Government grants are recognised at their fair value where there is reasonable assurance that the grant will be received and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognised as income on a systematic basis over the periods that the costs, which it is intended to compensate, are expensed.

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Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual instalments or deducted from the carrying amount of the asset and released to profit or loss by way of a reduced depreciation charge.

Revenue recognition

Revenue from contracts with customers

Revenue from contracts with customers is recognised when control of goods or services is transferred to the customers at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services.

When the consideration in a contract includes a variable amount, the amount of consideration is estimated to which the Group will be entitled in exchange for transferring the goods or services to the customer. The variable consideration is estimated at contract inception and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognised will not occur when the associated uncertainty with the variable consideration is subsequently resolved.

During the Relevant Periods, revenue of the Group was primarily derived from research and development services to the customers. Revenue from the provision of services is recognised over the scheduled period, because the customer simultaneously receives and consumes the benefits provided by the Group.

Other income

Revenue from the sale of raw materials is recognised at the point in time when control of the asset is transferred to the customer, generally on delivery of the products.

Rental income is recognised on a time proportion basis over the lease terms. Variable lease payments that do not depend on an index or a rate are recognised as income in the accounting period in which they are incurred.

Interest income is recognised on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Share-based payments

The Group operates a share award for the purpose of providing incentives and rewards to eligible participants who contribute to the success of the Group’s operations. Employees of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity investments (“equity-settled transactions”).

The cost of equity-settled transactions with employees is measured by reference to the fair value at the date at which they are granted. The fair value of share options and restricted shares is determined by an external valuer using Black Scholes Option Pricing Model and discounted cash flow model, respectively. Further details are included in note 27 to the Historical Financial Information.

The cost of equity-settled transactions is recognised in employee benefit expense, together with a corresponding increase in equity, over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognised for equity-settled transactions at the end of each of the Relevant Periods until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity investments that will ultimately vest. The charge or credit to profit or loss for a period represents the movement in the cumulative expense recognised as at the beginning and end of that period.

Service and non-market performance conditions are not taken into account when determining the grant date fair value of awards, but the likelihood of the conditions being met is assessed as part of the Group’s best estimate of the number of equity investments that will ultimately vest. Market performance conditions are reflected within the grant date fair value. Any other conditions attached to an award, but without an associated service requirement, are considered to be non-vesting conditions. Non-vesting conditions are reflected in the fair value of an award and lead to an immediate expensing of an award unless there are also service and/or performance conditions.

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For awards that do not ultimately vest because non-market performance and/or service conditions have not been met, no expense is recognised. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

Where the terms of an equity-settled award are modified, as a minimum an expense is recognised as if the terms had not been modified, if the original terms of the award are met. In addition, an expense is recognised for any modification that increases the total fair value of the share-based payments, or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognised for the award is recognised immediately. This includes any award where non-vesting conditions within the control of either the Group or the employee are not met. However, if a new award is substituted for the cancelled award, and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Other employee benefits

Pension scheme

The employees of the Group which operate in Mainland China are required to participate in a defined central pension scheme managed by the local municipal government. The subsidiaries operating in Mainland China are required to contribute a certain percentage of the relevant part of the payroll of these employees to the central pension scheme. The Group has no obligation for the payment of retirement benefits beyond the annual contributions. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme.

Borrowing costs

Borrowing costs directly attributable to the acquisition, construction or production of qualifying assets, i.e., assets that necessarily take a substantial period of time to get ready for their intended use or sale, are capitalised as part of the cost of those assets. The capitalisation of such borrowing costs ceases when the assets are substantially ready for their intended use or sale. Investment income earned on the temporary investment of specific borrowings pending their expenditure on qualifying assets is deducted from the borrowing costs capitalised. All other borrowing costs are expensed in the period in which they are incurred. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

Foreign currencies

The Historical Financial Information is presented in RMB. Each entity in the Group determines its own functional currency and items included in the financial statements of each entity are measured using that functional currency. Foreign currency transactions recorded by the entities in the Group are initially recorded using their respective functional currency rates prevailing at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of each of the Relevant Periods. Differences arising on settlement or translation of monetary items are recognised in profit or loss.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value was measured. The gain or loss arising on translation of a non-monetary item measured at fair value is treated in line with the recognition of the gain or loss on change in fair value of the item (i.e., translation difference on the item whose fair value gain or loss is recognised in other comprehensive income or profit or loss is also recognised in other comprehensive income or profit or loss, respectively).

In determining the exchange rate on initial recognition of the related asset, expense or income on the derecognition of a non-monetary asset or non-monetary liability relating to an advance consideration, the date of initial transaction is the date on which the Group initially recognises the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of the advance consideration.

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The functional currencies of certain overseas subsidiaries are currencies other than the RMB. As at the end of each of the Relevant Periods, the assets and liabilities of these entities are translated into RMB at the exchange rates prevailing at the end of each of Relevant Periods and their profit or loss is translated into RMB at the weighted average exchange rates for the year or period.

The resulting exchange differences are recognised in other comprehensive income and accumulated in the exchange fluctuation reserve. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognised in profit or loss.

For the purpose of the consolidated statement of cash flows, the cash flows of overseas subsidiaries are translated into RMB at the exchange rates ruling at the dates of the cash flows. Frequently recurring cash flows of overseas subsidiaries which arise throughout the year or period are translated into RMB at the weighted average exchange rates for the year or period.

3. SIGNIFICANT ACCOUNTING JUDGEMENTS AND ESTIMATES

The preparation of the Group’s Historical Financial Information requires management to make judgements, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and their accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that could require a material adjustment to the carrying amounts of the assets or liabilities affected in the future.

Estimation uncertainty

The key assumptions concerning the future and other key sources of estimation uncertainty at the end of each of the Relevant Periods, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below.

Recognition of income taxes and deferred tax assets

Determining income tax provision involves judgment on the future tax treatment of certain transactions and when certain matters relating to the income taxes have not been confirmed by the local tax bureau. Management evaluates tax implications of transactions and tax provisions are set up accordingly. The tax treatments of such transactions are reconsidered periodically to take into account all changes in tax legislation. Deferred tax assets are recognised in respect of deductible temporary differences and unused tax losses. As those deferred tax assets can only be recognised to the extent that it is probable that future taxable profits will be available against which the deductible temporary differences and the losses can be utilised, management’s judgment is required to assess the probability of future taxable profits. Management’s assessment is revised as necessary and additional deferred tax assets are recognised if it becomes probable that future taxable profits will allow the deferred tax asset to be recovered.

Impairment of non-financial assets (other than goodwill)

The Group assesses whether there are any indicators of impairment for all non-financial assets (including the right-of-use assets) at the end of each of the Relevant Periods. Indefinite life intangible assets are tested for impairment annually and at other times when such an indicator exists. Other non-financial assets are tested for impairment when there are indicators that the carrying amounts may not be recoverable. An impairment exists when the carrying value of an asset or a cash-generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The calculation of the fair value less costs of disposal is based on available data from binding sales transactions in an arm’s length transaction of similar assets or observable market prices less incremental costs for disposing of the asset. When value in use calculations are undertaken, management must estimate the expected future cash flows from the asset or cash-generating unit and choose a suitable discount rate in order to calculate the present value of those cash flows.

Useful lives and residual values of property, plant and equipment

In determining the useful lives and residual values of items of property, plant and equipment, the Group has to consider various factors, such as technical or commercial obsolescence arising from changes or improvements in production, or from a change in the market demand for the product or service output of the asset, expected usage of the asset, expected physical wear and tear, the care and maintenance of the asset and the legal or similar limits on the use of the asset. The estimation of the useful life of the asset is based on the experience of the Group with similar assets that are used in a similar way.

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Additional depreciation is recognised if the estimated useful lives and/or the residual values of items of property, plant and equipment are different from the previous estimation. Useful lives and residual values are reviewed at each financial year end date based on changes in circumstances.

Write-down of inventories to net realisable value

Write-down of inventories to net realisable value is made for those identified obsolete and slow-moving inventories and inventories with a carrying amount higher than the net realisable value. The assessment of the provision required involves management’s judgement and estimates on which are influenced by assumptions concerning future sales and usage and judgements in determining the appropriate level of inventory provisions against identified surplus or obsolete items. Where the actual outcome or expectation in future is different from the original estimate, such differences will have impact on the carrying amounts of inventories and the write-down/write-back of inventories in the period in which such estimate has been changed.

Fair value of unlisted equity investments

The unlisted equity investments have been valued based on the expected cash flows discounted at current rates applicable for items with similar terms and risk characteristics. This valuation requires the Group to make estimates about expected future cash flows, credit risk, volatility and discount rates, and hence they are subject to uncertainty. The fair values of unlisted equity investments at 31 December 2018 and 2019 and 31 March 2020 were RMB10,023,000, RMB11,448,000 and RMB11,448,000, respectively. Further details are included in note 16 to the Historical Financial Information.

4. OPERATING SEGMENT INFORMATION

The Group is engaged in biopharmaceutical research, biopharmaceutical service, and biopharmaceutical production, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group’s senior management for purposes of resource allocation and performance assessment. Therefore, no analysis by operating segment is presented.

Geographical information

(a) Revenue from external customers

During the Relevant Periods and the three months ended 31 March 2019, all of the Group’s revenue was derived from customers located in Mainland China.

(b) Non-current assets

	As at 31 December		As at 31 March
	2018	2019	2020
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Mainland China	455,933	540,020	635,359
USA	252	269	273
	456,185	540,289	635,632

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The non-current asset information above is based on the locations of the assets and excludes equity investments designated at fair value through other comprehensive income.

Information about a major customer

Revenue of RMB11,321,000 for the year ended 31 December 2018 was derived from a single related party.

5. REVENUE, OTHER INCOME AND GAINS

An analysis of revenue, other income and gains is as follows:

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(Unaudited)</i>	
<i>Revenue from contracts with customers</i>				
Rendering of services	11,321	–	–	–

Revenue from contracts with customers

(a) Disaggregated revenue information

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(Unaudited)</i>	
<u>Type of services</u>				
– Research and development services	11,321	–	–	–
<u>Geographical market</u>				
Mainland China	11,321	–	–	–
<u>Timing of revenue recognition</u>				
Services transferred over time	11,321	–	–	–

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(b) Performance obligations

Information about the Group’s performance obligations is summarised below:

Rendering of services

The performance obligation is satisfied over time as services are rendered and billed based on the time incurred from rendering the services.

	Notes	Year ended 31 December		Three months ended 31 March	
		2018 RMB’000	2019 RMB’000	2019 RMB’000	2020 RMB’000
<i>(Unaudited)</i>					
<u>Other income</u>					
Government grants*	7	11,704	33,471	1,918	5,858
Bank interest income	7	21	147	3	239
Rental income	14	–	2,452	544	425
Sales of materials		1,518	1,610	2	20
Others		438	763	69	25
		<u>13,681</u>	<u>38,443</u>	<u>2,536</u>	<u>6,567</u>
<u>Gains</u>					
Foreign exchange gains, net	7	–	–	–	695
Gain on disposal of property, plant and equipment		1,658	–	15	–
Others		38	38	–	54
		<u>1,696</u>	<u>38</u>	<u>15</u>	<u>749</u>
		<u>15,377</u>	<u>38,481</u>	<u>2,551</u>	<u>7,316</u>

* The government grants mainly represent subsidies received from government authorities for the purpose of compensation for expenditure arising from research activities and clinical trials, award for new drug development and capital expenditure incurred on certain projects. There are no unfulfilled conditions or contingencies relating to these government grants.

6. FINANCE COSTS

	Year ended 31 December		Three months ended 31 March	
	2018 RMB’000	2019 RMB’000	2019 RMB’000	2020 RMB’000
<i>(Unaudited)</i>				
Interest on borrowings from a related party (note 31(b))	39,791	41,649	12,346	8,012
Interest on bank borrowings	–	1,811	–	892
Interest on lease liabilities (note 14(b))	264	329	84	66
	<u>40,055</u>	<u>43,789</u>	<u>12,430</u>	<u>8,970</u>

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7. LOSS BEFORE TAX

The Group’s loss before tax is arrived at after charging/(crediting):

	Notes	Year ended 31 December		Three months ended 31 March	
		2018 RMB’000	2019 RMB’000	2019 RMB’000	2020 RMB’000
<i>(Unaudited)</i>					
Cost of sales (<i>note (a)</i>)		8,932	–	–	–
Research and development cost (<i>note (b)</i>)		216,438	352,066	69,137	75,210
Depreciation of property, plant and equipment (<i>note (c)</i>)	13	20,542	40,203	9,165	11,598
Depreciation of right-of-use assets	14	803	1,769	369	471
Amortisation of other intangible assets (<i>note (d)</i>)	15	1,294	800	200	200
Amortisation of long-term prepayment		–	28	–	12
[REDACTED] expenses		–	980	–	198
Auditor’s remuneration		–	661	–	476
Government grants	5	(11,704)	(33,471)	(1,918)	(5,858)
Lease payments not included in the measurement of lease liabilities	14	383	850	209	262
Employee benefit expenses (excluding directors’ and supervisors’ remuneration (<i>note 8</i>)):					
Wages, salaries and allowances		70,102	109,601	23,359	33,175
Pension scheme contributions		6,642	11,146	2,638	1,335
Staff welfare expenses		4,901	9,395	1,786	2,281
Share-based payment expenses		3,023	5,126	756	1,931
		<u>84,668</u>	<u>135,268</u>	<u>28,539</u>	<u>38,722</u>
Foreign exchange differences, net	5	–	–	–	(695)
Impairment of financial assets, net:					
Impairment of financial assets included in prepayments, other receivables and other assets (<i>note (e)</i>)	19	196	(134)	–	79
Bank interest income	5	(21)	(147)	(3)	(239)
(Gain)/loss on disposal of items of property, plant and equipment (<i>note (e)</i>)		(1,658)	340	(15)	6
		<u>(1,658)</u>	<u>340</u>	<u>(15)</u>	<u>6</u>

Notes:

- (a) The cost of sales includes RMB1,416,000 relating to employee benefit expenses, depreciation and amortisation for the year ended 31 December 2018, which are also included in the respective total amounts disclosed above for each type of expenses.
- (b) The research and development costs include RMB88,911,000, RMB145,368,000, RMB35,592,000 and RMB32,551,000 relating to employee benefit expenses, depreciation and amortisation, respectively, for the Relevant Periods and the three months ended 31 March 2019, which are also included in the respective total amounts disclosed above for each type of expenses. Research and development costs also included share award expenses, which is set out in note 27 to the Historical Financial Information, RMB1,284,000, RMB2,165,000, RMB504,000 and RMB321,000 for the Relevant Periods and the three months ended 31 March 2019.
- (c) Included in “Cost of sales”, “Administrative expenses” and “Research and development costs” in the consolidated statements of profit or loss.
- (d) Included in “Cost of sales” and “Research and development costs” in the consolidated statements of profit or loss.
- (e) Included in “Other expenses” and “other income and gains” in the consolidated statements of profit or loss.

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8. DIRECTORS’ AND SUPERVISORS’ REMUNERATION

The remuneration of each director and supervisor as recorded in each of the Relevant Periods and the three months ended 31 March 2019, disclosed pursuant to the Rules Governing the Listing of Securities on the Hong Kong Stock Exchange (the “Listing Rules”), section 383(1)(a), (b), (c) and (f) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation, is set out below:

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	RMB’000	RMB’000	RMB’000	RMB’000
			(Unaudited)	
Other emoluments:				
Salaries, allowances and benefits in kind	1,711	2,583	498	756
Performance related bonuses	220	560	66	168
Pension scheme contributions	94	121	31	21
	<u>2,025</u>	<u>3,264</u>	<u>595</u>	<u>945</u>

Year ended 31 December 2018

	Salaries, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Total remuneration
	RMB’000	RMB’000	RMB’000	RMB’000
Directors				
Mr. Wang Weidong (note (a))	231	101	24	356
Dr. Fang Jianmin (note (b))	423	35	5	463
Mr. Lin Jian (note (c))	154	11	–	165
Mr. Deng Yong (note (d))	–	–	–	–
Ms. Tao Luqun (note (d))	672	–	41	713
	<u>1,480</u>	<u>147</u>	<u>70</u>	<u>1,697</u>
Supervisor				
Mr. Wen Qingkai (note (e))	231	73	24	328
	<u>1,711</u>	<u>220</u>	<u>94</u>	<u>2,025</u>

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Year ended 31 December 2019

	Salaries, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Total remuneration
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Directors				
Mr. Wang Weidong (<i>note (a)</i>)	398	140	24	562
Dr. Fang Jianmin (<i>note (b)</i>)	517	140	25	682
Mr. Lin Jian (<i>note (c)</i>)	479	140	–	619
Mr. Deng Yong (<i>note (d)</i>)	–	–	–	–
Ms. Tao Luqun (<i>note (d)</i>)	701	–	43	744
	<u>2,095</u>	<u>420</u>	<u>92</u>	<u>2,607</u>
Supervisor				
Mr. Wen Qingkai (<i>note (e)</i>)	488	140	29	657
	<u>2,583</u>	<u>560</u>	<u>121</u>	<u>3,264</u>

Three months ended 31 March 2020

	Salaries, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Total remuneration
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Directors				
Mr. Wang Weidong (<i>note (a)</i>)	108	42	–	150
Dr. Fang Jianmin (<i>note (b)</i>)	157	42	5	204
Mr. Lin Jian (<i>note (c)</i>)	120	42	–	162
Mr. Deng Yong (<i>note (d)</i>)	–	–	–	–
Ms. Tao Luqun (<i>note (d)</i>)	177	–	11	188
	<u>562</u>	<u>126</u>	<u>16</u>	<u>704</u>
Supervisor				
Mr. Wen Qingkai (<i>note (e)</i>)	194	42	5	241
	<u>756</u>	<u>168</u>	<u>21</u>	<u>945</u>

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Three months ended 31 March 2019 (Unaudited)

	Salaries, allowances and benefits in kind	Performance related bonuses	Pension scheme contributions	Total remuneration
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Directors				
Mr. Wang Weidong (<i>note (a)</i>)	82	30	7	119
Dr. Fang Jianmin (<i>note (b)</i>)	108	11	7	126
Mr. Lin Jian (<i>note (c)</i>)	62	3	–	65
Mr. Deng Yong (<i>note (d)</i>)	–	–	–	–
Ms. Tao Luqun (<i>note (d)</i>)	171	–	10	181
	<u>423</u>	<u>44</u>	<u>24</u>	<u>491</u>
Supervisor				
Mr. Wen Qingkai (<i>note (e)</i>)	75	22	7	104
	<u>498</u>	<u>66</u>	<u>31</u>	<u>595</u>

Notes:

- (a) Mr. Wang Weidong was designated as an executive director in May 2020, and was appointed as the Chairman of the Board with effect from June 2019.
- (b) Dr. Fang Jianmin is also the chief executive officer of the Company with effect from October 2008, and his remuneration disclosed above included the services rendered by him as the chief executive officer. Dr. Fang Jianmin was designated as an executive director in May 2020.
- (c) Mr. Lin Jian served as the Chairman of the Board from July 2008 to June 2019 and was designated as an executive director in May 2020.
- (d) Mr. Deng Yong and Ms. Tao Luqun retired as directors of the Company in May 2020.
- (e) Mr. Wen Qingkai retired as a supervisor of the Company in May 2020.
- (f) Dr. He Ruyi, Dr. Wang Liqiang and Dr. Su Xiaodi were appointed as directors of the Company and designated as executive director, non-executive director and non-executive director in May 2020, respectively.
- (g) Ms. Yu Shanshan, Mr. Hao Xianjing and Dr. Lorne Alan Babiuk were appointed as independent non-executive directors of the Company in May 2020.
- (h) Mr. Ren Guangke, Mr. Li Yupeng and Mr. Li Zhuanglin were appointed as supervisors of the Company in May 2020.

There was no arrangement under which a director waived or agreed to waive any remuneration during the Relevant Periods. No emoluments were paid by the Group to any of the directors or supervisors as an inducement to join or upon joining the Group or as compensation for loss of office.

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9. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees were neither a director nor chief executive of the Company during the Relevant Periods and the three months ended 31 March 2019. Details of the remuneration of the five highest paid employees are as follows:

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(Unaudited)</i>	
Salaries, bonuses, allowances and benefits in kind	3,730	3,968	1,023	881
Performance related bonuses	524	967	174	329
Pension scheme contributions	101	104	27	8
Share-based payment expenses	1,634	2,003	496	1,020
	<u>5,989</u>	<u>7,042</u>	<u>1,720</u>	<u>2,238</u>

The number of the five highest paid employees whose remuneration fell within the following bands is as follows:

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(Unaudited)</i>	
Nil to HK\$1,000,000	–	–	5	5
HK\$1,000,001 to HK\$2,000,000	5	4	–	–
HK\$2,000,001 to HK\$3,000,000	–	1	–	–
	<u>–</u>	<u>5</u>	<u>–</u>	<u>–</u>

* During the Relevant Periods and the three months ended 31 March 2019, share awards were granted to the five highest paid employees in respect of their services to the Group, further details of which are included in the disclosures in note 27 to the Historical Financial Information. The fair value of such awarded shares, which has been recognised in the consolidated statements of profit or loss over the vesting period, was determined as at the date of grant and the amount included in the Historical Financial Information for the Relevant Periods and the three months ended 31 March 2019 is included in the above five highest paid employees’ remuneration disclosures.

No emoluments were paid by the Group to any of the above non-director or non-supervisor highest paid employees as an inducement to join or upon joining the Group or as compensation for loss of office.

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10. INCOME TAX

The provision for corporate income tax in Mainland China is based on the statutory rate of 25% of the assessable profits as determined in accordance with the PRC Corporate Income Tax Law which was approved and became effective on 1 January 2008.

The subsidiary incorporated in the USA is subject to American federal and California state income tax. America federal income tax was provided at the rate of 21% during the Relevant Periods, and California income tax was provided at the rate of 8.84% during the Relevant Periods on the estimated assessable profits arising in the USA.

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% on any estimated assessable profits arising in Hong Kong during the Relevant Periods. No provision for Hong Kong profits tax has been made as the Group has no assessable profits derived from or earned in Hong Kong during the Relevant Periods.

The income tax expense of the Group for the Relevant Periods and the three months ended 31 March 2019 is analysed as follows:

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(Unaudited)</i>	
Current				
Charge for the year/period	–	–	–	–
Deferred	–	–	–	–
Total tax charge for the year/period	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>

A reconciliation of the tax expense applicable to loss before tax at the statutory rates for the jurisdictions in which the Company and its subsidiaries are domiciled to the tax expense at the effective tax rate is as follows:

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	RMB'000	RMB'000	RMB'000	RMB'000
			<i>(Unaudited)</i>	
Loss before tax	<u>(269,948)</u>	<u>(430,280)</u>	<u>(87,761)</u>	<u>(99,593)</u>
Tax calculated at the statutory tax rate of 25%	(67,487)	(107,570)	(21,940)	(24,898)
Effect of tax rate differences in other jurisdictions	77	215	6	34
Expenses not deductible for tax	9,383	2,956	3,127	1,150
Additional deductible allowance for research and development expenses	(36,449)	(59,558)	(11,645)	(11,787)
Deductible temporary difference and tax losses not recognised	<u>94,476</u>	<u>163,957</u>	<u>30,452</u>	<u>35,501</u>
Tax charge at the Group’s effective rate	<u>–</u>	<u>–</u>	<u>–</u>	<u>–</u>

The Group has tax losses in Mainland China of RMB324,210,000, RMB608,600,000, RMB143,430,000 and RMB114,516,000 as at the end of each of the Relevant Periods and 31 March 2019, respectively, that will expire in one to five years for offsetting against future taxable profits of the companies in which the losses arose.

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The Group also has tax losses in the USA of RMB1,923,000, RMB5,387,000, RMB855,000 and RMB153,000 as at the end of each of the Relevant Periods and 31 March 2019, respectively, that will be carried forward indefinitely for offsetting against future taxable profits of the companies in which the losses arose.

Deferred tax assets have not been recognised in respect of these losses as they have arisen in the Group that have been loss-making for some time and it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

11. DIVIDENDS

No dividends have been declared and paid by the Company during the Relevant Periods and the three months ended 31 March 2019.

12. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

Loss per share information is not presented as its inclusion, for the purposes of this report, is not considered meaningful because the number of ordinary shares as at the end of each of the Relevant Periods is different from the number of ordinary shares immediately after the completion of [REDACTED] of the Group.

13. PROPERTY, PLANT AND EQUIPMENT

The Group

	Buildings	Plant and machinery	Office equipment and others	Motor vehicles	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2018						
At 1 January 2018:						
Cost	72,619	135,242	7,988	305	67,142	283,296
Accumulated depreciation	(6,969)	(35,238)	(1,678)	(198)	–	(44,083)
Net carrying amount	<u>65,650</u>	<u>100,004</u>	<u>6,310</u>	<u>107</u>	<u>67,142</u>	<u>239,213</u>
At 1 January 2018, net of accumulated depreciation	65,650	100,004	6,310	107	67,142	239,213
Additions	–	64,501	8,760	–	97,073	170,334
Disposals	(53)	(1,244)	(57)	–	–	(1,354)
Depreciation provided during the year	(3,614)	(14,897)	(1,994)	(37)	–	(20,542)
Transfers	108,711	37,087	679	–	(146,477)	–
Exchange realignment	–	11	1	–	–	12
At 31 December 2018, net of accumulated depreciation	<u>170,694</u>	<u>185,462</u>	<u>13,699</u>	<u>70</u>	<u>17,738</u>	<u>387,663</u>
At 31 December 2018:						
Cost	181,254	233,769	17,319	305	17,738	450,385
Accumulated depreciation	(10,560)	(48,307)	(3,620)	(235)	–	(62,722)
Net carrying amount	<u>170,694</u>	<u>185,462</u>	<u>13,699</u>	<u>70</u>	<u>17,738</u>	<u>387,663</u>

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	Buildings	Plant and machinery	Office equipment and others	Motor vehicles	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2019						
At 1 January 2019:						
Cost	181,254	233,769	17,319	305	17,738	450,385
Accumulated depreciation	(10,560)	(48,307)	(3,620)	(235)	–	(62,722)
Net carrying amount	<u>170,694</u>	<u>185,462</u>	<u>13,699</u>	<u>70</u>	<u>17,738</u>	<u>387,663</u>
At 1 January 2019, net of accumulated depreciation	170,694	185,462	13,699	70	17,738	387,663
Additions	–	56,957	9,671	–	49,294	115,922
Disposals	(140)	(441)	(8)	–	–	(589)
Depreciation provided during the year	(10,725)	(25,714)	(3,728)	(36)	–	(40,203)
Adjustment	(3,084)	–	–	–	–	(3,084)
Transfers	2,775	24,038	52	–	(26,865)	–
Exchange realignment	–	4	–	–	–	4
At 31 December 2019, net of accumulated depreciation	<u>159,520</u>	<u>240,306</u>	<u>19,686</u>	<u>34</u>	<u>40,167</u>	<u>459,713</u>
At 31 December 2019:						
Cost	180,773	313,968	26,972	305	40,167	562,185
Accumulated depreciation	(21,253)	(73,662)	(7,286)	(271)	–	(102,472)
Net carrying amount	<u>159,520</u>	<u>240,306</u>	<u>19,686</u>	<u>34</u>	<u>40,167</u>	<u>459,713</u>

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	Buildings	Plant and machinery	Office equipment and others	Motor vehicles	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 March 2020						
At 1 January 2020:						
Cost	180,773	313,968	26,972	305	40,167	562,185
Accumulated depreciation	(21,253)	(73,662)	(7,286)	(271)	–	(102,472)
Net carrying amount	<u>159,520</u>	<u>240,306</u>	<u>19,686</u>	<u>34</u>	<u>40,167</u>	<u>459,713</u>
At 1 January 2020, net of accumulated depreciation	159,520	240,306	19,686	34	40,167	459,713
Additions	–	7,423	895	–	13,799	22,117
Disposals	–	(28)	(1)	–	–	(29)
Depreciation provided during the period	(2,660)	(7,746)	(1,183)	(9)	–	(11,598)
Adjustment	(378)	–	–	–	–	(378)
Transfers	108	3,741	–	–	(3,849)	–
Exchange realignment	–	4	–	–	–	4
At 31 March 2020, net of accumulated depreciation	<u>156,590</u>	<u>243,700</u>	<u>19,397</u>	<u>25</u>	<u>50,117</u>	<u>469,829</u>
At 31 March 2020:						
Cost	180,503	324,958	27,850	305	50,117	583,733
Accumulated depreciation	(23,913)	(81,258)	(8,453)	(280)	–	(113,904)
Net carrying amount	<u>156,590</u>	<u>243,700</u>	<u>19,397</u>	<u>25</u>	<u>50,117</u>	<u>469,829</u>

The Group’s building and the corresponding land use right with net carrying amounts of RMB85,956,000 and RMB2,368,000, respectively, as at 31 December 2019 were pledged to secure bank loans (note 23).

The Group’s buildings with net carrying amounts of RMB63,480,000 and RMB145,899,000, respectively, as at 31 December 2019 and 31 March 2020 were pledged to obtain banking facilities of RMB26,000,000 and RMB109,272,000, respectively. The corresponding land use right of the aforementioned buildings with net carrying amounts of RMB3,182,000 and RMB5,516,000, respectively, were also pledged for banking facilities accordingly.

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The Company

	Buildings	Plant and machinery	Office equipment and others	Motor vehicles	Construction in progress	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2018						
At 1 January 2018:						
Cost	72,619	135,016	7,974	305	67,142	283,056
Accumulated depreciation	(6,969)	(35,238)	(1,678)	(198)	–	(44,083)
Net carrying amount	<u>65,650</u>	<u>99,778</u>	<u>6,296</u>	<u>107</u>	<u>67,142</u>	<u>238,973</u>
At 1 January 2018, net of accumulated depreciation	65,650	99,778	6,296	107	67,142	238,973
Additions	–	64,501	8,760	–	97,073	170,334
Disposals	(53)	(1,244)	(57)	–	–	(1,354)
Depreciation provided during the year	(3,614)	(14,897)	(1,994)	(37)	–	(20,542)
Transfers	108,711	37,087	679	–	(146,477)	–
At 31 December 2018, net of accumulated depreciation	<u>170,694</u>	<u>185,225</u>	<u>13,684</u>	<u>70</u>	<u>17,738</u>	<u>387,411</u>
At 31 December 2018:						
Cost	181,254	233,532	17,304	305	17,738	450,133
Accumulated depreciation	(10,560)	(48,307)	(3,620)	(235)	–	(62,722)
Net carrying amount	<u>170,694</u>	<u>185,225</u>	<u>13,684</u>	<u>70</u>	<u>17,738</u>	<u>387,411</u>

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	<u>Buildings</u>	<u>Plant and machinery</u>	<u>Office equipment and others</u>	<u>Motor vehicles</u>	<u>Construction in progress</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 December 2019						
At 1 January 2019:						
Cost	181,254	233,532	17,304	305	17,738	450,133
Accumulated depreciation	(10,560)	(48,307)	(3,620)	(235)	–	(62,722)
Net carrying amount	<u>170,694</u>	<u>185,225</u>	<u>13,684</u>	<u>70</u>	<u>17,738</u>	<u>387,411</u>
At 1 January 2019, net of accumulated depreciation	170,694	185,225	13,684	70	17,738	387,411
Additions	–	56,957	9,658	–	49,294	115,909
Disposals	(140)	(441)	(8)	–	–	(589)
Depreciation provided during the year	(10,725)	(25,714)	(3,728)	(36)	–	(40,203)
Adjustment	(3,084)	–	–	–	–	(3,084)
Transfers	2,775	24,038	52	–	(26,865)	–
At 31 December 2019, net of accumulated depreciation	<u>159,520</u>	<u>240,065</u>	<u>19,658</u>	<u>34</u>	<u>40,167</u>	<u>459,444</u>
At 31 December 2019:						
Cost	180,773	313,727	26,944	305	40,167	561,916
Accumulated depreciation	(21,253)	(73,662)	(7,286)	(271)	–	(102,472)
Net carrying amount	<u>159,520</u>	<u>240,065</u>	<u>19,658</u>	<u>34</u>	<u>40,167</u>	<u>459,444</u>

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	<u>Buildings</u>	<u>Plant and machinery</u>	<u>Office equipment and others</u>	<u>Motor vehicles</u>	<u>Construction in progress</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
31 March 2020						
At 1 January 2020:						
Cost	180,773	313,727	26,944	305	40,167	561,916
Accumulated depreciation	<u>(21,253)</u>	<u>(73,662)</u>	<u>(7,286)</u>	<u>(271)</u>	–	<u>(102,472)</u>
Net carrying amount	<u>159,520</u>	<u>240,065</u>	<u>19,658</u>	<u>34</u>	<u>40,167</u>	<u>459,444</u>
At 1 January 2020, net of accumulated depreciation	159,520	240,065	19,658	34	40,167	459,444
Additions	–	7,423	895	–	13,799	22,117
Disposals	–	(28)	(1)	–	–	(29)
Depreciation provided during the period	(2,660)	(7,746)	(1,183)	(9)	–	(11,598)
Adjustment	(378)	–	–	–	(378)	–
Transfers	108	3,741	–	–	(3,849)	–
At 31 March 2020, net of accumulated depreciation	<u>156,590</u>	<u>243,455</u>	<u>19,369</u>	<u>25</u>	<u>50,117</u>	<u>469,556</u>
At 31 March 2020:						
Cost	180,503	324,713	27,822	305	50,117	583,460
Accumulated depreciation	<u>(23,913)</u>	<u>(81,258)</u>	<u>(8,453)</u>	<u>(280)</u>	–	<u>(113,904)</u>
Net carrying amount	<u>156,590</u>	<u>243,455</u>	<u>19,369</u>	<u>25</u>	<u>50,117</u>	<u>469,556</u>

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14. LEASES

The Group and the Company as a lessee

The Group has lease contracts for various items of land use rights, buildings, plant and machinery used in its operations. Lump sum payments were made upfront to acquire the leased land from the owners with lease periods of 50 years, and no ongoing payments will be made under the terms of these land leases. Leases of buildings, plant and machinery generally have lease terms between 2 and 5 years. Generally, the Group is restricted from assigning and subleasing the leased assets outside the Group.

(a) Right-of-use assets

The carrying amounts of the Group’s/the Company’s right-of-use assets and the movements during the Relevant Periods are as follows:

	Land use rights	Buildings	Plant and machinery	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
As at 1 January 2018	5,814	319	–	6,133
Additions	–	516	4,474	4,990
Depreciation charge	(132)	(287)	(384)	(803)
As at 31 December 2018	<u>5,682</u>	<u>548</u>	<u>4,090</u>	<u>10,320</u>
As at 1 January 2019	5,682	548	4,090	10,320
Additions	–	621	1,835	2,456
Depreciation charge	(132)	(481)	(1,156)	(1,769)
As at 31 December 2019	<u>5,550</u>	<u>688</u>	<u>4,769</u>	<u>11,007</u>
As at 1 January 2020	5,550	688	4,769	11,007
Additions	4,782	–	–	4,782
Depreciation charge	(43)	(111)	(317)	(471)
Remeasurement resulting from early termination of leases	–	(577)	–	(577)
As at 31 March 2020	<u>10,289</u>	<u>–</u>	<u>4,452</u>	<u>14,741</u>

Land use rights represent the land use rights granted by the PRC government authority on the use of land within the pre-approved lease period, the original terms of the land use rights of the Group held in the PRC are 50 years up to December 2061 and June 2062, respectively.

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(b) Lease liabilities

The carrying amount of lease liabilities and the movements during the Relevant Periods are as follows:

	As at 31 December		As at 31 March
	2018	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Carrying amount at beginning of the year/period	286	4,511	5,364
New lease arrangements	4,990	2,456	–
Accretion of interest recognised during the year/period	264	329	66
Remeasurement resulting from early termination of leases	–	–	(582)
Payments	(1,029)	(1,932)	(411)
	4,511	5,364	4,437
Analysed into:			
Current portion	1,131	1,602	1,189
Non-current portion	3,380	3,762	3,248
	4,511	5,364	4,437

The payments of lease liabilities to a related party for the Relevant Periods and the three months ended 31 March 2019 were nil, RMB1,824,000, RMB364,000 and nil, respectively, details of which are included in note 31 to the Historical Financial Information.

The balances of lease liabilities due to a related party as at the end of each of the Relevant Periods were RMB4,040,000, RMB4,734,000 and RMB4,437,000, respectively, details of which are included in note 31 to the Historical Financial Information. The maturity of lease liabilities is disclosed in note 34 to the Historical Financial Information.

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(e) The amounts recognised in profit or loss in relation to leases are as follows:

	Year ended 31 December		Three months ended 31 March	
	2018	2019	2019	2020
	RMB'000	RMB'000	RMB'000	RMB'000
			(Unaudited)	
Interest on lease liabilities (note 6)	264	329	84	66
Depreciation charge of right-of-use assets	803	1,769	369	471
Expense relating to short-term leases*	343	848	209	261
Expense relating to leases of low-value assets*	40	2	–	1
Total amount recognised in profit or loss	1,450	2,948	662	799

* Included in “Research and development costs” and “Selling and distribution expenses” in the consolidated statement of profit or loss.

The total cash outflow for leases included in the consolidated statement of cash flows is disclosed in note 28(b) to the Historical Financial Information.

The Group and the Company as a lessor

The Group leases its properties under operating lease arrangements. Rental income recognised by the Group for the Relevant Periods and the three months ended 31 March 2019 were nil, RMB2,452,000, RMB425,000 and RMB544,000, details of which are included in note 5 to the Historical Financial Information.

At the end of each of the Relevant Periods, the undiscounted lease payments receivable by the Group/the Company in future periods under non-cancellable operating leases with its tenants are as follows:

	As at 31 December		As at 31 March
	2018	2019	2020
	RMB'000	RMB'000	RMB'000
Within one year	–	74	74
After one year but within two years	–	74	74
After two years but within three years	–	74	74
After three years but within four years	–	74	74
After four years but within five years	–	68	50
	–	364	346

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15. OTHER INTANGIBLE ASSETS

The Group and the Company

	<u>Patents and licenses</u>
	<i>RMB'000</i>
31 December 2018	
Cost at 1 January 2018,	
net of accumulated amortisation	4,227
Amortisation provided during the year	<u>(1,294)</u>
At 31 December 2018	<u><u>2,933</u></u>
At 31 December 2018:	
Cost	13,388
Accumulated amortisation	<u>(10,455)</u>
Net carrying amount	<u><u>2,933</u></u>
31 December 2019	
Cost at 1 January 2019,	
net of accumulated amortisation	2,933
Amortisation provided during the year	<u>(800)</u>
At 31 December 2019	<u><u>2,133</u></u>
At 31 December 2019:	
Cost	13,388
Accumulated amortisation	<u>(11,255)</u>
Net carrying amount	<u><u>2,133</u></u>
31 March 2020	
Cost at 1 January 2020,	
net of accumulated amortisation	2,133
Amortisation provided during the period	<u>(200)</u>
At 31 March 2020	<u><u>1,933</u></u>
At 31 March 2020:	
Cost	13,388
Accumulated amortisation	<u>(11,455)</u>
Net carrying amount	<u><u>1,933</u></u>

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16. EQUITY INVESTMENTS DESIGNATED AT FAIR VALUE THROUGH OTHER COMPREHENSIVE INCOME

The Group and the Company

	As at 31 December		As at 31 March
	2018	2019	2020
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Unlisted equity investments, at fair value Yantai Heyuan Addis Biomedical Technology, Ltd.*	10,023	11,448	11,448
	10,023	11,448	11,448

* The English name of the entity represented the best efforts made by the management of the Group to translate the Chinese name as it did not have an official English name registered in the PRC.

The above equity investment was irrevocably designated as at fair value through other comprehensive income as the Group considers this investment to be strategic in nature.

In June 2018, the Group sold its equity interest in MabPlex International Ltd. as this investment no longer coincided with the Group’s investment strategy. The fair value on the date of sale was RMB15,000,000.

17. OTHER NON-CURRENT ASSETS

The Group and the Company

	As at 31 December		As at 31 March
	2018	2019	2020
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Prepayments for property, plant and equipment	24,193	19,825	75,217
Value-added tax recoverable	31,076	47,548	44,567
Prepayments for land lease	–	–	29,290
Long-term prepayments	–	63	55
	55,269	67,436	149,129

18. INVENTORIES

The Group and the Company

	As at 31 December		As at 31 March
	2018	2019	2020
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Raw materials	28,620	29,876	31,899
Low-value consumption materials	1,051	1,371	1,398
	29,671	31,247	33,297

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19. PREPAYMENTS, OTHER RECEIVABLES AND OTHER ASSETS

The Group

	As at 31 December		As at
	2018	2019	31 March
	RMB’000	RMB’000	2020
Cash in transit*	–	–	109,819
Value-added tax recoverable	–	16,786	12,362
Prepayments	14,674	10,156	22,292
Due from other related parties (note 31)	3,764	64	2,812
Deposits and other receivables	959	2,940	7,181
	19,397	29,946	154,466
Impairment allowance	(222)	(88)	(167)
	19,175	29,858	154,299

* Included in “Cash in transit” was the amount of capital invested by a shareholder which has not been transferred to the bank account of the Group as at 31 March 2020 due to the ongoing approval process by the State Administration of Foreign Exchange. On 8 April 2020, the amount had been transferred to the bank account of the Group.

Financial assets included in prepayments, other receivables and other assets mainly represent deposits with suppliers and other parties. The Group has applied the general approach to provide for expected credit losses for non-trade other receivables under IFRS 9. Other receivables had no historical default, the financial assets included in the above balances were categorized in stage 1 at the end of each of the Relevant Periods. In calculating the expected credit loss rate, the Group considers the historical loss rate and adjusts for forward-looking macroeconomic data. As at the end of each of the Relevant Periods, the Group estimated the expected loss rate for other receivables is minimal.

The credit quality of the financial assets included in prepayments, other receivables and other assets is considered to be normal because they are not past due and there is no information indicating that the financial assets had a significant increase in credit risk.

The Group applies an “expected credit loss (“ECL”) model” to evaluate the credit losses for other receivables. The movements in provision for impairment of other receivables are as follows:

	As at 31 December		As at
	2018	2019	31 March
	RMB’000	RMB’000	2020
At beginning of year/period	26	222	88
Impairment losses, net (note 7)	196	(134)	79
At end of year/period	222	88	167

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The Company

	As at 31 December		As at
	2018	2019	31 March
	RMB'000	RMB'000	2020
Cash in transit	–	–	109,819
Value-added tax recoverable	–	16,786	12,362
Prepayments	14,674	10,156	22,292
Due from a subsidiary (note 31)	–	1	–
Due from other related parties (note 31)	3,764	64	2,812
Deposits and other receivables	959	2,940	7,070
	19,397	29,947	154,355
Impairment allowance	(222)	(88)	(167)
	<u>19,175</u>	<u>29,859</u>	<u>154,188</u>

The movements in provision for impairment of other receivables are as follows:

	As at 31 December		As at
	2018	2019	31 March
	RMB'000	RMB'000	2020
At beginning of year/period	26	222	88
Impairment losses, net (note 7)	196	(134)	79
At end of year/period	<u>222</u>	<u>88</u>	<u>167</u>

20. CASH AND CASH EQUIVALENTS AND PLEDGED DEPOSITS

The Group

	As at 31 December		As at
	2018	2019	31 March
	RMB'000	RMB'000	2020
Cash and bank balances	5,069	75,411	310,859
Less: Pledged for bills payable (note(a))	–	(40,866)	(22,642)
Pledged for wages of migrant workers (note(b))	–	–	(614)
Cash and cash equivalents	<u>5,069</u>	<u>34,545</u>	<u>287,603</u>

Notes:

- (a) As at the end of each of the Relevant Periods, the amounts of bank balances of nil, RMB40,866,000 and RMB22,642,000, respectively, were pledged for bills payable.
- (b) As at the end of each of the Relevant Periods, the amounts of bank balances of nil, nil and RMB614,000, respectively, were pledged for wages of migrant workers.

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The Group’s cash and cash equivalents as at the end of each of the Relevant Periods are denominated in the following currencies:

	As at 31 December		As at
	2018	2019	31 March
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Denominated in RMB	4,305	34,295	285,285
Denominated in USD	764	250	2,318
	<u>5,069</u>	<u>34,545</u>	<u>287,603</u>

The Company

	As at 31 December		As at
	2018	2019	31 March
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Cash and bank balances	4,299	74,161	309,848
Less: Pledged for bills payable	–	(40,866)	(22,642)
Pledged for wages of migrant workers	–	–	(614)
Cash and cash equivalents	<u>4,299</u>	<u>33,295</u>	<u>286,592</u>

The Company’s cash and cash equivalents as at the end of each of the Relevant Periods are denominated in the following currencies:

	As at 31 December		As at
	2018	2019	31 March
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Denominated in RMB	4,299	33,295	285,154
Denominated in USD	–	–	1,438
	<u>4,299</u>	<u>33,295</u>	<u>286,592</u>

The RMB is not freely convertible into other currencies, however, under Mainland China’s Foreign Exchange Control Regulations and Administration of Settlement, Sale and Payment of Foreign Exchange Regulations, the Group is permitted to exchange RMB for other currencies through banks authorised to conduct foreign exchange business.

Cash at banks earns interest at floating rates based on daily bank deposit rates. The bank balances are deposited with creditworthy banks with no recent history of default.

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21. TRADE AND BILLS PAYABLES

The Group and the Company

An ageing analysis of the trade and bills payables as at the end of each of the Relevant Periods, based on the invoice date, is as follows:

	As at 31 December		As at
	2018	2019	31 march
	RMB'000	RMB'000	2020
			RMB'000
Within 3 months	15,188	46,209	37,201
3 to 6 months	5	21,417	20,225
6 months to 1 year	–	54	52
Over 1 year	1,552	17	43
	<u>16,745</u>	<u>67,697</u>	<u>57,521</u>

Included in the trade and bills payables are trade payables of RMB4,159,000, RMB10,507,000 and RMB11,374,000 (note 31) due to the Group’s related parties as at the end of each of the Relevant Periods, respectively, which are repayable within 180 days and represent credit terms similar to those offered by the related parties to their major customers.

Trade and bills payables are non-interest-bearing and are normally settled on terms of one to three months.

22. OTHER PAYABLES AND ACCRUALS

The Group

	As at 31 December		As at
	2018	2019	31 March
	RMB'000	RMB'000	2020
			RMB'000
Payables for purchase of property, plant and equipment	52,624	47,751	37,646
Payroll payable	14,680	28,091	24,093
Other tax payables	498	1,087	848
Accruals	848	1,196	908
Due to key management personnel (note 31)	70	4	13
Due to related parties (note 31)	902,591	615,857	548,180
Other payables	890	26,616	2,653
	<u>972,201</u>	<u>720,602</u>	<u>614,341</u>

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Other payables are non-interest-bearing and repayable on demand.

Included in other payables and accruals were borrowings and interest payables due to a related party of RMB858,288,000, RMB588,082,000 and RMB523,661,000, and other payables due to related parties of RMB44,373,000, RMB27,779,000 and RMB24,532,000 as at the end of each of the Relevant Periods, respectively.

The Company

	As at 31 December		As at 31 March
	2018	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Payables for purchase of property, plant and equipment	52,624	47,751	37,646
Payroll payable	14,635	27,980	21,657
Other tax payables	498	1,087	769
Accruals	848	1,196	908
Due to key management personnel (note 31)	70	4	13
Due to subsidiaries (note 31)	15,000	–	3,095
Due to other related parties (note 31)	902,388	615,661	547,976
Other payables	874	26,612	2,640
	986,937	720,291	614,704

23. INTEREST-BEARING BANK BORROWINGS

The Group and the Company

	As at 31 December		As at 31 March
	2018	2019	2020
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Analysed into:			
Bank loans repayable:			
Within one year	–	60,000	–
	–	60,000	–

Notes:

- (a) The bank loan was secured by the mortgage of the Group’s building and its corresponding land use right with net carrying amounts of RMB85,956,000 and RMB2,368,000, respectively, and guaranteed by Mr. Wang Weidong, the Company’s Chairman of the Board, as at 31 December 2019.
- (b) The secured bank loan with an interest rate of 6.31% per annum is denominated in RMB, and RMB30,000,000 of which was repaid in January 2020, and the remaining RMB30,000,000 was repaid in March 2020.

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24. DEFERRED INCOME

The Group and the Company

	As at 31 December		As at
	2018	2019	31 March
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Government grants:			
Current	6,862	7,052	6,973
Non-current	28,951	60,565	56,047
	<u>35,813</u>	<u>67,617</u>	<u>63,020</u>

The movements in government grants during the Relevant Periods are as follows:

	As at 31 December		As at
	2018	2019	31 March
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
At beginning of the year/period	40,603	35,813	67,617
Grants received during the year/period	8,628	65,325	1,284
Released to profit or loss during the year/period	(13,418)	(33,521)	(5,881)
At end of the year/period	<u>35,813</u>	<u>67,617</u>	<u>63,020</u>

The grants are related to the subsidies received from the government for the purpose of compensation for expenses arising from research activities and clinical trial, award for new drugs development and capital expenditure incurred on certain projects.

25. PAID-IN CAPITAL

	As at 31 December		As at
	2018	2019	31 March
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Issued and fully paid	<u>70,000</u>	<u>168,654</u>	<u>182,645</u>

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A summary of movements in the Company’s paid-in capital is as follows:

	Number of shares in issue	Share capital
		<i>RMB’000</i>
At 1 January 2018, 31 December 2018 and 1 January 2019	70,000	70,000
Capital contributions from shareholders (<i>note(a)</i>)	98,654	98,654
At 31 December 2019 and 1 January 2020	<u>168,654</u>	<u>168,654</u>
Capital contributions from shareholders (<i>note(b)</i>)	13,991	13,991
At 31 March 2020	<u>182,645</u>	<u>182,645</u>

Notes:

- (a) In July 2019, the Company entered into a capital increase agreement with Yantai Rongchang Pharmaceuticals Co., Ltd. (“Rongchang Pharmaceuticals”), pursuant to which total borrowings of RMB600,000,000 were to be transferred into the Company’s capital with approximately RMB95,913,000 and RMB504,087,000 credited to the Company’s paid-in capital and capital reserve, respectively. In December 2019, the Company entered into a capital increase agreement with PAG Growth Holding I (HK) Limited, pursuant to which total capital of RMB90,000,000 was to be injected into the Company with approximately RMB2,741,000 and RMB87,259,000 credited to the Company’s paid-in capital and capital reserve, respectively.
- (b) In February 2020, the Company entered into a capital increase agreement with LAV Remegen Limited, LBC Sunshine Healthcare Fund L.P., Suzhou Likang Equity Investment Center L.P., Suzhou Lirui Equity Investment Center L.P., Janchor Partners Pan-Asian Master Fund, Hudson Bay Master Fund Ltd., ORBIMED PARTNERS MASTER FUND LIMITED, ORBIMED GENESIS MASTER FUND, L.P., Vivo Capital Fund IX, L.P., PAG Growth Holding IV (HK) Limited, Yantai Hongda Investment Co., Ltd., Wholly Sunbeam Limited, Shandong Jifu Jingu New Kinetic Energy Equity Investment Fund Partnership L.P. and Tibet Longpan Yijing Venture Capital Center L.P., pursuant to which total capital of USD105,355,000 (equivalent to RMB733,906,000) was to be injected into the Company with approximately RMB13,991,000 and RMB721,835,000 credited to the Company’s paid-in capital and capital reserve, respectively.

26. RESERVES

The Group

The amounts of the Group’s reserves and the movements therein for the Relevant Periods are presented in the consolidated statements of changes in equity.

(a) Capital reserve

The capital reserve of the Group represents the share premium contributed by the shareholders of the Company.

(b) Other reserve

Other reserve of the Group represents the share-based compensation reserve due to equity-settled share award.

(c) Fair value reserve

It represents the fair value of equity investments at fair value through other comprehensive income.

(d) Exchange fluctuation reserve

The exchange fluctuation reserve is used to record exchange differences arising from the translation of the financial statements of entities of which the functional currency is not RMB.

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	Capital reserve	Other reserve	Fair value reserve	Accumulated losses	Total
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2018	127	1,356	–	(289,549)	(288,066)
Loss for the year	–	–	–	(268,025)	(268,025)
Change in fair value of equity investments at fair value through other comprehensive income, net of tax	–	–	23	–	23
Share-based payment expenses	–	3,023	–	–	3,023
At 31 December 2018 and 1 January 2019	<u>127</u>	<u>4,379</u>	<u>23</u>	<u>(557,574)</u>	<u>(553,045)</u>
Loss for the year	–	–	–	(424,896)	(424,896)
Capital contribution from shareholders	591,346	–	–	–	591,346
Change in fair value of equity investments at fair value through other comprehensive income, net of tax	–	–	1,425	–	1,425
Share-based payment expenses	–	5,126	–	–	5,126
At 31 December 2019	<u>591,473</u>	<u>9,505</u>	<u>1,448</u>	<u>(982,470)</u>	<u>(380,044)</u>
Loss for the period	–	–	–	(98,736)	(98,736)
Capital contribution from shareholders	721,835	–	–	–	721,835
Share-based payment expenses	–	1,931	–	–	1,931
At 31 March 2020	<u>1,313,308</u>	<u>11,436</u>	<u>1,448</u>	<u>(1,081,206)</u>	<u>244,986</u>

27. SHARE AWARD

The Company adopted a share award scheme for certain personnel in order to recognise and reward the contribution of certain employees to the growth and development of the Group, and retain certain eligible employees for the continual operation and development of the Group. Before the reorganization of the Company, certain employees (the “Granted Employees”) are granted share options of Rongchang Pharmaceuticals and the Company.

Pursuant to the share award during the period from the year of 2015 to 2017, 724,070 share options in Rongchang Pharmaceuticals were granted to fourteen selected employees of the Company and the earliest vesting date is 1 January 2020. There is no other performance target required except the eligible participant remains as an employee of Rongchang Pharmaceuticals and its subsidiaries for five years after the grant dates.

Pursuant to the share award during the year ended 31 December 2018, 1,370,000 share options in Rongchang Pharmaceuticals were granted to fifteen selected employees of the Company and the earliest vesting date is 1 January 2023. There is no other performance target required except the eligible participant remains as an employee of Rongchang Pharmaceuticals and its subsidiaries for five years after the grant dates.

Pursuant to the share award during the year ended 31 December 2019, 265,000 share options in the Company were granted to nine selected employees of the Company and the earliest vesting date is 1 June 2024. There are no other performance targets required except the eligible participant remains as an employee of the Group for five years after the grant dates.

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In December 2019, the equity interests in the Company was transferred to the then ultimate shareholders of the Company pursuant to a reorganization (“Reorganization”). Prior to the Reorganization, the Company was wholly-owned by Rongchang Pharmaceuticals. Upon completion of the Reorganization, the Company and Rongchang Pharmaceuticals were owned immediately by the then ultimate shareholders of the Company. Yantai Rongjian Enterprise Management Center LP (“Rongjian”) and Yantai Rongyi Enterprise Management Center LP (“Rongyi”) were established by the then ultimate shareholders of the Company as the Group’s additional ultimate shareholders. The purpose to establish Rongjian and Rongyi (collectively, the “PRC Share Incentive Entities”) was to hold incentive shares of the Company for the Granted Employees during the period of the years from 2015 to 2019. Some Granted Employees became limited partners of Rongjian and Rongyi which subscribed for restricted stocks of the Company (“restricted stocks”) and share options of Rongchang Pharmaceuticals in the PRC Share Incentive Entities to replace the original share options in Rongchang Pharmaceuticals granted during the period of the year from 2015 to 2018. Other Granted Employees became limited partners of Rongjian and Rongyi which subscribed for restricted stocks of the Company to replace the share options in the Company granted to them during the year of 2019. The percentage of partnership in the PRC Share Incentive Entities was determined based on percentage of his/her previous granted options and percentage of shares in the Company as held by the PRC Share Incentive Entities. There was no significant change to the terms of the employee incentive plans.

The Granted employees shall not have any right to receive any shares of the Company awarded to them and all other interests attributable thereto unless and until the legal and beneficial ownership of the awarded shares of the Company were transferred to them and the legal and beneficial ownership of those awarded shares vested to them. When the Granted Employees ceased to be the Group’s employees, the unvested shares of the Company would be retained by the PRC Share Incentive Entities.

The Granted employees shall not have any right to transfer the legal and beneficial ownership in the PRC Share Incentive Entities until the original vesting date defined in the employee incentive plans granted prior to the Reorganization.

The fair value of services received in return for share options granted is measured by reference to the fair value of share options granted. The fair value of the share options granted is measured at the grant date at the market value of the share options and is determined using an option pricing model and a discounted cash flow model, adjusted for the exclusion of expected dividends to be received in the vesting period.

On the day of the Reorganization, restricted stocks of the Company and share options of Rongchang Pharmaceuticals were granted to the Granted Employees through their respective ownership interest in the PRC Share Incentive Entities, the Company identified these new equity instruments as replacement equity instruments for the original granted share options in Rongchang Pharmaceuticals and the Company. The Company accounted for the granting of replacement equity instruments in the same way as a modification of the original grant of equity instruments. The incremental fair value granted is the difference between the fair value of the restricted stock of the Group and the net fair value of the share options granted on the day of the Reorganization. The incremental fair value represented additional share based payment which is charged to profit or loss over the remaining vesting periods under straight-line amortisation basis.

During the Relevant Periods and the three months ended 31 March 2019, share award expenses (including above incremental share based payments) of RMB3,023,000, RMB5,126,000, RMB1,931,000 and RMB756,000, respectively, were charged to profit or loss.

28. NOTES TO THE CONSOLIDATED STATEMENTS OF CASH FLOWS

(a) Major non-cash transactions

In July 2019, the capital of the Group was increased by RMB600,000,000, of which RMB95,913,000 was included in the paid-in capital and the remaining RMB504,087,000 was included in the capital reserve. The transaction was made by converting the amount of RMB600,000,000 due to Rongchang Pharmaceuticals, the original parent of the Group (before December 2019), into equity.

During the Relevant Periods and the three months ended 31 March 2019, the Group endorsed bills receivable amounting to RMB86,769,000, RMB27,079,000, nil and RMB25,621,000 for the purchase of equipment, construction services and raw materials.

During the Relevant Periods and the three months ended 31 March 2019, the Group had non-cash additions to right-of-use assets of RMB4,990,000, RMB2,456,000, nil and RMB1,713,000, and non-cash additions to lease liabilities of RMB4,990,000, RMB2,456,000, nil and RMB1,713,000, respectively, in respect of lease arrangements for plant and machinery, buildings and land use rights.

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(b) Changes in liabilities arising from financing activities

	Interest-bearing borrowings	Other borrowings and interest payables included in other payables and accruals	Lease liabilities
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
At 1 January 2018	–	524,411	286
Changes from financing cash flows	–	294,087	(1,029)
New lease arrangements	–	–	4,990
Accretion of interest	–	–	264
Interest expense	–	39,791	–
At 31 December 2018 and 1 January 2019	<u>–</u>	<u>858,289</u>	<u>4,511</u>
Changes from financing cash flows	60,000	286,333	(1,932)
Capital contributions from shareholders	–	(600,000)	–
New lease arrangements	–	–	2,456
Accretion of interest	–	–	329
Interest expense	–	43,460	–
At 31 December 2019 and 1 January 2020	<u>60,000</u>	<u>588,082</u>	<u>5,364</u>
At 1 January 2020	60,000	588,082	5,364
Changes from financing cash flows	(60,000)	(73,325)	(411)
Remeasurement upon early termination of leases	–	–	(582)
Accretion of interest	–	–	66
Interest expense	–	8,904	–
At 31 March 2020	<u>–</u>	<u>523,661</u>	<u>4,437</u>
At 1 January 2019	–	858,289	4,511
Changes from financing cash flows	–	103,930	(405)
Accretion of interest	–	–	84
New lease arrangements	–	–	1,713
Interest expense	–	12,346	–
At 31 March 2019 (Unaudited)	<u>–</u>	<u>974,565</u>	<u>5,903</u>

During the Relevant Periods and the three months ended 31 March 2019, the total cash outflow for leases included in the consolidated statements of cash flows was RMB1,283,000, RMB2,757,000, RMB705,000 and RMB405,000, respectively, among which RMB254,000, RMB825,000, RMB294,000 and nil was within operating activities, RMB1,029,000, RMB1,932,000, RMB411,000 and RMB405,000 was within financing activities.

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29. PLEDGE OF ASSETS

Details of the Group’s assets pledged for the Group’s bills payable and bank borrowings are included in notes 13, 20 and 23 to the Historical Financial Information.

30. COMMITMENTS

(a) The Group had the following capital commitments at the end of each of the Relevant Periods:

	As at 31 December		As at 31 March
	2018	2019	2020
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Contracted, but not provided for:			
Purchases of items of property, plant and equipment	25,020	653,810	761,694
	25,020	653,810	761,694

(b) The Group had the following lease contracts not yet commenced at the end of each of the Relevant Periods:

	As at 31 December		As at 31 March
	2018	2019	2020
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Lease contracts not yet commenced:			
Within one year	–	–	4,482
Two to five years	–	–	10,187
Over five years	–	–	–
	–	–	14,669

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31. RELATED PARTY TRANSACTIONS

The Directors are of the view that the following companies are related parties that have material transactions or balances with the Group during the Relevant Periods.

(a) Name and relationships of the related parties

Name	Relationship
MabPlex International Ltd. (“煙台邁百瑞國際生物醫藥有限公司”) (“MabPlex International”)	(i)
CelluPro Biotechnology Ltd. (“煙台賽普生物技術有限公司”) (“CelluPro Biotechnology”)	(i)
Yantai Yeda International Biomedical Innovation Incubator Center Ltd. (“煙台業達國際生物醫藥創新孵化中心有限公司”) (“Yeda International”)	(i)
Rongchang Pharmaceuticals (“煙台榮昌製藥股份有限公司”)	(ii)
Yantai Lida Pharmaceutical Co., Ltd. (“煙台立達醫藥有限公司”) (“Lida Pharmaceutical”)	(i)
Beijing Rongchang Medical Research Institute Ltd. (“北京榮昌藥物研究院有限公司”) (“Rongchang Medical Research”)	(i)
Shanghai Kangkang Medical Technology Center (“上海康康醫藥科技中心”) (“Kangkang Medical”)	(i)
Rongchang Pharmaceuticals (Zibo), Ltd. (“榮昌製藥(淄博)有限公司”) (“Rongchang Pharmaceuticals (Zibo)”)	(i)
Yantai Dasike Biotechnology Co., Ltd. (“煙台達思生物科技股份有限公司”) (“Dasike Biotechnology”)	(i)
Yantai Rongchang Biomedical Industry Technology Research Institute Co., Ltd. (“煙台榮昌生物醫藥產業技術研究院有限公司”) (“Rongchang Biomedical Industry”)	(i)
Dr. Fu Daotian (“傅道田”)	President
Dr. Fang Jianmin (“房健民”)	Chief executive officer and Executive Director
Mr. Wang Weidong (“王威東”)	Chairman and Executive Director

Notes:

- (i) These entities were subsidiaries of Rongchang Pharmaceuticals which was majority-owned by the Concert Parties as defined below during the Relevant Periods.
- (ii) Rongchang Pharmaceuticals held 100% equity interest in the Company before December 2019.

The English names of the companies registered in the PRC represent the best efforts made by the management of the Company in directly translating the Chinese names of these companies as no English names have been registered.

Before the reorganization of the Group in December 2019, all of the Group’s paid-in capital was injected by Rongchang Pharmaceuticals. Pursuant to the Group reorganization, the paid-in capital of the Group held by Rongchang Pharmaceuticals has been transferred to various shareholders in proportion to their respective shareholdings in Rongchang Pharmaceuticals.

Pursuant to a concert party agreement dated 16 April 2020 entered into by and amongst Dr. Fang Jianmin, Mr. Wang Weidong, Mr. Lin Jian, Mr. Xiong Xiaobin, Dr. Wang Liqiang, Mr. Wang Xudong, Mr. Deng Yong, Ms. Yang Minhua, Mr. Wen Qingkai and Mr. Wei Jianliang, Yantai Rongda Venture Capital Center (Limited Partnership), RongChang Holding Group Ltd., and I-NOVA Limited (together, the “Concert Parties”), the Concert Parties confirmed that they have acted in concert in the management, decision-making and all major decisions of the Group since 1 January 2017, and they have agreed to continue to act in concert and reach consensus on any proposal presented to the general meeting of the shareholders of the Company for voting. In the event they fail to reach such consensus, each of Concert Parties shall exercise their respective indirect voting rights in accordance with majority vote amongst the Concert Parties. The Concert Parties collectively held 56.35% of equity interests in the Company.

In the opinion of the Directors, the Company was controlled by the Concert Parties during the Relevant Periods and up to the date of this report.

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(b) In addition to the transactions detailed elsewhere in these financial statements, the Group had the following transactions with related parties during the Relevant Periods and the three months ended 31 March 2019:

	Notes	Year ended 31 December		Three months ended 31 March	
		2018	2019	2019	2020
		RMB'000	RMB'000	RMB'000	RMB'000
Sales of materials					
Dasike Biotechnology	(i)	–	1	–	–
Rongchang Biomedical Industry	(i)	–	–	–	1
MabPlex International	(i)	13	1,451	1	–
CelluPro Biotechnology	(i)	1,505	155	–	19
Yeda International	(i)	–	1	1	–
		<u>1,518</u>	<u>1,608</u>	<u>2</u>	<u>20</u>
Rendering of services					
Rongchang Pharmaceuticals (Zibo)					
	(i)	11,321	–	–	–
MabPlex International	(i)	–	474	–	–
CelluPro Biotechnology	(i)	372	215	–	17
		<u>11,693</u>	<u>689</u>	<u>–</u>	<u>17</u>
Rental income					
MabPlex International	(i)	–	2,449	544	408
Lida Pharmaceutical	(i)	–	3	–	17
		<u>–</u>	<u>2,452</u>	<u>544</u>	<u>425</u>
Sales of equipment					
MabPlex International	(i)	1,177	–	–	–
CelluPro Biotechnology	(i)	122	194	–	–
		<u>1,299</u>	<u>194</u>	<u>–</u>	<u>–</u>
Purchases of materials					
MabPlex International	(i)	–	–	–	41
CelluPro Biotechnology	(i)	2,258	1,450	–	826
Yeda International	(i)	–	2	–	–
		<u>2,258</u>	<u>1,452</u>	<u>–</u>	<u>867</u>
Purchases of services					
Kangkang Medical	(i)	–	390	–	1,209
MabPlex International	(i)	–	10,236	–	2,868
Rongchang Pharmaceuticals	(i)	15,103	21,619	4,557	5,681
Yeda International	(i)	57	–	–	–
		<u>15,160</u>	<u>32,245</u>	<u>4,557</u>	<u>9,758</u>

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	Notes	Year ended 31 December		Three months ended 31 March	
		2018 RMB’000	2019 RMB’000	2019 RMB’000 (Unaudited)	2020 RMB’000
Purchases of equipment					
MabPlex International	(i)	1,194	–	–	–
Rongchang Pharmaceuticals	(i)	292	–	–	–
Yeda International	(i)	–	685	–	–
		<u>1,486</u>	<u>685</u>	<u>–</u>	<u>–</u>
Purchases of land use right					
MabPlex International	(i)	–	–	–	4,589
		<u>–</u>	<u>–</u>	<u>–</u>	<u>4,589</u>
Rental expenses					
MabPlex International	(i)	–	512	–	–
Yeda International	(i)	665	388	180	257
		<u>665</u>	<u>900</u>	<u>180</u>	<u>257</u>
Interest expenses on borrowings					
Rongchang Pharmaceuticals	(ii)	39,791	41,649	12,392	8,012
		<u>39,791</u>	<u>41,649</u>	<u>12,392</u>	<u>8,012</u>
Borrowings from a related party					
Rongchang Pharmaceuticals	(ii)	380,875	584,054	110,969	134,753
		<u>380,875</u>	<u>584,054</u>	<u>110,969</u>	<u>134,753</u>
Repayment of interest expenses					
Rongchang Pharmaceuticals	(ii)	–	86,860	–	–
		<u>–</u>	<u>86,860</u>	<u>–</u>	<u>–</u>
Repayment of borrowings					
Rongchang Pharmaceuticals	(ii)	86,788	209,050	7,039	207,186
		<u>86,788</u>	<u>209,050</u>	<u>7,039</u>	<u>207,186</u>
Repayment of lease liabilities					
Yeda International	(i)	–	1,824	–	364
		<u>–</u>	<u>1,824</u>	<u>–</u>	<u>364</u>
Interest expenses on lease liabilities					
Yeda International	(i)	230	281	74	61
		<u>230</u>	<u>281</u>	<u>74</u>	<u>61</u>

Notes:

- (i) During the Relevant Periods and the three months ended 31 March 2019, the transactions were carried out in accordance with the terms and conditions similar to those offered to/by third parties in the ordinary course of business.
- (ii) During the Relevant Periods and the three months ended 31 March 2019, the Group obtained borrowings from Rongchang Pharmaceuticals. The loans are unsecured and payable on demand. The Directors consider that the applicable interest rates are determined in accordance with the prevailing market borrowing rates. During the Relevant Periods and the three months ended 31 March 2019, RMB86.77 million, RMB25.62 million, nil and RMB25.62 million, respectively, of the borrowings were obtained by the endorsement of bank acceptance bills to the Group by Rongchang Pharmaceuticals. Further details of the bills endorsement are disclosed in note 28 (a) to the Historical Financial Information.

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(c) Outstanding balances with related parties:

The Group

	As at 31 December		As at
	2018	2019	31 March
	RMB'000	RMB'000	2020
			RMB'000
Trade and bills payables			
MabPlex International	1,540	–	41
CelluPro Biotechnology	2,619	1,577	2,403
Rongchang Pharmaceuticals (Zibo)	–	8,930	8,930
	<u>4,159</u>	<u>10,507</u>	<u>11,374</u>
Prepayments, other receivables and other assets			
MabPlex International	1,366	–	2,800
CelluPro Biotechnology	2,283	–	12
Yeda International	115	64	–
	<u>3,764</u>	<u>64</u>	<u>2,812</u>
Other payables and accruals			
Dr. Fang Jianmin	70	–	–
Dr. Fu Daotian	–	4	13
Yeda International	721	2,392	686
MabPlex International	2,962	10,275	971
Rongchang Pharmaceuticals	897,956	603,184	546,517
Lida Pharmaceutical	648	6	6
Rongchang Medical Research	304	–	–
	<u>902,661</u>	<u>615,861</u>	<u>548,193</u>
Lease liabilities			
Yeda International	<u>4,040</u>	<u>4,734</u>	<u>4,437</u>

Note:

The Group’s balances due from and due to the related companies are trade in nature, unsecured, interest-free and have no fixed terms of repayment, except for the amounts of RMB858,288,000, RMB588,082,000 and RMB523,661,000 due to Rongchang Pharmaceuticals which was repayable on demand with interest rates at 6.25%, 5.955% and 5.955%, respectively, per annum, as at the end of each of the Relevant Periods.

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	As at 31 December		As at
	2018	2019	31 March
	RMB'000	RMB'000	2020
			RMB'000
Trade and bills payables			
MabPlex International	1,540	–	41
CelluPro Biotechnology	2,619	1,577	2,403
Rongchang Pharmaceuticals (Zibo)	–	8,930	8,930
	<u>4,159</u>	<u>10,507</u>	<u>11,374</u>
Prepayments, other receivables and other assets			
MabPlex International	1,366	–	2,800
CelluPro Biotechnology	2,283	–	–
Ruimeijing (Beijing) Pharmaceutical Technology Co., Ltd.	–	1	–
Yeda International	115	64	12
	<u>3,764</u>	<u>65</u>	<u>2,812</u>
Other payables and accruals			
Dr. Fang Jianmin	70	–	–
Dr. Fu Daotian	–	4	13
Yeda International	721	2,392	686
Yantai Tongyi Pharmaceuticals, Ltd.	15,000	–	–
Ruimeijing (Beijing) Pharmaceutical Technology Co., Ltd.	–	–	3,095
MabPlex International	2,759	10,079	767
Rongchang Pharmaceuticals	897,956	603,184	546,517
Lida Pharmaceutical	648	6	6
Rongchang Medical Research	304	–	–
	<u>917,458</u>	<u>615,665</u>	<u>551,084</u>
Lease liabilities			
Yeda International	4,040	4,734	4,437
	<u>4,040</u>	<u>4,734</u>	<u>4,437</u>

Note:

The Group’s balances due from and due to the related companies are trade in nature, unsecured, interest-free and have no fixed terms of repayment, except for the amounts of RMB858,288,000, RMB588,082,000 and RMB523,661,000 due to Rongchang Pharmaceuticals which was repayable on demand with interest rates at 6.25%, 5.955% and 5.955%, respectively, per annum, as at the end of each of the Relevant Periods.

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(d) Compensation of key management personnel of the Group:

	Year ended 31 December		Three months ended 31 March	
	2018 <i>RMB'000</i>	2019 <i>RMB'000</i>	2019 <i>RMB'000</i>	2020 <i>RMB'000</i>
			<i>(Unaudited)</i>	
Salaries, allowances and benefits in kind	1,480	2,187	423	659
Performance related bonuses	147	564	44	169
Pension scheme contributions	70	102	24	21
Total compensation paid to key management personnel	<u>1,697</u>	<u>2,853</u>	<u>491</u>	<u>849</u>

Further details of directors’ and supervisors’ remuneration are included in note 8 to the Historical Financial Information.

(e) Other transactions with related parties

During the Relevant Periods, Mr. Wang Weidong had provided the Group with banking facilities guarantees, one of which was from September 2019 to September 2022 and the maximum amount was RMB70,000,000, the other of which was from February 2020 to February 2023 and the maximum amount was RMB143,000,000.

During the year of 2018, the Group provided Rongchang Pharmaceuticals’ loan of RMB36,000,000 with a credit guarantee, which was from September 2018 to August 2019.

32. FINANCIAL INSTRUMENTS BY CATEGORY

The carrying amounts of each of the categories of financial instruments as at the end of each of the Relevant Periods are as follows:

As at 31 December 2018

Financial assets

	Financial assets at fair value through other comprehensive income	Financial assets at amortised cost	Total
	Equity investments <i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Equity investments designated at fair value through other comprehensive income	10,023	–	10,023
Debt investments at fair value through other comprehensive income	10,969	–	10,969
Financial assets included in prepayments, other receivables and other assets	–	4,501	4,501
Cash and cash equivalents	–	5,069	5,069
	<u>20,992</u>	<u>9,570</u>	<u>30,562</u>

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Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB’000</i>
Trade and bills payables	16,745
Financial liabilities included in other payables and accruals	957,023
Lease liabilities	4,511
	<u>978,279</u>

As at 31 December 2019

Financial assets

	Financial assets at fair value through other comprehensive income		
	Equity investments	Financial assets at amortised cost	Total
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Equity investments designated at fair value through other comprehensive income	11,448	–	11,448
Debt investments at fair value through other comprehensive income	1,058	–	1,058
Financial assets included in prepayments, other receivables and other assets	–	2,064	2,064
Pledged deposits	–	40,866	40,866
Cash and cash equivalents	–	34,545	34,545
	<u>12,506</u>	<u>77,475</u>	<u>89,981</u>

Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB’000</i>
Trade and bills payables	67,697
Financial liabilities included in other payables and accruals	691,424
Interest-bearing bank borrowings	60,000
Lease liabilities	5,364
	<u>824,485</u>

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As at 31 March 2020

Financial assets

	Financial assets at fair value through other comprehensive income	Financial assets at amortised cost		Total
	Equity investments			
	<i>RMB’000</i>	<i>RMB’000</i>		<i>RMB’000</i>
Equity investments designated at fair value through other comprehensive income	11,448	–		11,448
Financial assets included in prepayments, other receivables and other assets	–	5,820		5,820
Pledged deposits	–	23,256		23,256
Cash and cash equivalents	–	287,603		287,603
	11,448	316,679		328,127

Financial liabilities

	Financial liabilities at amortised cost
	<i>RMB’000</i>
Trade and bills payables	57,521
Financial liabilities included in other payables and accruals	589,400
Lease liabilities	4,437
	651,358

33. FAIR VALUE AND FAIR VALUE HIERARCHY OF FINANCIAL INSTRUMENTS

Management has assessed that the fair values of pledged deposits, cash and cash equivalents, trade and bills payables, financial assets included in prepayments, other receivables and other assets, financial liabilities included in other payables and accruals, and interest-bearing bank borrowings approximate to their carrying amounts largely due to the short term maturities of these instruments.

The carrying amounts of the Group’s financial instruments, other than those with carrying amounts that reasonably approximate to fair values, are as follows:

	31 December 2018		31 December 2019		31 March 2020	
	Carrying amount	Fair value	Carrying amount	Fair value	Carrying amount	Fair value
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Financial assets						
Debt investments at fair value through other comprehensive income	10,969	10,969	1,058	1,058	–	–
Equity investments designated at fair value through other comprehensive income	10,023	10,023	11,448	11,448	11,448	11,448
	20,992	20,992	12,506	12,506	11,448	11,448

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The Group’s finance department headed by the financial controller is responsible for determining the policies and procedures for the fair value measurement of financial instruments. The finance department reports directly to the financial controller. At the end of each of the Relevant Periods, the finance department analyses the movements in the values of financial instruments and determines the major inputs applied in the valuation. The valuation is reviewed and approved by the financial controller. The valuation process and results are discussed with the Directors periodically for annual financial reporting.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale.

The fair values of unlisted equity investments designated at fair value through other comprehensive income, have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms.

Below is a summary of significant unobservable inputs to the valuation of financial instruments together with a quantitative sensitivity analysis as at the end of each of the Relevant Periods:

	Valuation technique	Significant unobservable input	Range	Sensitivity of fair value to the input
Unlisted equity investments	Discounted cash flow method	Discount rate	31 December 2018: 14.34%	Increase/ (decrease) in 1% would result in a (decrease)/increase in fair value by (RMB3,889,000)/ RMB8,072,000
			31 December 2019: 14.08%	Increase/ (decrease) in 1% would result in a (decrease)/increase in fair value by (RMB4,642,000)/ RMB4,896,000
			31 March 2020: 14.08%	Increase/ (decrease) in 1% would result in a (decrease)/increase in fair value by (RMB4,642,000)/ RMB4,896,000
		Discount for lack of marketability	31 December 2018: 26.94%	Increase/ (decrease) in 5% would result in a (decrease)/increase in fair value by (RMB686,000)/ RMB686,000
			31 December 2019: 28.09%	Increase/ (decrease) in 5% would result in a (decrease)/increase in fair value by (RMB796,000)/ RMB796,000
			31 March 2020: 28.09%	Increase/ (decrease) in 5% would result in a (decrease)/increase in fair value by (RMB796,000)/ RMB796,000

The discount for lack of marketability represents the amounts of premiums and discounts determined by the Group that market participants would take into account when pricing the investments.

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Fair value hierarchy

The following tables illustrate the fair value measurement hierarchy of the Group’s financial instruments:

Assets measured at fair values:

As at 31 December 2018

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Equity investments designated at fair value through other comprehensive income	–	–	10,023	10,023
Debt investments at fair value through other comprehensive income	–	10,969	–	10,969
	–	10,969	10,023	20,992

As at 31 December 2019

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Equity investments designated at fair value through other comprehensive income	–	–	11,448	11,448
Debt investments at fair value through other comprehensive income	–	1,058	–	1,058
	–	1,058	11,448	12,506

As at 31 March 2020

	Fair value measurement using			Total
	Quoted prices in active markets (Level 1)	Significant observable inputs (Level 2)	Significant unobservable inputs (Level 3)	
	RMB’000	RMB’000	RMB’000	RMB’000
Equity investments designated at fair value through other comprehensive income	–	–	11,448	11,448

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The movements in fair value measurements within Level 3 during the Relevant Periods are as follows:

	Year ended 31 December		Three months ended
	2018	2019	31 March
	RMB'000	RMB'000	2020 RMB'000
Equity investments designated at fair value through other comprehensive income			
At beginning of the year/period	10,368	10,023	11,448
Total gain recognised in other comprehensive income	1,964	1,425	–
Purchases	10,000	–	–
Disposals	(12,309)	–	–
At end of the year/period	<u>10,023</u>	<u>11,448</u>	<u>11,448</u>

The Group did not have any financial liabilities measured at fair value as at the end of each of the Relevant Periods.

During the Relevant Periods, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

Liabilities for which fair values are disclosed:

As at 31 December 2019

	Fair value measurement using			Total RMB'000
	Quoted prices in active markets (Level 1) RMB'000	Significant observable inputs (Level 2) RMB'000	Significant unobservable inputs (Level 3) RMB'000	
Interest-bearing bank borrowings	–	60,000	–	<u>60,000</u>

The Group did not have any liabilities for which fair values are disclosed as at 31 December 2018 and 31 March 2020.

34. FINANCIAL RISK MANAGEMENT OBJECTIVES AND POLICIES

The Group’s principal financial instruments mainly comprise cash and bank balances and interest-bearing borrowings. The main purpose of these financial instruments is to raise finance for the Group’s operations. The Group has various other financial assets and liabilities such as bills receivable, other receivables, trade and bills payables and other payables, which arise directly from its operations.

The main risks arising from the Group’s financial instruments are foreign currency risk, credit risk and liquidity risk. The Directors review and agree policies for managing each of these risks and they are summarised below.

Currency risk

Foreign currency risk is the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between RMB and other currencies in which the Group conducts business may affect the Group’s financial condition and results of operations.

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The following table demonstrates the sensitivity at the end of each of the Relevant Periods to a reasonably possible change in foreign currency exchange rate, with all other variables held constant, of the Group’s loss before tax (due to changes in the fair values of monetary assets and liabilities) and the Group’s equity.

	<u>Increase/ (decrease) in the rate of foreign currency</u>	<u>Increase/ (decrease) in loss before tax</u>	<u>Increase/ (decrease) in equity</u>
	%	RMB’000	RMB’000
31 December 2018			
If RMB weakens against USD	5	(38)	38
If RMB strengthens against USD	(5)	38	38
31 December 2019			
If RMB weakens against USD	5	(12)	(12)
If RMB strengthens against USD	(5)	12	12
31 March 2020			
If RMB weakens against USD	5	(791)	(791)
If RMB strengthens against USD	(5)	791	791

Credit Risk

The Group trades only with recognised and creditworthy parties. Receivable balances are monitored on an ongoing basis and the Group’s exposure to bad debts is not significant. The credit risk of the Group’s other financial assets, which comprise cash and cash equivalents, pledged deposits and financial assets included in prepayments, other receivables and other assets, arises from default of the counterparty, with a maximum exposure equal to the carrying amounts of these instruments.

For other receivables and other assets, management makes periodic collective assessment as well as individual assessment on the recoverability of other receivables based on historical settlement records and past experience. The Directors believe that there is no material credit risk inherent in the Group’s outstanding balance of other receivables.

As at the end of the each of the Relevant Periods, cash and cash equivalents were deposited in financial institutions in high quality without significant credit risk.

Maximum exposure and year-end staging

The tables below show the credit quality and the maximum exposure to credit risk based on the Group’s credit policy, which is mainly based on past due information unless other information is available without undue cost or effort, and year-end staging classification as at the end of each of the Relevant Periods.

The amounts presented are gross carrying amounts for financial assets.

As at 31 December 2018

	<u>12-month ECLs</u>	<u>Lifetime ECLs</u>		
	<u>Stage 1</u>	<u>Stage 2</u>	<u>Stage 3</u>	<u>Total</u>
	RMB’000	RMB’000	RMB’000	RMB’000
Debt investments at fair value through other comprehensive income	10,969	–	–	10,969
Financial assets included in prepayments, other receivables and other assets	4,501	–	–	4,501
Cash and cash equivalents	5,069	–	–	5,069
	<u>20,539</u>	<u>–</u>	<u>–</u>	<u>20,539</u>

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As at 31 December 2019

	12-month ECLs	Lifetime ECLs		
	Stage 1	Stage 2	Stage 3	Total
	RMB'000	RMB'000	RMB'000	RMB'000
Debt investments at fair value through other comprehensive income	1,058	–	–	1,058
Financial assets included in prepayments, other receivables and other assets	2,064	–	–	2,064
Pledged deposits	40,866	–	–	40,866
Cash and cash equivalents	34,545	–	–	34,545
	<u>78,533</u>	<u>–</u>	<u>–</u>	<u>78,533</u>

As at 31 March 2020

	12-month ECLs	Lifetime ECLs		
	Stage 1	Stage 2	Stage 3	Total
	RMB'000	RMB'000	RMB'000	RMB'000
Financial assets included in prepayments, other receivables and other assets	5,820	–	–	5,820
Pledged deposits	23,256	–	–	23,256
Cash and cash equivalents	287,603	–	–	287,603
	<u>316,679</u>	<u>–</u>	<u>–</u>	<u>316,679</u>

Liquidity risk

The Group monitors and maintains a level of cash and cash equivalents deemed adequate by the management of the Group to finance the operations and mitigate the effects of fluctuations in cash flows.

The maturity profile of the Group’s financial liabilities as at the end of each of the Relevant Periods, based on the contractual undiscounted payments, is as follows:

As at 31 December 2018

	On demand	Within one year	One to five years	Over five years	Total
	RMB'000	RMB'000	RMB'000	RMB'000	RMB'000
Trade and bills payables	–	16,745	–	–	16,745
Financial liabilities included in other payables and accruals	957,023	–	–	–	957,023
Lease liabilities	–	1,345	3,737	–	5,082
	<u>957,023</u>	<u>18,090</u>	<u>3,737</u>	<u>–</u>	<u>978,850</u>

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As at 31 December 2019

	<u>On demand</u>	<u>Within one year</u>	<u>One to five years</u>	<u>Over five years</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade and bills payables	–	67,697	–	–	67,697
Financial liabilities included in other payables and accruals	691,424	–	–	–	691,424
Interest-bearing bank borrowings	–	60,000	–	–	60,000
Lease liabilities	–	1,851	4,087	–	5,938
	<u>691,424</u>	<u>129,548</u>	<u>4,087</u>	<u>–</u>	<u>825,059</u>

As at 31 March 2020

	<u>On demand</u>	<u>Within one year</u>	<u>One to five years</u>	<u>Over five years</u>	<u>Total</u>
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Trade and bills payables	–	57,521	–	–	57,521
Financial liabilities included in other payables and accruals	589,400	–	–	–	589,400
Lease liabilities	–	1,366	3,549	–	4,915
	<u>589,400</u>	<u>58,887</u>	<u>3,549</u>	<u>–</u>	<u>651,836</u>

Capital management

The primary objectives of the Group’s capital management are to safeguard the Group’s ability to continue as a going concern and to maintain healthy capital ratios in order to support its business and maximise shareholders’ value.

The Group manages its capital structure and makes adjustments to it in light of changes in economic conditions and the risk characteristics of the underlying assets. To maintain or adjust the capital structure, the Group may return capital to shareholders or issue new shares. The Group is not subject to any externally imposed capital requirements. No changes were made in the objectives, policies or processes for managing capital during the Relevant Periods.

35. EVENTS AFTER THE RELEVANT PERIODS

(a) The impact of COVID-19

There has been an outbreak of COVID-19 around the world.

The management of the Company currently expected that clinical trials in and outside of Mainland China will not be significantly affected by the outbreak of COVID-19. The Directors believe that, based on the information available as of the date of this report, the outbreak of COVID-19 would not result in a material disruption to the Group’s business operations or material impact on the financial position or financial performance of the Group.

It is uncertain when and whether COVID-19 could be contained globally. The above analysis is made by the management of the Company based on the currently available information concerning COVID-19. The management of the Company cannot assure that the outbreak of COVID-19 will not further escalate or have a material adverse effect on the Group’s results of operations.

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(b) The joint stock reform of the Company

Pursuant to the shareholders’ resolutions dated 12 May 2020 and the Promoters’ agreement dated 11 May 2020, the then existing shareholders of the Company agreed to convert the Company into a joint stock limited liability company. The net assets of the Company as of the conversion base date, including paid-in capital, other reserve and accumulated losses, amounting to RMB427,631,000 were converted into 401,819,202 ordinary shares at RMB1.00 each. The excess of the net assets converted over the nominal value of the ordinary shares was credited to the Company’s capital reserve. Upon the completion of registration with the Yantai Administration for Industry and Commerce on 12 May 2020, the Company was converted into a joint stock company with limited liability under the PRC Company Law, and renamed from RemeGen, Ltd. to RemeGen Co., Ltd. In accordance with business license of the Company, the Company became joint stock limited liability company on 12 May 2020.

(c) The share award in the Offshore Share Incentive Entity

In December 2019, RC-Biology Investment Ltd. (“RC-Biology”), a company limited by shares and incorporated in the British Virgin Islands was established by the Concert Parties of the Group and acquired shares from the original shareholder of the Group as the Group’s immediate shareholders. The purpose to establish RC-Biology was to hold incentive shares for the foreign employees.

On 5 May 2020, 8,624,319 special shares of the RC-Biology (“Special Shares”) were granted to nine foreign employees (the “Purchaser”). According to the agreement, upon each twelve-month anniversary of the [REDACTED] of the Group, 20% of the Special Shares that are not vested (“Unvested Shares”) will become Special Shares that are vested (“Vested Shares”), if the Purchaser provides continuous full-time employment to the Company or its affiliates through each such anniversary date. No Unvested Shares will become Vested Shares after the date on which Purchaser’s employment terminates.

36. SUBSEQUENT FINANCIAL STATEMENTS

No audited financial statements have been prepared by the Group or any of its subsidiaries in respect of any period subsequent to 31 March 2020.

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

The following information does not form part of the Accountants’ Report from Ernst & Young, Certified Public Accountants, Hong Kong, the Company’s reporting accountants, as set out in Appendix I to this document, and is included for information purposes only. The unaudited pro forma financial information should be read in conjunction with the “Financial Information” section in this document and the Accountants’ Report set out in Appendix I to this document.

A. UNAUDITED PRO FORMA STATEMENT OF ADJUSTED CONSOLIDATED NET TANGIBLE ASSETS

The following unaudited pro forma statement of adjusted consolidated net tangible assets of the Group prepared in accordance with Rule 4.29 of the Hong Kong Listing Rules and with reference to Accounting Guideline 7 “Preparation of Pro Forma Financial Information for inclusion in Investment Circulars” issued by the Hong Kong Institute of Certified Public Accountants is to illustrate the effect of the [REDACTED] on the consolidated net tangible assets of the Group attributable to owners of the parent as at 31 March 2020 as if the [REDACTED] had taken place on that date.

The unaudited pro forma statement of adjusted consolidated net tangible assets of the Group has been prepared for illustrative purposes only and because of its hypothetical nature, it may not provide a true picture of the consolidated net tangible assets attributable to owners of the Company had the [REDACTED] been completed as at 31 March 2020 or at any future date.

	Audited consolidated net tangible assets attributable to owners of the parent as at 31 March 2020	Estimated net [REDACTED] from the [REDACTED]	Unaudited pro forma adjusted consolidated net tangible assets	Unaudited pro forma adjusted consolidated net tangible assets per Share	
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB</i>	<i>HK\$</i>
	<i>(Note 1)</i>	<i>(Note 2)</i>		<i>(Note 3)</i>	<i>(Note 4)</i>

Based on an [REDACTED] of HK\$[REDACTED] per Share	404,283	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Based on an [REDACTED] of HK\$[REDACTED] per Share	404,283	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Notes:

- (1) The consolidated net tangible assets attributable to owners of the parent as at 31 March 2020 is arrived at after deducting intangible assets of RMB1,933,000 from the audited net assets attributable to owners of the parent of RMB406,216,000 as at 31 March 2020, as shown in the Accountants’ Report, the text of which is set out in Appendix I to this document.
- (2) The estimated net [REDACTED] from the [REDACTED] are based on estimated low end and high end [REDACTED] of HK\$[REDACTED] or HK\$[REDACTED] per Share after deduction of the [REDACTED] fees and other related expenses payable by the Company and do not take into account any share which may be sold and offered upon exercise of the [REDACTED].
- (3) The unaudited pro forma adjusted consolidated net tangible assets per Share is arrived at after adjustments referred to in the preceding paragraphs and on the basis that [REDACTED] Shares are in issue assuming the [REDACTED] has been completed on 31 March 2020.
- (4) The unaudited pro forma adjusted consolidated net tangible assets per Share are converted into Hong Kong dollars at an exchange rate of RMB0.9181 to HK\$1.00.
- (5) No adjustment has been made to the unaudited pro forma adjusted consolidated net tangible assets to reflect any trading results or other transactions of the Group entered into subsequent to 31 March 2020.

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

APPENDIX II UNAUDITED PRO FORMA FINANCIAL INFORMATION

[REDACTED]

APPENDIX III

PROPERTY VALUATION REPORT

The following is the text of a letter, summary of values and valuation certificates prepared for the purpose of incorporation in this document received from Jones Lang LaSalle Corporate Appraisal and Advisory Limited, an independent valuer, in connection with its valuation as at 31 March 2020 of the property held by RemeGen Co., Ltd.



Jones Lang LaSalle Corporate Appraisal and Advisory Limited
7th Floor, One Taikoo Place
979 King's Road Hong Kong
tel +852 2846 5000 fax +852 2169 6001
Company Licence No.: C-030171

[●] 2020

The Board of Directors
RemeGen Co., Ltd
58 Middle Beijing Road,
Yantai Economic
Technological
Development Zone,
Shandong Province,
PRC

Dear Sirs,

In accordance with your instructions to value the property held by RemeGen Co., Ltd (the “**Company**”) and its subsidiaries (hereinafter together referred to as the “**Group**”) in the People’s Republic of China (the “**PRC**”), we confirm that we have carried out inspections, made relevant enquiries and searches and obtained such further information as we consider necessary for the purpose of providing you with our opinion of the market value of the property interest as at 31 March 2020 (the “**valuation date**”).

Our valuation is carried out on a market value basis. Market value is defined as “the estimated amount for which an asset or liability should exchange on the valuation date between a willing buyer and a willing seller in an arm’s-length transaction after proper marketing and where the parties had each acted knowledgeably, prudently and without compulsion”.

Due to the nature of the buildings and structures of the property interest in Group I which are held and occupied by the Group and the particular location in which they are situated, there are unlikely to be relevant market comparable sales readily available, the relevant property interest has been valued by the cost approach with reference to their depreciated replacement costs.

APPENDIX III

PROPERTY VALUATION REPORT

Depreciated replacement cost is defined as "the current cost of replacing an asset with its modern equivalent asset less deductions for physical deterioration and all relevant forms of obsolescence and optimization." It is based on an estimate of the market value for the existing use of the land, plus the current cost of replacement of the improvements, less deduction for physical deterioration and all relevant forms of obsolescence and optimization. In arriving at the value of the land portion, reference has been made to the sales evidence as available in the locality. The depreciated replacement cost of the property interest is subject to adequate potential profitability of the concerned business. In our valuation, it applies to the whole of the complex or development as a unique interest, and no piecemeal transaction of the complex or development is assumed.

We have attributed no commercial value to the property interest in Group II, which has not been assigned to the Group as at the valuation date, thus the title of the property is not vested in the Group.

Our valuation has been made on the assumption that the seller sells the property interest in the market without the benefit of a deferred term contract, leaseback, joint venture, management agreement or any similar arrangement, which could serve to affect the value of the property interest.

No allowance has been made in our report for any charge, mortgage or amount owing on any of the property interest valued nor for any expense or taxation which may be incurred in effecting a sale. Unless otherwise stated, it is assumed that the property is free from encumbrances, restrictions and outgoings of an onerous nature, which could affect its value.

In valuing the property interest, we have complied with all requirements contained in Chapter 5 and Practice Note 12 of the Rules Governing the Listing of Securities issued by the Stock Exchange of Hong Kong Limited; the RICS Valuation – Global Standards published by the Royal Institution of Chartered Surveyors; the HKIS Valuation Standards published by the Hong Kong Institute of Surveyors, and the International Valuation Standards issued by the International Valuation Standards Council.

We have relied to a very considerable extent on the information given by the Group and have accepted advice given to us on such matters as tenure, planning approvals, statutory notices, easements, particulars of occupancy, lettings, and all other relevant matters.

We have been shown copies of various title documents including State-owned Land Use Rights Certificate, Real Estate Title Certificate and other official plans relating to the property interest and have made relevant enquiries. Where possible, we have examined the original documents to verify the existing title to the property interest in the PRC and any material encumbrance that might be attached to the property interest or any tenancy amendment. We have relied considerably on the advice given by the Company's PRC legal advisers – King & Wood Mallesons, concerning the validity of the property interest in the PRC.

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We have not carried out detailed measurements to verify the correctness of the areas in respect of the property but have assumed that the areas shown on the title documents and official site plans handed to us are correct. All documents and contracts have been used as reference only and all dimensions, measurements and areas are approximations. No on-site measurement has been taken.

We have inspected the exterior and, where possible, the interior of the property. However, we have not carried out investigation to determine the suitability of the ground conditions and services for any development thereon. Our valuation has been prepared on the assumption that these aspects are satisfactory. Moreover, no structural survey has been made, but in the course of our inspection, we did not note any serious defect. We are not, however, able to report whether the property is free of rot, infestation or any other structural defect. No tests were carried out on any of the services.

Inspection of the property was carried out on 8 May 2020 by Ms. Maggie Ding who has obtained the master degree with a specialization in Professional Accounting and has 3 years' experience in the valuation of properties in the PRC.

We have had no reason to doubt the truth and accuracy of the information provided to us by the Group. We have also sought confirmation from the Group that no material factors have been omitted from the information supplied. We consider that we have been provided with sufficient information to arrive an informed view, and we have no reason to suspect that any material information has been withheld.

The outbreak of the Novel Coronavirus (COVID-19), declared by the World Health Organisation as a "Global Pandemic" on the 11th March 2020, has impacted global financial markets. Travel restrictions have been implemented by many countries. Market activity is being impacted in many sectors. As at the valuation date, we consider that we can attach less weight to previous market evidence for comparison purposes, to inform opinions of value. Indeed, the current response to COVID-19 means that we are faced with an unprecedented set of circumstances on which to base a judgement. Our valuation is therefore reported on the basis of "material valuation uncertainty" as per VPS 3 and VPGA 10 of the RICS Red Book Global. Consequently, less certainty – and a higher degree of caution – should be attached to our valuation than would normally be the case. Given the unknown future impact that COVID-19 might have on the real estate market, we recommend that you keep the valuation of this property under frequent review."

We are instructed to provide our opinion of value as per the valuation date only. It is based on economic, market and other conditions as they exist on, and information made available to us as of, the valuation date and we assume no obligation to update or otherwise revise these materials for events in the time since then. In particular, the outbreak of COVID-19 has caused much disruption to economic activities around the world. This disruption has increased the risk towards the achievability of the rental/income projections/assumptions. It may also have a negative impact towards investment sentiment, and hence any form of required rate of return as well as liquidity of any asset. As of the report date, it is uncertain how long the disruption

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PROPERTY VALUATION REPORT

will last and to what extent it will affect the economy. As a result it causes volatility and uncertainty that values may change significantly and unexpectedly even over short periods. The period required to negotiate a sale may also extend considerably beyond the normally expected period, which would also reflect the nature and size of the property. Readers are reminded that we do not intend to provide an opinion of value as of any date after the valuation date in this report.

Unless otherwise stated, all monetary figures stated in this report are in Renminbi (RMB).

Our summary of value and valuation certificate are attached below for your attention.

Yours faithfully,

For and on behalf of

Jones Lang LaSalle Corporate Appraisal and Advisory Limited

Eddie T. W. Yiu

MRICS MHKIS RPS (GP)

Senior Director

Note: Eddie T.W. Yiu is a Chartered Surveyor who has 26 years' experience in the valuation of properties in Hong Kong and the PRC as well as relevant experience in the Asia-Pacific region.

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PROPERTY VALUATION REPORT

SUMMARY OF VALUES

Group I – Property interest owned and occupied by the Group in the PRC

<u>No.</u>	<u>Property</u>	Market value in existing state as at 31 March 2020
		<i>RMB</i>
1.	2 parcels of land, 3 buildings and various structures located at 58 Middle Beijing Road, Yantai Economic Technological Development Zone Shandong Province PRC	200,400,000
	Sub-total:	200,400,000

Group II – Property interest contracted to be acquired by the Group in the PRC

<u>No.</u>	<u>Property</u>	Market value in existing state as at 31 March 2020
		<i>RMB</i>
2.	A parcel of land located at No. B-41 District and the southern side of Nanjing Avenue Economic Development Zone Yantai City Shandong Province PRC	No commercial value
	Sub-total:	Nil
	Grand total:	<u><u>200,400,000</u></u>

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VALUATION CERTIFICATE

Group I – Property interest held and occupied by the Group in the PRC

<u>No.</u>	<u>Property</u>	<u>Description and tenure</u>	<u>Particulars of occupancy</u>	<u>Market value in existing state as at 31 March 2020</u>
				<i>RMB</i>
1.	2 parcels of land, 3 buildings and various structures located at 58 Middle Beijing Road, Yantai Economic Technological Development Zone, Shandong Province, PRC	<p>The property comprises 2 parcels of land with a total site area of approximately 37,975.97 sq.m. and 3 buildings and various ancillary structures erected thereon which were completed in various stages between 2015 and 2018.</p> <p>The 3 buildings have a total gross floor area of approximately 36,999.40 sq.m. These three buildings are industrial buildings for research & development, production and office use.</p> <p>The structures mainly include sheds, boundary walls and roads.</p> <p>Apart from the completed buildings, there is an antibody building which was under construction ("CIP building") on the subject land parcels as at the valuation date. As advised by the Group, the CIP building is scheduled to be completed in December 2021. Upon completion, the CIP building will have a gross floor area of approximately 36,159.48 sq.m. The total investment cost (include construction cost and equipment cost) is estimated to be approximately RMB323,403,500, of which approximately RMB18,120,000 had been paid as at the valuation date.</p> <p>The land use rights of the property have been granted for a term with the expiry dates on 6 June 2061 and 7 June 2062 for industrial use.</p>	<p>As at the valuation date, except for portions of the property with a total lettable area of approximately 3,440.25 sq.m. which were rented to two connected parties for cold storage, office and laboratory uses, the remaining portions of the property were occupied by the Group for research & development, production and office purpose, whilst the CIP building was under construction.</p>	200,400,000

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PROPERTY VALUATION REPORT

Notes:

1. Pursuant to 2 State-owned Land Use Rights Certificates – Yan Guo Yong (2012) Di No. 50042 and Lu (2020) Yan Tai Shi Kai Bu Dong Chan Quan Di No. 0002262, the land use rights of the property with a total site area of approximately 37,975.97 sq.m. have been granted to the Company for a term with the expiry dates on 6 June 2061 and 7 June 2062 for industrial use.
2. Pursuant to 3 Real Estate Title Certificates – Lu (2017) Yan Tai Shi Kai Bu Dong Chan Quan Di No. 0001936, Lu (2017) Yan Tai Shi Kai Bu Dong Chan Quan Di No. 0001935 and Lu (2019) Yan Tai Shi Kai Bu Dong Chan Quan Di No. 0013848, 3 buildings with a total gross floor area of approximately 36,999.40 sq.m. are owned by the Company.
3. Pursuant to a Construction Work Planning Permit – Jian Zi Di No. 370601202000019 in favour of the Company, the CIP building with a gross floor area of approximately 36,159.48 sq.m. has been approved for construction.
4. Pursuant to a Construction Work Commencement Permit – No. 370603202003180101 in favour of the Company, permission by the relevant local authority was given to commence the construction of the CIP building with a gross floor area of approximately 36,159.48 sq.m.
5. We have been provided with a legal opinion regarding the property interest by the Company’s PRC legal advisers, which contains, inter alia, the following:
 - (a) Pursuant to 2 Mortgage Contracts, the building ownership rights of portions of the property are subject to 2 mortgages in favour of 2 independent third parties; and
 - (b) The Company is legally and validly in possession of the property. The Company has the rights to occupy, use, lease, transfer or otherwise dispose of the property and upon consent from the mortgagee to transfer, lease, re-mortgage or otherwise dispose of the building ownership rights of the mortgaged portion of the property.
6. Pursuant to a Tenancy Agreement entered into between the Company and a connected party Yantai Lida Medicine Co., Ltd (煙台立達醫藥有限公司, “Lida”), portions of the property with a total lettable area of approximately 41.47 sq.m. is leased out for cold storage use with the expiry date on 31 December 2020. The total annual rental as at the valuation date is RMB74,400, exclusive of water and electricity charges.
7. Pursuant to a Tenancy Agreement entered into between the Company and a connected party Yantai MabPlex International Biomedical Co., Ltd. (煙台邁百瑞國際生物醫藥有限公司, “MabPlex”), portions of the property with a total lettable area of approximately 3,398.78 sq.m. is leased out for office and laboratory use with the expiry date on 31 December 2022. The total annual rental as at the valuation date is RMB1,081,200, exclusive of water and electricity charges.
8. As the property is the major asset held by the Group, we are of the view that the property is a material property. Details of the material property
 - (a) General description of location of the property : The property is located at 58 Middle Beijing Road, Yantai Economic Technological Development Zone, Shandong Province, PRC. It is surrounded by Baiyinhe Park and residential developments namely Zhongjian Yuehai He Garden and Penghu Bay Square. The property is close to the national highway G228, enjoying convenient accessibility and is well served by public transportation, such as bus route No. 28 and No. 216. Yantai Penglai International Airport and Yantai West Station are less than half an hour driving distance away from the property.

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- (b) Details of encumbrances, liens, pledges, mortgages against the property : Pursuant to a Mortgage Contract – 882022019 Gao Di Zi Di No. 00017, the ownership rights of a manufacturing and research & development building of the property with a gross floor area of approximately 15,592.52 sq.m. are subject to a mortgage as a security in favour of Bank of Qingdao, Yantai Branch for bank loan at a maximum amount of RMB26,000,000 with the security term from 17 June 2019 to 17 June 2022.
- Pursuant to a Mortgage Contract – Yan Yin (2019110112200200082), the ownership rights of a manufacturing and office building of the property with a gross floor area of approximately 21,406.88 sq.m. are subject to a mortgage as a security in favour of Yantai Bank, Development Zone Branch for bank loan at a maximum amount of RMB66,147,200 with the security term from 6 September 2019 to 6 September 2022.
- (c) Environmental Issue : As advised by the Group, according to two construction project environmental approval opinions, portions of the property have been completed and passed the environmental protection inspection acceptance on 6 September 2016 and 20 March 2019. The remaining portions of the property are expected to be completed and passed the environmental protection inspection acceptance in 2022.
- (d) Details of investigations, notices, pending litigation, breaches of law or title defects : Nil.
- (e) Future plans for construction, renovation, improvement or development of the property and estimated associated costs : As advised by the Group, the CIP building is scheduled to be completed in December 2021. The total investment is estimated to be approximately RMB323,403,500.

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Group II – Property interest contracted to be acquired by the Group in the PRC

No.	Property	Description and tenure	Particulars of occupancy	Market value in existing state as at 31 March 2020
				<i>RMB</i>
2.	A parcel of land, located at No. B-41 District and the southern side of Nanjing Avenue Economic Development Zone Yantai City Shandong Province PRC	<p>The property comprises a parcel of land with a site area of approximately 69,726.50 sq.m. which was vacant as at the valuation date.</p> <p>As advised by the Group, three antibody buildings, an integrated warehouse, a quality control building, two ancillary buildings and various important production related fixed building facilities and equipment are scheduled to commence the construction in 2021 and are expected to be completed in 2024.</p>	As at the valuation date, the property was bare land.	No commercial value

Notes:

1. According to a State-owned Land Use Rights Confirmation Letter of Transaction for Online Listing and Transfer (“國有建設用地使用權網上掛牌出讓成交確認書”) dated 24 March 2020, entered into between the Company and Yantai Natural Resources and Planning Bureau, the Company agreed to purchase the land use rights of a parcel of land with a site area of 69,726.50 sq.m. at a total consideration of RMB29,290,000.
2. As at the valuation date, the property has not been assigned to the Company and thus the title of the property has not been vested in the Company. Therefore, we have attributed no commercial value to the property.
3. As advised by the Company, a sum of approximately RMB18,683,978.03 had been incurred by the Company to do the land levelling and project design of this property up to the valuation date.
4. We have been provided with a legal opinion regarding the property interest by the Company’s PRC legal advisers, which contains, inter alia, the following:
 - a. The aforesaid State-owned Land Use Rights Confirmation Letter of Transaction for Online Listing and Transfer is legal and valid.

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TAXATION OF SECURITY HOLDERS

The taxation of income and capital gains of holders of H Shares is subject to the laws and practices of the PRC and of jurisdictions in which holders of H Shares are residents or otherwise subject to tax. The following summary of certain relevant taxation provisions is based on current effective laws and practices, and no predictions are made about changes or adjustments to relevant laws or policies, and no comments or suggestions will be made accordingly. The discussion has no intention to cover all possible tax consequences resulting from the investment in H Shares, nor does it take the specific circumstances of any particular investor into account, some of which may be subject to special regulations. Accordingly, you should consult your own tax advisor regarding the tax consequences of an investment in H Shares. The discussion is based upon laws and relevant interpretations in effect as of the date of this document, which is subject to change or adjustment and may have retrospective effect.

No issues on PRC or Hong Kong taxation other than income tax, capital appreciation and profit tax, business tax/appreciation tax, stamp duty and estate duty was referred in the discussion. Prospective investors are urged to consult their financial advisors regarding the PRC, Hong Kong and other tax consequences of owning and disposing of H Shares.

The PRC Taxation

Taxation on Dividends

Individual Investor

Pursuant to the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法》), which was latest amended on August 31, 2018 and the Implementation Provisions of the Individual Income Tax Law of the PRC (《中華人民共和國個人所得稅法實施條例》), which was latest amended on December 18, 2018 (hereinafter collectively referred to as the “IIT Law”), dividends distributed by PRC enterprises are subject to individual income tax levied at a flat rate of 20%. For a foreign individual who is not a resident of the PRC, the receipt of dividends from an enterprise in the PRC is normally subject to individual income tax of 20% unless specifically exempted by the tax authority of the State Council or reduced by relevant tax treaty.

Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal

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Evasion issued by the State Administration of Taxation (《<內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排>第五議定書》), which came into effect on December 6, 2019, adds a criteria for the qualification of entitlement to enjoy treaty benefits. Although there may be other provisions under the Arrangement, the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Arrangement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81).

Enterprise Investors

In accordance with the Corporate Income Tax Law of the PRC (《中華人民共和國企業所得稅法》) issued by NPC on March 16, 2007, implemented on January 1, 2008 and subsequently amended on February 24, 2017 and December 29, 2018 and the Implementation Provisions of the Corporate Income Tax Law of the PRC (《中華人民共和國企業所得稅法實施條例》) issued by the State Council on December 6, 2007, came into effect on January 1, 2008 and amended in 2019 (hereinafter collectively referred to as the "CIT Law"), a nonresident enterprise is generally subject to a 10% corporate income tax on PRC-sourced income (including dividends received from a PRC resident enterprise), if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. The aforesaid income tax payable for nonresident enterprises are deducted at source, where the payer of the income are required to withhold the income tax from the amount to be paid to the nonresident enterprise when such payment is made or due.

The Circular of the SAT on Issues Relating to the Withholding and Remitting of Corporate Income Tax by PRC Resident Enterprises on Dividends Distributed to Overseas Non-Resident Enterprise Shareholders of H Shares (《國家稅務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得稅有關問題的通知》) (Guo Shui Han [2008] No.897), which was issued and implemented by the SAT on November 6, 2008, further clarified that a PRC-resident enterprise must withhold corporate income tax at a rate of 10% on the dividends of 2008 and onwards that it distributes to overseas nonresident enterprise shareholders of H Shares. In addition, the Response to Questions on Levying Corporate Income Tax on Dividends Derived by Nonresident Enterprise from Holding Stock such as B Shares (《關於非居民企業取得B股等股票股息徵收企業所得稅問題的批覆》) (Guo Shui Han [2009] No.394), which was issued by the SAT and implemented on July 24, 2009, further provides that any PRC-resident enterprise listed on overseas stock exchanges must withhold and remit corporate income tax at a rate of 10% on dividends of 2008 and onwards that it distributes to nonresident enterprises. Such tax rates may be further modified pursuant to the tax treaty or agreement that China has entered into with the relevant jurisdictions, where applicable.

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Pursuant to the Arrangement between the Mainland and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion (《內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排》), which was signed on August 21, 2006, the Chinese Government may levy taxes on the dividends paid by a Chinese company to Hong Kong residents (including natural persons and legal entities) in an amount not exceeding 10% of the total dividends payable by the Chinese company. If a Hong Kong resident directly holds 25% or more of the equity interest in a Chinese company, then such tax shall not exceed 5% of the total dividends payable by the Chinese company. The Fifth Protocol of the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region on the Avoidance of Double Taxation and the Prevention of Fiscal Evasion issued by the State Administration of Taxation (《<內地和香港特別行政區關於對所得避免雙重徵稅和防止偷漏稅的安排>第五議定書》), which came into effect on December 6, 2019, adds a criteria for the qualification of entitlement to enjoy treaty benefits. Although there may be other provisions under the Arrangement, the treaty benefits under the criteria shall not be granted in the circumstance where relevant gains, after taking into account all relevant facts and conditions, are reasonably deemed to be one of the main purposes for the arrangement or transactions which will bring any direct or indirect benefits under this Arrangement, except when the grant of benefits under such circumstance is consistent with relevant objective and goal under the Arrangement. The application of the dividend clause of tax agreements is subject to the requirements of PRC tax law and regulation, such as the Notice of the State Administration of Taxation on the Issues Concerning the Application of the Dividend Clauses of Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81).

Tax Treaties

Non-resident investors residing in jurisdictions which have entered into treaties or adjustments for the avoidance of double taxation with the PRC are entitled to a reduction of the Chinese corporate income tax imposed on the dividends received from PRC companies. The PRC currently has entered into Avoidance of Double Taxation Treaties or Arrangements with a number of countries and regions including Hong Kong Special Administrative Region, Macau Special Administrative Region, Australia, Canada, France, Germany, Japan, Malaysia, the Netherlands, Singapore, the United Kingdom and the United States. Non-PRC resident enterprises entitled to preferential tax rates in accordance with the relevant taxation treaties or arrangements are required to apply to the Chinese tax authorities for a refund of the corporate income tax in excess of the agreed tax rate, and the refund application is subject to approval by the Chinese tax authorities.

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Taxation on Share Transfer

VAT and Local Additional Tax

Pursuant to the Notice on Fully Implementing the Pilot Reform for the Transition from Business Tax to Value-added Tax (《關於全面推開營業稅改徵增值稅試點的通知》) (Cai Shui [2016] No. 36) (hereinafter referred to as “**Notice 36**”), which was implemented on May 1, 2016, entities and individuals engaged in the services sale in the PRC are subject to VAT and “engaged in the services sale in the PRC” means that the seller or buyer of the taxable services is located in the PRC. Circular 36 also provides that transfer of financial products, including transfer of the ownership of marketable securities, shall be subject to VAT at 6% on the taxable revenue (which is the balance of sales price upon deduction of purchase price), for a general or a foreign VAT taxpayer. However, individuals who transfer financial products are exempt from VAT.

According to these regulations, if the holder is a nonresident individual, the PRC VAT is exempted from the sale or disposal of H shares; if the holder is a nonresident enterprise and the H-share buyer is an individual or entity located outside China, the holder is not necessarily required to pay the PRC VAT, but if the H-share buyer is an individual or entity located in China, the holder may be required to pay the PRC VAT.

However, in view of no clear regulations, whether the non-Chinese resident enterprises are required to pay the PRC VAT for the disposal of H shares, there is still uncertainty in the interpretation and application of the above provisions.

At the same time, VAT payers are also required to pay urban maintenance and construction tax, education surtax and local education surcharge (hereinafter collectively referred to as “Local Additional Tax”), which shall be usually subject to 12% of the VAT payable (if any).

Income tax

Individual Investors

According to the IIT Law, gains on the transfer of equity interests in the PRC resident enterprises are subject to individual income tax at a rate of 20%.

Pursuant to the Circular of the MOF and the State Administration of Taxation on Declaring that Individual Income Tax Continues to be Exempted over Income of Individuals from the Transfer of Shares (《財政部、國家稅務總局關於個人轉讓股票所得繼續暫免徵收個人所得稅的通知》) (Cai Shui Zi [1998] No. 61) issued by the MOF and the State Administration of Taxation on March 30, 1998, from January 1, 1997, income of individuals from transfer of the shares of listed enterprises continues to be exempted from individual income tax. The State Administration of Taxation has not expressly stated whether it will continue to exempt tax on income of individuals from transfer of the shares of listed enterprises in the latest amended Individual Income Tax Law.

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However, on December 31, 2009, the MOF, the State Administration of Taxation and CSRC jointly issued the Circular on Related Issues on Levying Individual Income Tax over the Income Received by Individuals from the Transfer of Listed Shares Subject to Sales Limitation (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的通知》) (Cai Shui [2009] No. 167), which came into effect on January 1, 2010, which states that individuals' income from the transfer of listed shares obtained from the public offering of listed companies and transfer market on the Shanghai Stock Exchange and the Shenzhen Stock Exchange shall continue to be exempted from individual income tax, except for the relevant shares which are subject to sales restriction (as defined in the Supplementary Notice on Issues Concerning the Levy of Individual Income Tax on Individuals' Income from the Transfer of Restricted Stocks of Listed Companies (《關於個人轉讓上市公司限售股所得徵收個人所得稅有關問題的補充通知》) (Cai Shui [2010] No. 70) jointly issued and implemented by such departments on November 10, 2010). As of the Latest Practicable Date, no aforesaid provisions have expressly provided that individual income tax shall be levied from non-Chinese resident individuals on the transfer of shares in PRC resident enterprises listed on overseas stock exchanges, and no such income tax was levied by PRC tax authorities in practice.

Enterprise Investors

In accordance with the CIT Law, a nonresident enterprise is generally subject to corporate income tax at the rate of a 10% on PRC-sourced income, including gains derived from the disposal of equity interests in a PRC resident enterprise, if it does not have an establishment or premise in the PRC or has an establishment or premise in the PRC but its PRC-sourced income has no real connection with such establishment or premise. Such income tax payable for nonresident enterprises are deducted at source, where the payer of the income are required to withhold the income tax from the amount to be paid to the nonresident enterprise when such payment is made or due. Such tax may be reduced or exempted pursuant to relevant tax treaties or agreements on avoidance of double taxation.

Stamp Duty

Pursuant to the Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例》), which was issued on August 6, 1998 and latest amended on January 8, 2011, and the Implementation Provisions of Provisional Regulations of the PRC on Stamp Duty (《中華人民共和國印花稅暫行條例施行細則》), which came into effect on October 1, 1988, PRC stamp duty only applies to specific taxable document executed or received within the PRC, having legally binding force in the PRC and protected under the PRC laws, thus the requirements of the stamp duty imposed on the transfer of shares of PRC listed companies shall not apply to the acquisition and disposal of H Shares by non-PRC investors outside of the PRC.

Estate Duty

As of the date of this document, no estate duty has been levied in the PRC under the PRC laws.

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TAXATION AND FOREIGN EXCHANGE

HONG KONG TAXATION

Taxation on Dividends

No tax is payable in Hong Kong in respect of dividends paid by our Company.

Profits Tax

Hong Kong profits tax will not be payable by any Shareholders (other than Shareholders carrying on a trade, profession or business in Hong Kong and holding the Shares for trading purposes) on any capital gains made on the sale or other disposal of the Shares. Shareholders should take advice from their own professional advisers as to their particular tax position.

Stamp Duty

Hong Kong stamp duty will be charged on the sale and purchase of Shares at the current rate of 0.2% of the consideration for, or (if greater) the value of, the Shares being sold or purchased, whether or not the sale or purchase is on or off the Stock Exchange. The Shareholder selling the Shares and the purchaser will each be liable for one-half of the amount of Hong Kong stamp duty payable upon such transfer. In addition, a fixed duty of HK\$5 is currently payable on any instrument of transfer of Shares.

Estate Duty

Hong Kong estate duty was abolished effective from February 11, 2006. No Hong Kong estate duty is payable by Shareholders in relation to the Shares owned by them upon death.

PRINCIPAL TAXATION OF OUR COMPANY IN THE PRC

Enterprise Income Tax

According to the EIT Law, a resident enterprise shall pay EIT on its income originating from both inside and outside PRC at an EIT rate of 25%. Foreign invested enterprises in the PRC falls into the category of resident enterprises, which shall pay EIT for the income originated from domestic and overseas sources at an EIT rate of 25%.

Value-added Tax

According to the Provisional Regulations of the PRC on Value-Added Tax (《中華人民共和國增值稅暫行條例》), which was promulgated by the State Council on December 13, 1993 and latest amended on November 19, 2017 (the “**Regulations on VAT**”), and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value-added Tax (《中華人民共和國增值稅暫行條例實施細則》), which was promulgated by the Ministry of Finance of the PRC (the “**MOF**”), came into effect on December 25, 1993 and latest amended on October 28, 2011, all the taxpayers engaged in sales of goods or provision of processing,

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repair and maintenance labor or import of goods in China shall be subject to value-added tax. Unless specified by the Regulations on VAT, for the sales or import of goods by general taxpayers, the VAT rate shall be 17%; for provision of processing, repair and maintenance labor by taxpayers, the VAT rate shall be 17%; for export of goods by taxpayers, the VAT rate shall be nil, unless otherwise provided. According to the Circular of the Ministry of Finance and the State Administration of Foreign Exchange on Adjusting Value-added Tax Rates (《財政部、國家稅務總局關於調整增值稅稅率的通知》), which was issued on April 4, 2018 and came into effect on May 1, 2018, where a tax payer engages in a taxable sales activity for the value-added tax purpose or imports goods, the previous applicable reduced 17% and 11% tax rates are adjusted to be 16% and 10%, respectively. According to the Announcement on Deepening Policies in relation to Value-added Tax Reform (《關於深化增值稅改革有關政策的公告》) which was promulgated on March 20, 2019 and became effective on April 1, 2019, the VAT rates are reduced to 13% and 9%, respectively.

TAXATION OF OUR COMPANY IN HONG KONG

Profits Tax

Our Company will be subject to Hong Kong profits tax in respect of profits arising in or derived from Hong Kong at the current rate of 16.5%. Dividend income derived by our Company from its subsidiaries will be excluded from Hong Kong profits tax.

FOREIGN EXCHANGE

The lawful currency of the PRC is Renminbi, which is currently subject to foreign exchange control and cannot be freely converted into foreign currency. The SAFE, with the authorization of the PBOC, is empowered with the functions of administering all matters relating to foreign exchange, including the enforcement of foreign exchange control regulations.

The Regulations on Foreign Exchange Control of the PRC (《中華人民共和國外匯管理條例》) (the “**Foreign Exchange Control Regulations**”), which was issued by the State Council on January 29, 1996 and implemented on April 1, 1996 classifies all international payments and transfers into current items and capital items. Most of the current items are not subject to the approval of foreign exchange administration agencies, while capital items are subject to such approval. Pursuant to the Foreign Exchange Control Regulations amended on January 14, 1997 and August 1, 2008, the PRC will not impose any restriction on international current payments and transfers.

According to the Regulations for the Administration of Settlement, Sale and Payment of Foreign Exchange (《結匯、售匯及付匯管理規定》) (the “**Settlement Regulations**”), which was promulgated by the PBOC on June 20, 1996 and implemented on July 1, 1996, it removes other restrictions on convertibility of foreign exchange under current items, while imposing existing restrictions on foreign exchange transactions under capital account items.

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According to the Announcement on Improving the Reform of the Renminbi Exchange Rate Formation Mechanism (《關於完善人民幣匯率形成機制改革的公告》) (the PBOC Announcement [2005] No. 16), which was issued by the PBOC and implemented on July 21, 2005, the PRC has started to implement a managed floating exchange rate system in which the exchange rate would be determined based on market supply and demand and adjusted with reference to a basket of currencies since July 21, 2005. Therefore, the Renminbi exchange rate was no longer pegged to the U.S. dollar. PBOC would publish the closing price of the exchange rate of the Renminbi against trading currencies such as the U.S. dollar in the interbank foreign exchange market after the closing of the market on each working day, as the central parity of the currency against Renminbi transactions on the following working day.

On August 5, 2008, the State Council promulgated the revised Foreign Exchange Control Regulations, which have made substantial changes to the foreign exchange supervision system of the PRC. First, it has adopted an approach of balancing the inflow and outflow of foreign exchange. Foreign exchange income received overseas can be repatriated or deposited overseas, and foreign exchange and foreign exchange settlement funds under the capital account are required to be used only for purposes as approved by the competent authorities and foreign exchange administrative authorities; second, it has improved the RMB exchange rate formation mechanism based on market supply and demand; third, in the event that international revenues and expenditure occur or may occur a material imbalance, or the national economy encounters or may encounter a severe crisis, the State may adopt necessary safeguard and control measures on international revenues and expenditure; fourth, it has enhanced the supervision and administration of foreign exchange transactions and grant extensive authorities to the SAFE to enhance its supervisory and administrative powers.

According to the relevant laws and regulations in the PRC, PRC enterprises (including foreign investment enterprises) which need foreign exchange for current item transactions may, without the approval of the foreign exchange administrative authorities, effect payment through foreign exchange accounts opened at the designated foreign exchange bank, on the strength of valid transaction receipts and proof. Foreign investment enterprises which need foreign exchange for the distribution of profits to their shareholders and PRC enterprises which, in accordance with regulations, are required to pay dividends to their shareholders in foreign exchange (such as our Company) may, on the strength of resolutions of the board of directors or the shareholders' meeting on the distribution of profits, effect payment from foreign exchange accounts at the designated foreign exchange bank, or effect exchange and payment at the designated foreign exchange bank.

According to the Decisions on Matters including Canceling and Adjusting a Batch of Administrative Approval Items (《國務院關於取消和調整一批行政審批項目等事項的決定》) (Guo Fa [2014] No. 50) which was promulgated by the State Council on October 23, 2014, it decided to cancel the approval requirement of the SAFE and its branches for the remittance and settlement of the proceeds raised from the overseas listing of the foreign shares into RMB domestic accounts.

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According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) (Hui Fa [2014] No. 54) issued by the SAFE and implemented on December 26, 2014, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of State Administration of Foreign Exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the prospectus and other disclosure documents.

According to the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving Policies for the Foreign Exchange Administration of Direct Investment (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》) (Hui Fa [2015] No. 13), which was issued by the SAFE on February 13, 2015 and came into effect on June 1, 2015, it has canceled two of the administrative examination and approval items, being the confirmation of foreign exchange registration under domestic direct investment and the confirmation of foreign exchange registration under overseas direct investment, instead, banks shall directly examine and handle foreign exchange registration under domestic direct investment and foreign exchange registration under overseas direct investment, and the SAFE and its branch offices shall indirectly regulate the foreign exchange registration of direct investment through banks.

According to the Notice of the State Administration of Foreign Exchange of the PRC on Revolutionizing and Regulating Capital Account Settlement Management Policies (國家外匯管理局關於改革和規範資本項目結匯管理政策的通知) (Hui Fa [2016] No. 16) which was promulgated by the SAFE and implemented on June 9, 2016, foreign currency earnings in capital account that relevant policies of willingness exchange settlement have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions. The tentative percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%, subject to adjust of the SAFE in due time in accordance with international revenue and expenditure situations.

Circular 37

The Circular on Issues Concerning the Administration of Foreign Exchange in Offshore Investments and Financing and Return Investments by Domestic Residents through Special Purpose Vehicles (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》) ("Circular 37") was promulgated and implemented by the SAFE on July 4, 2014. According to Circular 37, domestic residents, individuals and entities shall apply to the SAFE for registration of foreign exchange for offshore investment before making contributions to special purpose vehicles with domestic and overseas legal assets or equities. In addition, any domestic resident who is a shareholder of an overseas special purpose vehicle shall complete the registration formality of foreign exchange alteration for offshore investment with the SAFE in a timely manner in the event of any change of significant matters of such overseas special

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TAXATION AND FOREIGN EXCHANGE

purpose vehicle such as capital increase/decrease, equity transfer or swap, merge and spin-off. The subsequent foreign exchange business (including remittance of profits and dividend) of a domestic resident who fails to comply with the registration requirements as set out in Circular 37 may be restricted. Domestic residents that have made contributions to special purpose vehicles with domestic and overseas legal assets or equities without the required registration of foreign exchange for offshore investment prior to the implementation of Circular 37 shall issue a letter of explanation to the SAFE containing specific reasons. The SAFE shall make a post-registration following the principles of legality and rationality, and impose administrative penalties in case of suspected violation of foreign exchange control regulations.

According to the Circular on Further Simplifying and Improving Policies for the Foreign Exchange Administration Applicable to Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》), which was issued by the SAFE on February 13, 2015 and came into effect on June 1, 2015, banks that have obtained financial institution identification codes from foreign exchange authorities and have connected to the Capital Account Information System with the local foreign exchange authorities may directly handle the registration under Circular 37 and the foreign exchange authorities shall indirectly regulate the foreign exchange registration of direct investment through banks.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

This Appendix summarizes certain aspects of PRC laws and regulations, which are relevant to the Company’s operations and business. Laws and regulations relating to taxation in the PRC are discussed separately in “Appendix VI-Taxation and Foreign Exchange” to this document. This Appendix also contains a summary of certain Hong Kong legal and regulatory provisions, including summaries of certain material differences between the PRC Company Law and the Companies (Winding Up and Miscellaneous Provisions) Ordinance, certain requirements of the Listing Rules and additional provisions required by the Hong Kong Stock Exchange for inclusion in the articles of association of PRC issuers. The principal objective of this summary is to provide potential investors with an overview of the principal laws and regulatory provisions applicable to the Company. This summary is not intended to include all the information which are important to the potential investors. For discussion of laws and regulations which are relevant to the Company’s business, see “Regulatory Overview” in this document.

PRC LAWS AND REGULATIONS

The PRC Legal System

The PRC legal system is based on the PRC Constitution (hereinafter referred to as the “Constitution”) and is made up of written laws, administrative regulations, local regulations, autonomous regulations, separate regulations, rules and regulations of State Council departments, rules and regulations of local governments, laws of special administrative regions and international treaties of which the PRC government is the signatory and other regulatory documents. Court judgments do not constitute legally binding precedents, although they are used for the purposes of judicial reference and guidance.

According to the Constitution and the Legislation Law of the PRC (hereinafter referred to as the “Legislation Law”), the National People’s Congress (hereinafter referred to as the “NPC”) and its Standing Committee are empowered to exercise the legislative power of the State. The NPC has the power to formulate and amend basic laws governing State organs, civil, criminal and other matters. The Standing Committee of the NPC formulates and amends the laws other than those required to be enacted by the NPC and to supplement and amend parts of the laws enacted by the NPC during the adjournment of the NPC, provided that such supplements and amendments are not in conflict with the basic principles of such laws.

The State Council is the highest organ of state administration and has the power to formulate administrative regulations based on the Constitution and laws. The people’s congresses of the provinces, autonomous regions and municipalities and their standing committees may formulate local regulations based on the specific circumstances and actual needs of their respective administrative areas, provided that such regulations do not contravene any provision of the Constitution, laws or administrative regulations. The people’s congresses of cities divided into districts and their respective standing committees may formulate local regulations on aspects such as urban and rural construction and management, environmental protection and historical and cultural protection based on the specific circumstances and actual needs of such cities, provided that such local regulations do not contravene any provision of

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

the Constitution, laws, administrative regulations and local regulations of their respective provinces or autonomous regions. If the law provides otherwise on the formulation of local regulations by cities divided into districts, those provisions shall prevail. Such local regulations will become enforceable after being reported to and approved by the standing committees of the people's congresses of the relevant provinces or autonomous regions. The standing committees of the people's congresses of the provinces or autonomous regions shall examine the legality of local regulations submitted for approval, and such approval shall be granted within four months if they are not in conflict with the Constitution, laws, administrative regulations and local regulations of the relevant provinces or autonomous regions. Where, during the examination for approval of local regulations of cities divided into districts by the standing committees of the people's congresses of the provinces or autonomous regions, conflicts are identified with the rules and regulations of the people's governments of the provinces or autonomous regions, a decision should be made to resolve the issue. People's congresses of national autonomous areas have the power to enact autonomous regulations and separate regulations in light of the political, economic and cultural characteristics of the ethnic groups in the areas concerned.

The ministries and commissions of the State Council, PBOC, NAO and the subordinate institutions with administrative functions directly under the State Council may formulate departmental rules and regulations within the permissions of their respective departments based on the laws and administrative regulations, and the decisions and orders of the State Council. Provisions of departmental rules should be the matters related to the enforcement of the laws and administrative regulations, and the decisions and orders of the State Council. The people's governments of the provinces, autonomous regions, municipalities and cities or autonomous prefectures divided into districts may formulate rules and regulations based on the laws, administrative regulations and local regulations of such provinces, autonomous regions and municipalities.

Pursuant to the Resolution of the Standing Committee of the NPC Providing an Improved Interpretation of the Law (《全國人民代表大會常務委員會關於加強法律解釋工作的決議》) passed on June 10, 1981, in cases where the scope of provisions of laws or decrees needs to be further defined or additional stipulations need to be made, the Standing Committee of the NPC shall provide interpretations or make stipulations by means of decrees. Issues related to the application of laws in a court trial should be interpreted by the Supreme People's Court, issues related to the application of laws in a prosecution process of the procuratorate should be interpreted by the Supreme People's Procuratorate, and issues related to laws other than the abovementioned should be interpreted by the State Council and the competent authorities. The State Council and its ministries and commissions are also vested with the power to give interpretations of the administrative regulations and departmental rules which they have promulgated. At the regional level, the power to interpret regional regulations is vested in the regional legislative and administrative authorities which promulgate such regulations.

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The PRC Judicial System

Under the Constitution, the Law of Organization of the People’s Court of the PRC (2018 Revision) (中華人民共和國人民法院組織法(2018修訂)) and the Law of Organization of the People’s Procuratorate of the PRC (2018 Revision) (中華人民共和國人民檢察院組織法(2018修訂)), the people’s courts of the PRC are divided into the Supreme People’s Court, the local people’s courts at all levels and special people’s courts. The local people’s courts at all levels are divided into three levels, namely, the basic people’s courts, the intermediate people’s courts and the higher people’s courts. The basic people’s courts may set up certain people’s tribunals based on the status of the region, population and cases. The Supreme People’s Court shall be the highest judicial organ of the state. The Supreme People’s Court shall supervise the administration of justice by the local people’s courts at all levels and by the special people’s courts. The people’s courts at a higher level shall supervise the judicial work of the people’s courts at lower levels. The people’s procuratorates of the PRC are divided into the Supreme People’s Procuratorate, the local people’s procuratorates at all levels, Military Procuratorates and other special people’s procuratorates. The Supreme People’s Procuratorate shall be the highest procuratorial organ. The Supreme People’s Procuratorate shall direct the work of the local people’s procuratorates at all levels and of the special people’s procuratorates; the people’s procuratorates at higher levels shall direct the work of those at lower levels.

The people’s courts employ a two-tier appellate system, i.e., judgments or rulings of the second instance at the people’s courts are final. A party may appeal against the judgment or ruling of the first instance of a local people’s courts. The people’s procuratorate may present a protest to the people’s courts at the next higher level in accordance with the procedures stipulated by the laws. In the absence of any appeal by the parties and any protest by the people’s procuratorate within the stipulated period, the judgments or rulings of the people’s courts are final. Judgments or rulings of the second instance of the intermediate people’s courts, the higher people’s courts and the Supreme People’s Court and those of the first instance of the Supreme People’s Court are final. However, if the Supreme People’s Court or the people’s courts at the next higher level finds any definite errors in a legally effective final judgment or ruling of the people’s court at a lower level, or if the chief judge of a people’s court at any level finds any definite errors in a legally effective final judgment or ruling of such court, the case can be retried according to judicial supervision procedures.

The Civil Procedure Law of the PRC (《中華人民共和國民事訴訟法》) (hereinafter referred to as the “PRC Civil Procedure Law”) adopted on April 9, 1991 and amended three times on October 28, 2007, August 31, 2012 and June 27, 2017 respectively, prescribes the conditions for instituting a civil action, the jurisdiction of the people’s court, the procedures for conducting a civil action, and the procedures for enforcement of a civil judgment or ruling. All parties to a civil action conducted within the PRC must abide by the PRC Civil Procedure Law. A civil case is generally heard by the court located in the defendant’s place of domicile. The court of jurisdiction in respect of a civil action may also be chosen by explicit agreement among the parties to a contract, provided that the people’s court having jurisdiction should be located at places directly connected with the disputes, such as the plaintiff’s or the defendant’s place of domicile, the place where the contract is executed or signed or the place where the object of the action is located. Meanwhile, such choice shall not in any circumstances contravene the regulations of differential jurisdiction and exclusive jurisdiction.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

A foreign individual, a person without nationality, a foreign enterprise or a foreign organization is given the same litigation rights and obligations as a citizen, a legal person or other organizations of the PRC when initiating actions or defending against litigations at a people’s court. Should a foreign court limit the litigation rights of PRC citizens or enterprises, the PRC court may apply the same limitations to the citizens or enterprises of such foreign country. A foreign individual, a person without nationality, a foreign enterprise or a foreign organization must engage a PRC lawyer in case he or it needs to engage a lawyer for the purpose of initiating actions or defending against litigations at a people’s court. In accordance with the international treaties to which the PRC is a signatory or participant or according to the principle of reciprocity, a people’s court and a foreign court may request each other to serve documents, conduct investigation and collect evidence and conduct other actions on its behalf. A people’s court shall not accommodate any request made by a foreign court which will result in the violation of sovereignty, security or public interests of the PRC.

All parties to a civil action shall perform the legally effective judgments and rulings. If any party to a civil action refuses to abide by a judgment or ruling made by a people’s court or an award made by an arbitration tribunal in the PRC, the other party may apply to the people’s court for the enforcement of the same within two years subject to application for postponed enforcement or revocation. If a party fails to satisfy within the stipulated period a judgment which the court has granted an enforcement approval, the court may, upon the application of the other party, mandatorily enforce the judgment against such party.

Where a party requests for enforcement of an effective judgment or ruling made by a people’s court, but the opposite party or his property is not within the territory of the People’s Republic of China, the party may directly apply to the foreign court with jurisdiction for recognition and enforcement of the judgment or ruling, or the people’s court may, in accordance with the provisions of international treaties to which the PRC is a signatory or in which the PRC is a participant or according to the principle of reciprocity, request for recognition and enforcement by the foreign court. Similarly, for an effective judgment or ruling made by a foreign court that requires recognition and enforcement by a people’s court of the PRC, a party may directly apply to an intermediate people’s court of the PRC with jurisdiction for recognition and enforcement of the judgment or ruling, or the foreign court may, in accordance with the provisions of international treaties to which its country and the PRC are signatories or in which its country is a participant or according to the principle of reciprocity, request for recognition and enforcement by the people’s court, unless the people’s court considers that the recognition or enforcement of such judgment or ruling would violate the basic legal principles of the PRC, its sovereignty or national security or would not be in social and public interest.

The Company Law of the People’s Republic of China, the Special Regulations of the State Council on the Overseas Offering and the Listing of Shares by Joint Stock Limited Companies and the Mandatory Provisions for the Articles of Association of Companies to be Listed Overseas

The Company Law of the People’s Republic of China (hereinafter referred to as the “PRC Company Law”) was adopted by the Standing Committee of the Eighth NPC at its Fifth Session on December 29, 1993 and came into effect on July 1, 1994. It was successively amended on December 25, 1999, August 28, 2004, October 27, 2005, December 28, 2013 and October 26, 2018. The newly revised the PRC Company Law has been implemented since October 26, 2018.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

The Special Regulations of the State Council on the Overseas Offering and the Listing of Shares by Joint Stock Limited Companies (《國務院關於股份有限公司境外募集股份及上市的特別規定》) (hereinafter referred to as the “Special Regulations”) were passed at the 22nd Standing Committee Meeting of the State Council on July 4, 1994 and promulgated and implemented on August 4, 1994. The Special Regulations include provisions in respect of the overseas share offering and listing of joint stock limited companies.

The Mandatory Provisions for the articles of association of Companies to be Listed Overseas (hereinafter referred to as the “Mandatory Provisions”) jointly promulgated by the former Securities Commission of the State Council and the former State Commission for Restructuring the Economic System on September 29, 1994 prescribe that the provisions should be incorporated in the articles of association of joint stock limited companies to be listed overseas stock exchanges. Accordingly, the Mandatory Provisions have been incorporated in the articles of association. References to a “company” made in this Appendix are to a joint stock limited company established under the PRC Company Law with H Shares to be issued.

Set out below is a summary of the major provisions of the PRC Company Law, the Special Regulations and the Mandatory Provisions.

General

A “joint stock limited company” refers to a corporate legal person incorporated in China under the PRC Company Law with independent legal person properties and entitlements to such legal person properties. The liability of the company for its own debts is limited to the total amount of all assets it owns and the liability of its shareholders for the company is limited to the extent of the shares they subscribe for.

Incorporation

A company may be established by promotion or subscription. A company shall have a minimum of two but no more than 200 people as its promoters, over half of which must be residents within the PRC. Companies established by promotion are companies of which the registered capital is the total share capital subscribed for by all the promoters registered with the company’s registration authorities. No share offering shall be made before the shares subscribed for by promoters are fully paid up. For companies established by share offering, the registered capital is the total paid-up share capital as registered with the company’s registration authorities. If laws, administrative regulations and State Council decisions provide otherwise on paid-in registered capital and the minimum registered capital, a company should follow such provisions.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

For companies incorporated by way of promotion, the promoters shall subscribe in writing for the shares required to be subscribed for by them and pay up their capital contributions under the articles of association. Procedures relating to the transfer of titles to non-monetary assets shall be duly completed if such assets are to be contributed as capital. Promoters who fail to pay up their capital contributions in accordance with the foregoing provisions shall assume default liabilities in accordance with the covenants set out in the promoters' agreements. After the promoters have confirmed the capital contribution under the articles of association, a board of directors and a supervisory board shall be elected and the board of directors shall apply for registration of establishment by filing the articles of association with the company registration authorities, and other documents as required by the law or administrative regulations.

Where companies are incorporated by subscription, not less than 35% of their total number of shares must be subscribed for by the promoters, unless otherwise provided by laws or administrative regulations. A promoter who offers shares to the public must publish a prospectus and prepare a subscription letter to be completed, signed and sealed by subscribers, specifying the number and amount of shares to be subscribed for and the subscribers' addresses. The subscribers shall pay up monies for the shares they subscribe for. Where a promoter is offering shares to the public, such offer shall be underwritten by security companies established under PRC law, and underwriting agreements shall be entered into. A promoter offering shares to the public shall also enter into agreements with banks in relation to the receipt of subscription monies. The receiving banks shall receive and keep in custody the subscription monies, issue receipts to subscribers who have paid the subscription monies and is obliged to furnish evidence of receipt of those subscription monies to relevant authorities. After the subscription monies for the share issue have been paid in full, a capital verification institution established under PRC laws must be engaged to conduct a capital verification and furnish a certificate thereof. The promoters shall preside over and convene an inauguration meeting within 30 days from the date of the full payment of subscription money. The inauguration meeting shall be formed by the promoters and subscribers. Where the shares issued remain undersubscribed by the deadline stipulated in the prospectus, or where the promoter fails to convene an inauguration meeting within 30 days of the subscription monies for the shares issued being fully paid up, the subscribers may demand that the promoters refund the subscription monies so paid together with the interest at bank rates of a deposit for the same period. Within 30 days after the conclusion of the inauguration meeting, the board of directors shall apply to the company registration authority for registration of the establishment of the company. A company is formally established and has the capacity of a legal person after approval of registration has been given by the relevant company registration authority for industry and commerce and a business license has been issued.

A company's promoters shall be liable for: (1) the debts and expenses incurred in the establishment process jointly and severally if the company cannot be incorporated; (2) the subscription monies paid by the subscribers together with interest at bank rates of deposit for the same period jointly and severally if the company cannot be incorporated; and (3) the compensation of any damages suffered by the company in the course of its establishment as a result of the promoters' fault.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Share Capital

The promoters may make a capital contribution in currencies, or non-monetary assets such as in kind or intellectual property rights or land use rights which can be appraised with monetary value and transferred lawfully, except for assets which are prohibited from being contributed as capital by the laws or administrative regulations. If a capital contribution is made in non-monetary assets, a valuation of the assets contributed must be carried out pursuant to the provisions of the laws or administrative regulations on valuation without any over-valuation or under-valuation.

The issuance of shares shall be conducted in a fair and equitable manner. Each share of the same class must carry equal rights. Shares issued at the same time and within the same class must be issued on the same conditions and at the same price. The same price per share shall be paid by any share subscriber (whether an entity or an individual). The share offering price may be equal to or greater than the nominal value of the share, but may not be less than the nominal value.

A company must obtain the approval of CSRC to offer its shares to the overseas public. The Special Regulations and the Mandatory Provisions provide that the shares issued to foreign investors and listed overseas by a company shall be in registered form, denominated in Renminbi and subscribed for in foreign currencies. Shares issued to foreign investors (including the investors from the territories of Hong Kong, Macau and Taiwan) and listed in Hong Kong are classified as H Shares, and those shares issued to investors within the PRC, other than these regions mentioned above, are known as domestic shares. Under the Special Regulations, upon approval of CSRC, a company may agree, in the underwriting agreement in respect of an issue of H Shares, to retain not more than 15% of the aggregate number of such overseas listed foreign shares proposed to be issued in addition to the number of underwritten shares. The issuance of retained shares is deemed to be a part of this offering.

Under the PRC Company Law, a company issuing registered share certificates shall maintain a shareholder registry which sets forth the following matters: (1) the name and domicile of each shareholder; (2) the number of shares held by each shareholder; (3) the serial numbers of shares held by each shareholder; and (4) the date on which each shareholder acquired the shares.

Increase in Share Capital

Pursuant to the relevant provisions of the PRC Company Law, where a company is issuing new shares, resolutions shall be passed at general meeting in accordance with the articles of association in respect of the class and amount of the new shares, the issue price of the new shares, the commencement and end dates for the issue of the new shares and the class and amount of the new shares proposed to be issued to existing shareholders.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

When a company launches a public issue of new shares to the public upon the approval by CSRC, a new share offering prospectus and financial accounting report must be announced and a subscription letter must be prepared. After the new shares issued by the company has been paid up, the change must be registered with the company registration authority and a public announcement must be made accordingly. Where an increase in registered capital of a company is made by means of an issue of new shares, the subscription of new shares by shareholders shall be made in accordance with the relevant provisions on the payment of subscription monies for the establishment of a company.

Reduction of Share Capital

A company shall reduce its registered capital in accordance with the following procedures prescribed by the PRC Company Law: (1) the company shall prepare a balance sheet and an inventory of assets; (2) the reduction of registered capital must be approved by shareholders at general meeting; (3) the company shall notify its creditors within 10 days and publish an announcement in newspapers within 30 days from the day on which the resolution approving the reduction was passed; (4) the creditors of the company are entitled to require the company to repay its debts or provide guarantees for such debts within 30 days from receipt of the notification or within 45 days from the date of the announcement if he/she/it has not received any notification; and (5) the company must apply to the company registration authority for change in registration.

Repurchase of Shares

Pursuant to the PRC Company Law, a company may not repurchase its own shares other than for the following purposes: (1) reducing its registered capital; (2) merging with other companies which hold its shares; (3) granting shares to its employees as incentives; (4) acquiring its shares at the request of its shareholders who vote in a shareholders' general meeting against a resolution regarding a merger and division; (5) utilizing the shares for conversion of listed corporate bonds which are convertible into shares; and (6) where it is necessary for the listed company to safeguard the value of the company and the interests of its shareholders. The acquisition by a company of its own shares on the grounds set out in item (1) to (2) above shall be approved by way of a resolution of a shareholders' general meeting; the acquisition by a company of its own shares in circumstances as set out in items (3), (5) and (6) above may be approved by way of a resolution at a board meeting with two-third or more of the directors present in accordance with the provisions of the company's articles of association or the authorization of the shareholders' general meeting.

Following the acquisition by a company of its own shares in accordance with these requirements, such shares shall be canceled within 10 days from the date of the acquisition under the circumstance in item (1); such shares shall be transferred or canceled within six months under the circumstances in items (2) or (4); the total shares held by the Company shall not exceed 10% of the total shares issued by the Company and such shares shall be transferred or canceled within three years under the circumstances in items (3), (5) or (6).

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A listed company shall perform its information disclosure obligations in accordance with the provisions of the Securities Law of People's Republic of China when acquiring its own shares. The acquisition by a listed company of its own shares in circumstances as set out in items (3), (5) and (6) of this article shall be conducted through open centralized trading.

The Company shall not accept the shares of the Company as the subject of pledge.

Transfer of Shares

Shares held by shareholders may be transferred legally. Pursuant to the PRC Company Law, a shareholder should effect a transfer of his shares on a stock exchange established in accordance with laws or by any other means as required by the State Council. Registered shares may be transferred after the shareholders endorse the back of the share certificates or in other manner specified by laws and administrative regulations. Following the transfer, the company shall enter the names and addresses of the transferees into its share register. No changes of registration in the share register described above shall be effected during a period of 20 days prior to convening a shareholders' general meeting or 5 days prior to the record date for the purpose of determining entitlements to dividend distributions, unless otherwise stipulated by laws on the registration of changes in the share register of listed companies. The transfer of bearer share certificates shall become effective upon the delivery of the certificates to the transferee by the shareholder. The Mandatory Provision provides that changes due to share transfer should not be made to shareholder registry within 30 days before a shareholders' general meeting or within 5 days before the record date for the purpose of determining entitlements to dividend distributions.

Pursuant to the PRC Company Law, shares held by promoters may not be transferred within one year of the establishment of the company. Shares of the company issued prior to the public issue of shares may not be transferred within one year of the date of the company's listing on a stock exchange. Directors, supervisors and the senior management of a company shall declare to the company their shareholdings in it and changes in such shareholdings. During their terms of office, they may transfer no more than 25% of the total number of shares they hold in the company every year. They shall not transfer the shares they hold within one year from the date of the company's listing on a stock exchange, nor within six months after they leave their positions in the company. The articles of association may set out other restrictive provisions in respect of the transfer of shares in the company held by its directors, supervisors and the senior management.

Shareholders

Under the PRC Company Law, the rights of shareholders include the rights: (1) to receive a return on assets, participate in significant decision-making and select management personnel; (2) to petition the people's court to revoke any resolution passed on a shareholders' general meeting or a meeting of the board of directors that has been convened or whose voting has been conducted in violation of the laws, regulations or the articles of association, or any resolution the contents of which is in violation of the articles of association, provided that such petition

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shall be submitted within 60 days of the passing of such resolution; (3) to transfer the shares of the shareholders legally; (4) to attend or appoint a proxy to attend shareholders' general meetings and exercise the voting rights; (5) to inspect the articles of association, share register, counterfoil of company debentures, minutes of shareholders' general meetings, board resolutions, resolutions of the board of supervisors and financial and accounting reports, and to make suggestions or inquiries in respect of the company's operations; (6) to receive dividends in respect of the number of shares held; (7) to participate in distribution of residual properties of the company in proportion to their shareholdings upon the liquidation of the company; and (8) any other shareholders' rights provided for in laws, administrative regulations, other normative documents and the articles of association.

The obligations of shareholders include the obligation to abide by the company's articles of association, to pay the subscription monies in respect of the shares subscribed for, to be liable for the company's debts and liabilities to the extent of the amount of subscription monies agreed to be paid in respect of the shares taken up by them and any other shareholder obligation specified in the articles of association.

Shareholders' General Meetings

The general meeting is the organ of authority of the company, which exercises its powers in accordance with the PRC Company Law. The general meeting may exercise its powers: (1) to decide on the company's operational objectives and investment plans; (2) to elect and dismiss the directors and supervisors not being representative(s) of employees and to decide on the matters relating to the remuneration of directors and supervisors; (3) to review and approve the reports of the board of directors; (4) to review and approve the reports of the board of supervisors or the reports of the supervisors; (5) to review and approve the company's annual financial budgets proposals and final accounts proposals; (6) to review and approve the company's profit distribution proposals and loss recovery proposals; (7) to decide on any increase or reduction of the company's registered capital; (8) to decide on the issue of corporate bonds; (9) to decide on merger, division, dissolution and liquidation of the company or change of its corporate form; (10) to amend the company's articles of association; and (11) to exercise any other authority stipulated in the articles of association.

Pursuant to the PRC Company Law and the Mandatory Provisions, a shareholders' general meeting is required to be held once every year within six months after the end of the previous accounting year. An extraordinary general meeting is required to be held within two months upon the occurrence of any of the following: (1) the number of directors is less than the number required by law or less than two-thirds of the number specified in the articles of association; (2) the total outstanding losses of the company amounted to one-third of the company's total paid-in share capital; (3) shareholders individually or in aggregate holding 10% or more of the company's shares request to convene an extraordinary general meeting; (4) the board deems necessary; (5) the board of supervisors so proposes; or (6) any other circumstances as provided for in the articles of association.

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A shareholders' general meeting shall be convened by the board of directors and presided over by the chairman of the board of directors. In the event that the chairman is incapable of performing or is not performing his duties, the meeting shall be presided over by the vice chairman. In the event that the vice chairman is incapable of performing or is not performing his duties, a director recommended by half or more of the directors shall preside over the meeting. Where the board of directors is incapable of performing or is not performing its duties, the board of supervisors shall convene and preside over the shareholders' general meeting in a timely manner. If the board of supervisors fails to convene and preside over the shareholders' general meeting, shareholders individually or in aggregate holding 10% or more of the company's shares for 90 days or more consecutively may unilaterally convene and preside over the shareholders' general meeting.

In accordance with the PRC Company Law, a notice of the general meeting stating the date and venue of the meeting and the matters to be considered at the meeting shall be given to all shareholders 20 days prior to the meeting. A notice of extraordinary general meeting shall be given to all shareholders 15 days prior to the meeting. For the issuance of bearer share certificates, the time and venue of and matters to be considered at the meeting shall be announced 30 days prior to the meeting. A single shareholder who holds, or several shareholders who jointly hold, more than three percent of the shares of the company may submit an interim proposal in writing to the board of directors within 10 days before the general meeting. The board of directors shall notify other shareholders within two days upon receipt of the proposal, and submit the interim proposal to the general meeting for deliberation. The contents of the interim proposal shall fall within the scope of powers of the general meeting, and the proposal shall provide clear agenda and specific matters for a resolution is to be made. A general meeting shall not make any resolution in respect of any matter not set out in the notices. Holders of bearer share certificates who intend to attend a general meeting shall deposit their share certificates with the company during the time from five days before the meeting to the conclusion of the meeting.

In accordance with the Mandatory Provisions, a written notice of the general meeting stating, among other things, matters to be considered at the meeting as well as the time and venue of the meeting shall be given to all shareholders 45 days before the meeting. A shareholder who intends to attend the meeting shall deliver his written reply regarding his attendance of the meeting to the company 20 days before the date of the meeting.

There is no specific provision in the PRC Company Law regarding the number of shareholders constituting a quorum in a shareholders' general meeting, although the Special Regulations and the Mandatory Provisions provide that a company's general meeting may be convened when written replies to the notice of that meeting from shareholders holding shares representing no less than 50% of the voting rights in the company have been received 20 days before the proposed date. If that 50% level is not achieved, the company shall notify shareholders again within five days by announcement of the matters to be considered at the meeting as well as the date and venue of the meeting, and the general meeting may be held by the company thereafter.

Pursuant to the PRC Company Law, shareholders present at a shareholders' general meeting have one vote for each share they hold, save that the Company's shares held by the company are not entitled to any voting rights.

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An accumulative voting system may be adopted for the election of directors and supervisors at the general meeting pursuant to the provisions of the articles of association or a resolution of the general meeting. Under the accumulative voting system, each share shall be entitled to the number of votes equivalent to the number of directors or supervisors to be elected at the general meeting, and shareholders may consolidate their votes for one or more directors or supervisors when casting a vote.

Pursuant to the PRC Company Law, resolutions of the general meeting must be passed by more than half of the voting rights held by shareholders present at the meeting, with the exception of resolutions relating to merger, division or dissolution of the company, increase or reduction of registered share capital, change of corporate form or amendments to the articles of association, in each case of which must be passed by more than two-thirds of the voting rights held by the shareholders present at the meeting. Where the PRC Company Law and the articles of association provide that the transfer or acquisition of significant assets or the provision of external guarantees by the company and such other matters must be approved by way of resolution of the general meeting, the board of directors shall convene a shareholders' general meeting promptly to vote on such matters. A shareholder may entrust a proxy to attend the general meeting on his/her behalf. The proxy shall present the shareholders' power of attorney to the company and exercise voting rights within the scope of authorization.

Minutes shall be prepared in respect of matters considered at the general meeting and the chairperson and directors attending the meeting shall endorse such minutes by signature. The minutes shall be kept together with the shareholders' attendance register and the proxy forms.

Pursuant to the Mandatory Provisions, the increase or reduction of share capital, the issuance of shares of any class, warrants or other similar securities and bonds, the division, merger, dissolution and liquidation of the company, the amendments to the articles of association and any other matters, which, as resolved by way of an ordinary resolution of the general meeting, may have a material impact on the company and require adoption by way of a special resolution, must be approved through special resolutions by more than two-thirds of the voting rights held by shareholders (including his/her proxies) present at the meeting.

The Mandatory Provisions require a special resolution to be passed at the general meeting and a class meeting to be held in the event of a variation or derogation of the class rights of a shareholder class. For this purpose, holders of domestic shares and H shares are deemed to be shareholders of different classes.

Board of Directors

A company shall have a board of directors, which shall consist of 5 to 19 members. Members of the board of directors may include staff representatives, who shall be democratically elected by the company's staff at a staff representative assembly, general staff meeting or otherwise. The term of a director shall be stipulated in the articles of association, provided that no term of office shall last for more than three years. A director may serve consecutive terms if re-elected. A director shall continue to perform his/her duties as a director

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in accordance with the laws, administrative regulations and the articles of association until a duly reelected director takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of director results in the number of directors being less than the quorum.

Under the PRC Company Law, the board of directors may exercise its powers:

- (1) to convene shareholders' general meetings and report on its work to the shareholders' general meetings;
- (2) to implement the resolutions passed by the shareholders at the shareholders' general meetings;
- (3) to decide on the company's operational plans and investment proposals;
- (4) to formulate proposal for the company's annual financial budgets and final accounts;
- (5) to formulate the company's profit distribution proposals and loss recovery proposals;
- (6) to formulate proposals for the increase or reduction of the company's registered capital and the issue of corporate bonds;
- (7) to formulate proposals for the merger, division or dissolution of the company or change of corporate form;
- (8) to decide on the setup of the company's internal management organs;
- (9) to appoint or dismiss the company's manager and decide on his/her remuneration and, based on the manager's recommendation, to appoint or dismiss any deputy general manager and financial officer of the company and to decide on their remunerations;
- (10) to formulate the company's basic management system; and
- (11) to exercise any other authority stipulated in the articles of association.

Meetings of the board of directors shall be convened at least twice each year. Notices of meeting shall be given to all directors and supervisors 10 days before the meeting. Interim board meetings may be proposed to be convened by shareholders representing more than 10% of the voting rights, more than one-third of the directors or the supervisory board. The chairman shall convene the meeting within 10 days of receiving such proposal, and preside over the meeting. The board of directors may otherwise determine the means and the period of notice for convening an interim board meeting. Meetings of the board of directors shall be held only if more than half of the directors are present. Resolutions of the board of directors shall

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be passed by more than half of all directors. Each director shall have one vote for a resolution to be approved by the board. Directors shall attend board meetings in person. If a director is unable to attend for any reason, he/she may appoint another director to attend the meeting on his/her behalf by a written power of attorney specifying the scope of authorization. Meanwhile, the board of directors shall keep minutes of resolutions passed at board meetings. The minutes shall be signed by the directors present at the meeting.

If a resolution of the board of directors violates the laws, administrative regulations or the articles of association or resolutions of the general meeting, and as a result of which the company sustains serious losses, the directors participating in the resolution are liable to compensate the company. However, if it can be proved that a director expressly objected to the resolution when the resolution was voted on, and that such objection was recorded in the minutes of the meeting, such director shall be relieved from that liability.

Under the PRC Company Law, the following person may not serve as a director in a company: (1) a person who is unable or has limited ability to undertake any civil liabilities; (2) a person who has been convicted of an offense of corruption, bribery, embezzlement, misappropriation of property or destruction of the socialist economic order, or who has been deprived of his political rights due to his crimes, in each case where less than five years have elapsed since the date of completion of the sentence; (3) a person who has been a former director, factory manager or manager of a company or an enterprise that has entered into insolvent liquidation and who was personally liable for the insolvency of such company or enterprise, where less than three years have elapsed since the date of the completion of the bankruptcy and liquidation of the company or enterprise; (4) a person who has been a legal representative of a company or an enterprise that has had its business license revoked due to violations of the law or has been ordered to close down by law and the person was personally responsible, where less than three years have elapsed since the date of such revocation; and (5) a person who is liable for a relatively large amount of debts that are overdue.

Where a company elects or appoints a director to which any of the above circumstances applies, such election or appointment shall be null and void. A director to which any of the above circumstances applies during his/her term of office shall be released of his/her duties by the company.

In addition, the Mandatory Provisions further provide other circumstances under which a person is disqualified from acting as a director of a company, including: (1) the person is under investigation by the judicial authorities after a claim has been brought for violating the criminal law, pending conclusion of the case; (2) the person is not eligible for enterprise leadership under the laws and administrative regulations; (3) the person is not a natural person; and (4) no more than five years have lapsed since the person was found guilty of violating relevant securities regulations and involved in fraud or dishonesty as adjudged by relevant regulatory authorities.

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Under the PRC Company Law, the board shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman shall be elected with approval of more than half of all the directors. The chairman shall convene and preside over board meetings and review the implementation of board resolutions. The vice chairman shall assist the chairman to perform his/her duties. Where the chairman is incapable of performing, or is not performing his/her duties, the duties shall be performed by the vice chairman. Where the vice chairman is incapable of performing, or is not performing his/her duties, a director jointly elected by more than half of the directors shall perform his/her duties.

Supervisory Board

A company shall have a supervisory board composed of not less than three members. The supervisory board shall consist of representatives of the shareholders and an appropriate proportion of representatives of the company’s staff, among which the proportion of representatives of the company’s staff shall not be less than one-third, and the actual proportion shall be determined in the articles of association. Representatives of the company’s staff at the supervisory board shall be democratically elected by the company’s staff at the staff representative assembly, general staff meeting or otherwise. The supervisory board shall appoint a chairman and may appoint a vice chairman. The chairman and the vice chairman of the supervisory board shall be elected by more than half of all the supervisors. Directors and senior management members shall not act concurrently as supervisors.

According to the Reply of the Overseas Listing Department of CSRC and the Production System Department of the State Commission for Restructuring the Economic System on Opinions Concerning the Supplement and Amendment to Articles of Association by Companies to Be Listed in Hong Kong (《中國證監會海外上市部、國家體改委生產體制司關於到香港上市公司對公司章程作補充修改的意見的函》), the chairman of the supervisory board shall be selected by more than two-thirds of all the supervisors. Directors and senior management members shall not act concurrently as supervisors.

The chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the chairman of the supervisory board is incapable of performing, or is not performing his/her duties, the vice chairman of the supervisory board shall convene and preside over supervisory board meetings. Where the vice chairman of the supervisory board is incapable of performing, or is not performing his/her duties, a supervisor elected by more than half of the supervisors shall convene and preside over supervisory board meetings.

Each term of office of a supervisor is three years and he/she may serve consecutive terms if re-elected. A supervisor shall continue to perform his/her duties as a supervisor in accordance with the laws, administrative regulations and the articles of association until a duly re-elected supervisor takes office, if re-election is not conducted in a timely manner upon the expiry of his/her term of office or if the resignation of supervisor results in the number of supervisors being less than the quorum.

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The supervisory board may exercise its powers:

- (1) to review the company's financial position;
- (2) to supervise the directors and senior management in their performance of their duties and to propose the removal of directors and senior management who have violated laws, regulations, the articles of association or resolutions of the shareholders' general meetings;
- (3) when the acts of a director or a senior management personnel are detrimental to the company's interests, to require the director and senior management to correct these acts;
- (4) to propose the convening of extraordinary shareholders' general meetings and to convene and preside over shareholders' general meetings when the board fails to perform the duty of convening and presiding over shareholders' general meetings under the PRC Company Law;
- (5) to submit proposals to the shareholders' general meetings;
- (6) to bring actions against directors and senior management personnel pursuant to the relevant provisions of the PRC Company Law; and
- (7) to exercise any other authority stipulated in the articles of association.

Supervisors may be present at board meetings and make inquiries or proposals in respect of the resolutions of the board. The supervisory board may investigate any irregularities identified in the operation of the company and, when necessary, may engage an accounting firm to assist its work at the cost of the company.

Manager and Senior Management

Under the relevant requirements of the PRC Company Law, a company shall have a manager who shall be appointed or removed by the board of directors. Meanwhile, under the relevant requirements of the Mandatory Provisions, the manager, who reports to the board of directors, may exercise his/her powers:

- (1) to manage the production and operation and administration of the company and arrange for the implementation of the resolutions of the board of directors;
- (2) to arrange for the implementation of the company's annual operation plans and investment proposals;
- (3) to formulate proposals for the establishment of the company's internal management organs;

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- (4) to formulate the fundamental management system of the company;
- (5) to formulate the company's specific rules and regulations;
- (6) to recommend the appointment or dismissal of any deputy manager and any financial officer of the company;
- (7) to appoint or dismiss management personnel (other than those required to be appointed or dismissed by the board of directors); and
- (8) to exercise any other authority granted by the board of directors.

Other provisions in the articles of association on the manager's powers shall also be complied with. The manager shall be present at meetings of the board of directors. However, the manager shall have no voting rights at meetings of the board of directors unless he/she concurrently serves as a director.

According to the PRC Company Law, senior management refers to manager, deputy manager, financial officer, secretary to the board of a listed company and other personnel as stipulated in the articles of association.

Duties of Directors, Supervisors, General Managers and Other Senior Management

Directors, supervisors and senior management are required under the PRC Company Law to comply with the relevant laws, administrative regulations and the articles of association, and shall be obliged to be faithful and diligent towards the Company. Directors, supervisors and management personnel are prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's property.

Furthermore, directors and senior management are prohibited from:

- (1) misappropriating company funds;
- (2) depositing company funds into accounts under their own names or the names of other individuals;
- (3) loaning company funds to others or providing guarantees in favor of others supported by company's property in violation of the articles of association or without approval of the general meeting or the board of directors;
- (4) entering into contracts or transactions with the company in violation of the articles of association or without approval of the general meeting;
- (5) using their position to procure business opportunities for themselves or others that should have otherwise been available to the company or operating businesses similar to that of the company for their own benefits or on behalf of others without approval of the general meeting;

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- (6) accepting for their own benefit commissions from a third party for transactions conducted with the company;
- (7) unauthorized divulgence of confidential information of the company; and
- (8) other acts in violation of their duty of loyalty to the company.

Income generated by directors or senior management in violation of aforementioned shall be returned to the company.

A director, supervisor or senior management who contravenes law, administrative regulation or the articles of association in the performance of his/her duties resulting in any loss to the company shall be liable to the company for compensation.

Where a director, supervisor or senior management is required to attend a shareholders' general meeting, such director, supervisor or senior management shall attend the meeting and answer the inquiries from shareholders. Directors and senior management shall furnish all true information and data to the supervisory board, without impeding the discharge of duties by the supervisory board or supervisors.

Where a director or senior management contravenes laws, administrative regulations or the articles of association in the performance of his/her duties resulting in any loss to the company, shareholder(s) holding individually or in aggregate more than 1% of the company's shares consecutively for more than 180 days may request in writing that the supervisory board institute litigation at the people's court. Where the supervisory board violates the laws or administrative regulations or the articles of association in the discharge of its duties resulting in any loss to the company, such shareholder(s) may request in writing that the board of directors institute litigation at the people's court on its behalf. If the supervisory board or the board of directors refuses to institute litigation after receiving this written request from the shareholder(s), or fails to institute litigation within 30 days of the date of receiving the request, or in case of emergency where failure to institute litigation immediately will result in irrecoverable damage to the company's interests, such shareholder(s) shall have the power to institute litigation directly at the people's court in its own name for the company's benefit. For other parties who infringe the lawful interests of the company resulting in loss to the company, such shareholder(s) may institute litigation at the people's court in accordance with the procedure described above. Where a director or senior management contravenes any laws, administrative regulations or the articles of association in infringement of shareholders' interests, a shareholder may also institute litigation at the people's court.

The Special Regulations and the Mandatory Provisions provide that a company's directors, supervisors, manager and other senior management shall have duty of good faith to the company. They are required to faithfully perform their duties, to protect the interests of the company and not to use their positions in the company for their own benefits. The Mandatory Provisions contain detailed stipulations on these duties.

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Finance and Accounting

Under the PRC Company Law, A company shall establish its own financial and accounting systems according to the laws, administrative regulations and the regulations of the competent financial departments under the State Council. At the end of each accounting year, a company shall prepare a financial report which shall be audited by an accounting firm in accordance with laws. The financial and accounting reports shall be prepared in accordance with laws, administrative regulations and the regulations of the financial departments under the State Council. The company's financial and accounting reports shall be made available for shareholders' inspection at the company within 20 days before the convening of an annual general meeting. A joint stock limited company that makes public stock offerings shall announce its financial and accounting reports.

When distributing each year's profits after taxation, the company shall set aside 10% of its profits after taxation for the company's statutory common reserve fund until the fund has reached more than 50% of the PRC company's registered capital. When the company's statutory common reserve fund is not sufficient to make up for the company's losses for the previous years, the current year's profits shall first be used to make good the losses before any allocation is set aside for the statutory common reserve fund. After the company has made allocations to the statutory common reserve fund from its profits after taxation, it may, upon passing a resolution at a shareholders' general meeting, make further allocations from its profits after taxation to the discretionary common reserve fund. After the company has made good its losses and made allocations to its discretionary common reserve fund, the remaining profits after taxation shall be distributed in proportion to the number of shares held by the shareholders, except for those which are not distributed in a proportionate manner as provided by the articles of association.

Profits distributed to shareholders by a resolution of a shareholders' general meeting or the board of directors before losses have been made good and allocations have been made to the statutory common reserve fund in violation of the requirements described above must be returned to the company. The company shall not be entitled to any distribution of profits in respect of its own shares held by it.

The premium over the nominal value per share of the company on issue and other income as required by relevant governmental department to be treated as the capital reserve fund shall be accounted for as the capital reserve fund. The common reserve fund of a company shall be applied to make good the company's losses, expand its business operations or increase its capital. The capital reserve fund, however, shall not be used to make good the company's losses. Upon the transfer of the statutory common reserve fund into capital, the balance of the fund shall not be less than 25% of the registered capital of the company before such transfer.

The company shall have no accounting books other than the statutory books. The company's assets shall not be deposited in any account opened under the name of an individual.

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Appointment and Dismissal of Auditors

Pursuant to the PRC Company Law, the engagement or dismissal of an accounting firm responsible for the company's auditing shall be determined by a shareholders' general meeting or the board of directors in accordance with the articles of association. The accounting firm should be allowed to make representations when the general meeting or the board of directors conducts a vote on the dismissal of the accounting firm. The company should provide true and complete accounting evidence, accounting books, financial and accounting reports and other accounting information to the engaged accounting firm without any refusal or withholding or falsification of data.

The Special Regulations require a company to engage an independent qualified accounting firm to audit the company's annual reports and to review and check other financial reports of the company. The accounting firm's term of office shall commence from the end of the shareholders' annual general meeting to the end of the next shareholders' annual general meeting.

Profit Distribution

According to the PRC Company Law, a company shall not distribute profits before losses are covered and the statutory common reserve fund is provided. Additionally, the Special Regulations require that any dividend and other distribution to shareholders of H Shares shall be declared and calculated in RMB and paid in foreign currency. Under the Mandatory Provisions, a company shall make foreign currency payments to shareholders through receiving agents.

Amendments to the Articles of Association

Pursuant to PRC Company Law, the resolution of a shareholders' general meeting regarding any amendment to a company's articles of association requires affirmative votes by more than two-thirds of the votes held by shareholders attending the meeting. Pursuant to the Mandatory Provisions, the company may amend its articles of association according to the laws, administrative regulations and the articles of association. The amendment to articles of association involving content of the Mandatory Provisions will only be effective upon approval of the department in charge of company examination authorized by the State Council and approval of the securities regulatory department under by the State Council, while the amendment to articles of association involving matters of company registration must be registered with the relevant authority in accordance with laws.

Dissolution and Liquidation

Under the PRC Company Law, a company shall be dissolved for any of the following reasons:

- (1) the term of its operation set out in the articles of association has expired or other events of dissolution specified in the articles of association have occurred;

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- (2) the shareholders have resolved at a shareholders' general meeting to dissolve the company;
- (3) the company shall be dissolved by reason of its merger or division;
- (4) the business license of the company is revoked or the company is ordered to close down or to be dissolved in accordance with the laws; or
- (5) the company is dissolved by the people's court in response to the request of shareholders holding shares that represent more than 10% of the voting rights of all shareholders of the company, on the grounds that the operation and management of the company has suffered serious difficulties that cannot be resolved through other means, rendering ongoing existence of the company a cause for significant losses to the shareholders' interests.

In the event of paragraph (1) above, the company may carry on its existence by amending its articles of association. The amendments to the articles of association in accordance with the provisions described above shall require the approval of more than two-thirds of voting rights of shareholders attending a shareholders' general meeting.

Where the company is dissolved under the circumstances set forth in paragraph (1), (2), (4) or (5) above, it should establish a liquidation committee within 15 days of the date on which the dissolution matter occurs. The liquidation committee shall be composed of directors or any other person determined by a shareholders' general meeting. If a liquidation committee is not established within the stipulated period, the company's creditors can apply to the people's court for setting up a liquidation committee with designated relevant personnel to conduct the liquidation. The people's court should accept such application and form a liquidation committee to conduct liquidation in a timely manner.

The sort out committee may exercise following powers during the liquidation:

- (1) to sort out the company's assets and to prepare a balance sheet and an inventory of assets;
- (2) to notify the company's creditors or publish announcements;
- (3) to deal with any outstanding business related to the liquidation;
- (4) to pay any overdue tax together with any tax arising during the liquidation process;
- (5) to settle the company's claims and liabilities;
- (6) to handle the company's remaining assets after its debts have been paid off; and
- (7) to represent the company in any civil procedures.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

The liquidation committee shall notify the company's creditors within 10 days of its establishment, and publish an announcement in newspapers within 60 days.

A creditor shall lodge his claim with the liquidation committee within 30 days of receipt of the notification or within 45 days of the date of the announcement if he has not received any notification.

A creditor shall report all matters relevant to his claimed creditor's rights and furnish relevant evidence. The liquidation committee shall register such creditor's rights. The liquidation committee shall not make any settlement to creditors during the period of the claim.

Upon disposal of the company's property and preparation of the required balance sheet and inventory of assets, the liquidation committee shall draw up a liquidation plan and submit this plan to a shareholders' general meeting or a people's court for endorsement. The remaining part of the company's assets, after payment of liquidation expenses, employee wages, social insurance expenses and statutory compensation, outstanding taxes and the company's debts, shall be distributed to shareholders in proportion to shares held by them. The company shall continue to exist during the liquidation period, although it cannot conduct operating activities that are not related to the liquidation. The company's property shall not be distributed to shareholders before repayments are made in accordance with the requirements described above.

Upon liquidation of the company's property and preparation of the required balance sheet and inventory of assets, if the liquidation committee becomes aware that the company does not have sufficient assets to meet its liabilities, it must apply to a people's court for a declaration of bankruptcy in accordance with the laws. Following such declaration by the people's court, the liquidation committee shall hand over the administration of the liquidation to the people's court.

Upon completion of the liquidation, the liquidation committee shall prepare a liquidation report and submit it to the shareholders' general meeting or the people's court for verification, and to the company registration authority for the cancellation of company registration, and an announcement of its termination shall be published. Members of the liquidation committee shall be faithful in the discharge of their duties and shall perform their liquidation duties in compliance with laws. Members of the liquidation committee shall be prohibited from abusing their authority in accepting bribes or other unlawful income and from misappropriating the company's properties. Members of the liquidation committee who have caused the company or its creditors to suffer from any loss due to intentional fault or gross negligence, should be liable for making compensations to the company or its creditors. In addition, liquidation of a company declared bankrupt according to laws shall be processed in accordance with the laws on corporate bankruptcy.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Overseas Listing

The shares of a company shall only be listed overseas after obtaining approval from CSRC, and the listing must be arranged in accordance with procedures specified by the State Council. Pursuant to the Special Regulations, a company may issue shares to overseas investors and list its shares overseas upon approval from CSRC. Subject to approval of the company's plans to issue overseas-listed foreign shares and domestic shares by CSRC, the board of directors of the company may make arrangement to implement such plans for issuance of shares, respectively, within fifteen months from the date of approval by CSRC.

In addition, if a company fails to issue all the shares as planned in one issue, it is not allowed to issue new shares not covered by the plan. If a company needs to adjust the issue plan, the shareholders' general meeting shall adopt a resolution for the examination by the company examination and approval department authorized by the State Council and the approval by the Securities Committee of the State Council.

Loss of Share Certificates

A shareholder may, in accordance with the public notice procedures set out in the PRC Civil Procedure Law, apply to a people's court if his share certificate(s) in registered form is either stolen, lost or destroyed, for a declaration that such certificate(s) will no longer be valid. After the people's court declares that such certificate(s) will no longer be valid, the shareholder may apply to the company for the issue of a replacement certificate(s).

A separate procedure regarding the loss of share certificates and H Share certificates of the overseas-listed foreign shareholders of the PRC is provided for in the Mandatory Provisions, details of which are set out in the articles of association.

Merger and Division

Under the PRC Company Law, a merger agreement shall be signed by merging companies and the involved companies shall prepare respective balance sheets and inventory of assets. The companies shall within 10 days of the date of passing the resolution approving the merger notify their respective creditors and publicly announce the merger in Newspapers within 30 days. A creditor may, within 30 days from the date of reception of the notification, or within 45 days from the date of the announcement if he has not received such notification, request the company to settle any outstanding debts or provide corresponding guarantees.

In case of a merger, the credits and debts of the merging parties shall be assumed by the surviving or the new company. In case of a division, the company's assets shall be divided and a balance sheet and an inventory of assets shall be prepared. When a resolution regarding the company's division is approved, the company should notify all its creditors within 10 days of the date of passing such resolution and publicly announce the division in newspapers within 30 days. Unless an agreement in writing is reached with creditors before the company's division in respect of the settlement of debts, the liabilities of the company which have accrued prior to the division shall be jointly borne by the divided companies.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Changes in the registration as a result of the merger or division shall be registered with the relevant administration authority for industry and commerce.

The PRC Securities Laws, Regulations and Regulatory Regimes

The PRC has promulgated a series of regulations that relate to the issue and trading of the Shares and disclosure of information. In October 1992, the State Council established the Securities Committee and CSRC. The Securities Committee is responsible for coordinating the drafting of securities regulations, formulating securities-related policies, planning the development of securities markets, directing, coordinating and supervising all securities-related institutions in the PRC and administering CSRC. CSRC is the regulatory arm of the Securities Committee and is responsible for the drafting of regulatory provisions governing securities markets, supervising securities companies, regulating public offerings of securities by PRC companies in the PRC or overseas, regulating the trading of securities, compiling securities-related statistics and undertaking relevant research and analysis. In April 1998, the State Council consolidated the Securities Committee and CSRC and reformed CSRC.

On April 22, 1993, the State Council promulgated the Provisional Regulations Concerning the Issue and Trading of Shares (《股票發行與交易管理暫行條例》) govern the application and approval procedures for public offerings of shares, issuing of and trading of shares, the acquisition of listed companies, deposit, clearing and transfer of shares, the disclosure of information, investigation, penalties and dispute resolutions with respect to a listed company.

On December 25, 1995, the State Council promulgated the Special Regulations of the State Council Concerning Domestic Listed Foreign Shares of Joint Stock Limited Companies (《國務院關於股份有限公司境內上市外資股的特別規定》). These regulations principally govern the issue, subscription, trading and declaration of dividends and other distributions of domestic listed foreign shares and disclosure of information of joint stock limited companies having domestic listed foreign shares.

The PRC Securities Law (《中華人民共和國證券法》) (the “Securities Law”) took effect on July 1, 1999 and was revised as of August 28, 2004, October 27, 2005, June 29, 2013, August 31, 2014 and December 28, 2019, respectively. The latest Securities Law was implemented on March 1, 2020. It was the first national securities law in the PRC, and is divided into 14 chapters and 226 articles comprehensively regulating activities in the PRC securities market, including the issue and trading of securities, takeovers by listed companies and the duties and responsibilities of the securities exchanges, securities companies, securities clearing institutions and securities regulatory authorities. Article 224 of the PRC Securities Law provides that domestic enterprises shall satisfy the relevant requirements of the State Council when it issues shares or lists shares outside the PRC directly or indirectly. Currently, the issue and trading of foreign issued securities (including shares) are principally governed by the regulations and rules promulgated by the State Council and CSRC.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Arbitration and Enforcement of Arbitral Awards

The Arbitration Law of the PRC(2017 Amendment) (《中華人民共和國仲裁法(2017修正)》) (the “PRC Arbitration Law”) was enacted by the Standing Committee of the NPC on August 31, 1994, which became effective on September 1, 1995 and was amended on August 27, 2009 and September 1, 2017. It is applicable to, among other matters, economic disputes involving foreign parties where all parties have entered into a written agreement to resolve disputes by arbitration before an arbitration committee constituted in accordance with the PRC Arbitration Law. The PRC Arbitration Law provides that an arbitration committee may, before the promulgation of arbitration regulations by the PRC Arbitration Association, formulate interim arbitration provisions in accordance with the PRC Arbitration Law and the PRC Civil Procedure Law. Where the involved parties have agreed to settle disputes by means of arbitration, a people’s court will refuse to handle a legal proceeding initiated by one of the parties at such people’s court, unless the arbitration agreement has lapsed.

The Listing Rules and the Mandatory Provisions require an arbitration clause to be included in the articles of association of a company listed in Hong Kong and, the Listing Rules, also require contracts between the company and each director or supervisor shall include arbitration clauses. Pursuant to such clause, whenever a dispute or claim arises from right or obligation provided in the articles of association, the PRC Company Law or other relevant laws and administrative regulations concerning the affairs of the company between (1) a holder of overseas listed foreign shares and the company; (2) a holder of overseas listed foreign shares and a holder of domestic shares; or (3) a holder of overseas listed foreign shares and the company’s directors, supervisors or other management personnel, such parties shall be required to refer such dispute or claim to arbitration at either the China International Economic and Trade Arbitration Commission (“CIETAC”) or the Hong Kong International Arbitration Center (“HKIAC”). Disputes in respect of the definition of shareholder and disputes in relation to the company’s shareholder registry need not be resolved by arbitration. If the party seeking arbitration elects to arbitrate the dispute or claim at the HKIAC, then either party may apply to have such arbitration conducted in Shenzhen in accordance with the securities arbitration rules of the HKIAC.

Under the PRC Arbitration Law and PRC Civil Procedure Law, an arbitral award shall be final and binding on the parties involved in the arbitration. If one party fails to comply with the arbitral award, the other party to the award may apply to a people’s court for its enforcement. However, the people’s court may refuse to enforce an arbitral award made by an arbitration commission if there is any procedural irregularity (including but not limited to irregularity in the composition of the arbitration tribunal, the jurisdiction of the arbitration commission, or the making of an award on matters beyond the scope of the arbitration agreement or outside the jurisdiction of the arbitration commission).

Any party seeking to enforce an award of a foreign affairs arbitration organ of the PRC against a party who or whose property is not located within the PRC may apply to a foreign court with jurisdiction over the relevant matters for recognition and enforcement of the award. Likewise, an arbitral award made by a foreign arbitral body may be recognized and enforced by a PRC court in accordance with the principle of reciprocity or any international treaties concluded or acceded to by the PRC.

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The PRC acceded to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the "New York Convention") passed on June 10, 1958 pursuant to a resolution passed by the Standing Committee of the NPC on December 2, 1986. The New York Convention provides that all arbitral awards made in a state which is a party to the New York Convention shall be recognized and enforced by other parties thereto subject to their rights to refuse enforcement under certain circumstances, including where the enforcement of the arbitral award is against the public policy of that state. At the time of the PRC's accession to the Convention, the Standing Committee of the NPC declared that (1) the PRC will only apply the New York Convention to the recognition and enforcement of arbitral awards made in the territories of other parties based on the principle of reciprocity; and (2) the New York Convention will only apply to disputes deemed under PRC laws to be arising from contractual or non-contractual mercantile legal relations.

An arrangement for mutual enforcement of arbitral awards between Hong Kong and the Supreme People's Court of China was reached. The Supreme People's Court of China adopted the Arrangements on the Mutual Enforcement of Arbitral Awards between the Mainland and the Hong Kong Special Administrative Region on June 18, 1999, which went into effect on February 1, 2000. The arrangements reflects the spirit of the New York Convention. Under the arrangements, the awards by the Mainland arbitral bodies recognized by Hong Kong may be enforced in Hong Kong and the awards by the Hong Kong arbitral bodies may also be enforced in the Mainland China. If the Mainland court finds that the enforcement of awards made by the Hong Kong arbitral bodies in the Mainland will be against public interests of the Mainland, the awards may not be enforced.

SUMMARY OF MATERIAL DIFFERENCES BETWEEN HONG KONG AND PRC COMPANY LAW

The Hong Kong laws applicable to a company incorporated in Hong Kong are the Companies Ordinance and the Companies (Winding Up and Miscellaneous Provisions) Ordinance and are supplemented by common law and the rules of equity that are applicable to Hong Kong. As a joint stock limited company established in the PRC that is seeking a listing of shares on the Hong Kong Stock Exchange, the Company is governed by the PRC Company Law and all other rules and regulations promulgated pursuant to the PRC Company Law.

Set out below is a summary of certain material differences between Hong Kong Company Law applicable to a company incorporated in Hong Kong and the PRC Company Law applicable to a joint stock limited company incorporated under the PRC Company Law. This summary is, however, not intended to be an exhaustive comparison.

Incorporation of Corporate

Under Hong Kong company law, a company with share capital, shall be incorporated by the Registrar of Companies in Hong Kong and the company will acquire an independent corporate existence upon its incorporation. A company may be incorporated as a public company or a private company. Pursuant to the Companies Ordinance, the articles of association of a private company incorporated in Hong Kong shall contain provisions that restrict a member's right to transfer shares. A public company's articles of association do not contain such provisions.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Under the PRC Company Law, a joint stock limited company may be incorporated by promotion or subscription. The amended PRC Company Law which came into effect on October 26, 2018 has no provision on the minimum registered capital of joint stock companies, except that laws, administrative regulations and State Council decisions have separate provisions on paid-in registered capital and the minimum registered capital of joint stock, in which case the company should follow such provisions.

Share Capital

Under Hong Kong law, the directors of a Hong Kong company may, with the prior approval of the shareholders if required, issue new shares of the company. The PRC Company Law provides that any increase in our registered capital must be approved by our shareholders’ general meeting and the relevant PRC governmental and regulatory authorities. There are no such minimum capital requirements on a Hong Kong company under Hong Kong law.

Under the PRC Securities Law, a company which is approved by the relevant securities regulatory authority to list its shares on a stock exchange must have a total share capital of not less than RMB30 million. There is no such restriction on companies incorporated in Hong Kong under Hong Kong law.

Under the PRC Company Law, the shares may be subscribed for in the form of money or non-monetary assets (other than assets not entitled to be used as capital contributions under relevant laws and administrative regulations). For non-monetary assets to be used as capital contributions, appraisals and transfer procedures of property rights must be carried out to ensure no over-valuation or under-valuation of the assets. There is no such restriction on a Hong Kong company under Hong Kong law.

Restrictions on Shareholding and Transfer of Shares

Under PRC law, our Domestic Shares, which are denominated and subscribed for in Renminbi, may only be subscribed for and traded by the government or government authorized departments, PRC legal persons, natural persons, qualified foreign institutional investors, or eligible foreign strategic investors. Overseas listed shares, which are denominated in Renminbi and subscribed for in a foreign currency other than Renminbi, may only be subscribed for, and traded by investors from Hong Kong, Macau or Taiwan or any country and territory outside the PRC, or qualified domestic institutional investors. However, qualified institutional investors and individual investors may trade Southbound Hong Kong trading Link and Northbound Shanghai trading Link (or the Northbound Shenzhen trading Link) shares via participating in Shanghai-Hong Kong Stock Connect and Shenzhen-Hong Kong Stock Connect.

Under the PRC Company Law, a promoter of a joint stock limited company is not allowed to transfer the shares it holds for a period of one year after the date of establishment of the company. Shares in issue prior to the public offering cannot be transferred within one year from the listing date of the shares on a stock exchange. Shares in a joint stock limited company held by its directors, supervisors and senior management transferred each year during their term of

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

office shall not exceed 25% of the total shares they held in the company, and the shares they held in the company cannot be transferred within one year from the listing date of the shares, and also cannot be transferred within half a year after such person has left office. The articles of association may set other restrictive requirements on the transfer of the company’s shares held by its directors, supervisors and senior management. There are no such restrictions on shareholdings and transfers of shares under Hong Kong law apart from six-month lockup on the company’s issue of shares and the 12-month lockup on controlling shareholders’ disposal of shares.

Financial Assistance for Acquisition of Shares

The PRC Company Law does not prohibit or restrict a joint stock limited company or its subsidiaries from providing financial assistance for the purpose of an acquisition of its own or its holding company’s shares. However, the Mandatory Provisions contain special restrictions provisions on a company and its subsidiaries on providing aforesaid financial assistance similar to those under the Hong Kong Company Law.

Variation of Class Rights

The PRC Company Law has no special provision relating to variation of class rights. However, the PRC Company Law states that the State Council can promulgate separate regulations relating to other kinds of shares. The Mandatory Provisions contain elaborate provisions relating to the circumstances which are deemed to be variations of class rights and the approval procedure required to be followed in respect thereof. These provisions have been incorporated in the Articles of Association.

Under the Companies Ordinance, no rights attached to any class of shares can be varied except (i) with the approval of a special resolution of the holders of the relevant class at a separate meeting, (ii) with the consent in writing of the holders representing at least 75% of the total voting rights of holders of the relevant class of shares, or (iii) if there are provisions in the articles of association relating to the variation of those rights, then in accordance with those provisions.

Directors, Senior Management and Supervisors

The PRC Company Law, unlike Hong Kong Company Law, does not contain any requirements relating to the declaration of directors’ interests in material contracts, restrictions on companies providing certain benefits to directors and guarantees in respect of directors’ liability and prohibitions against compensation for loss of office without shareholders’ approval. The Mandatory Provisions, however, contain certain restrictions on interested contracts and specify the circumstances under which a director may receive compensation for loss of office.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Supervisory Board

Under the PRC Company Law, a joint stock limited company’s directors and members of the senior management are subject to the supervision of supervisory board. There is no mandatory requirement for the establishment of supervisory board for a company incorporated in Hong Kong. The Mandatory Provisions provide that each supervisor owes a duty, in the exercise of his powers, to act in good faith and honestly in what he considers to be in the best interests of the company and to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances.

Derivative Action by Minority Shareholders

According to Hong Kong law, as permitted by court, shareholders may initiate a derivative action on behalf of the company against directors who have any misconduct to the company if the directors control a majority of votes at a general meeting, thereby effectively preventing a company from suing the directors in breach of their duties in its own name.

The PRC Company Law provides shareholders of a joint stock limited company with the right so that in the event where the directors and senior management violate their obligations and cause damages to a company, the shareholders individually or jointly holding more than 1% of the shares in the company for more than 180 consecutive days may request in writing the supervisory board to initiate proceedings in the people’s court. In the event that the supervisory board violates their obligations and cause damages to company, the above said shareholders may send written request to the board of directors to initiate proceedings in the people’s court. Upon receipt of aforesaid written request from the shareholders, if the supervisory board or the board of directors refuses to initiate such proceedings, or has not initiated proceedings within 30 days from the date of receipt of the request, or if under urgent situations, failure of initiating immediate proceeding may cause irremediable damages to the company, the above said shareholders shall, for the benefit of the company’s interests, have the right to initiate proceedings directly to the people’s court in their own name.

The Mandatory Provisions also provide further remedies against the directors, supervisors and senior management who breach their duties to the company. In addition, as a condition to the listing of shares on the Hong Kong Stock Exchange, each director and supervisor of a joint stock limited company is required to give an undertaking in favor of the company acting as agent for the shareholders. This allows minority shareholders to take action against directors and supervisors of the company in default.

Protection of Minorities

Under Hong Kong law, a shareholder who complains that the business of a company incorporated in Hong Kong are conducted in a manner unfairly prejudicial to his interests may petition to the Court to make an appropriate order to give relief to the unfairly prejudicial conduct. Alternatively, pursuant to the Companies (Winding Up and Miscellaneous Provisions) Ordinance, a shareholder may seek to wind up the company on the just and equitable ground. In addition, on the application of a specified number of members, the Financial Secretary may appoint inspectors who are given extensive statutory powers to investigate the affairs of a company incorporated or registered in Hong Kong.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

According to the PRC Company Law, in the event that the company encounters substantial difficulties in its operation and management and its continuance shall cause a significant loss to the interest of its shareholders, and where this cannot be resolved through other means, the shareholders who hold more than 10% of the total shareholders' voting rights of the company may present a petition to the People's Court for the dissolution of the company. The Mandatory Provisions, however, contains provisions that a controlling shareholder may not exercise its voting rights in a prejudicial manner to the interests of the entire or part of shareholders of a company to relieve a director or supervisor of his duty to act honestly in the best interests of the company or to approve the expropriation by a director or supervisor of the company's assets or the individual rights of other shareholders.

Notice of Shareholders' General Meetings

Under the PRC Company Law, notice of a shareholders' annual general meeting and an extraordinary shareholders meeting must be given to shareholders at least 20 days and 15 days before the meeting, respectively. Under the Special Regulations and the Mandatory Provisions, at least 45 days' written notice must be given to all shareholders before the meeting and shareholders who wish to attend the meeting must send their writing replies to the company at least 20 days before the date of the meeting.

For a company incorporated in Hong Kong, the minimum period of notice is 14 days in the case of an annual general meeting. Further, where a meeting involves consideration of a resolution requiring special notice, the company must also give its shareholders notice of the resolution at least 14 days before the meeting. The notice period for the annual shareholders' general meeting is 21 days.

Quorum for Shareholders' General Meetings

Under the Companies Ordinance, the quorum for a general meeting must be at least two members unless the articles of association of the company otherwise provided. For companies with only one shareholder, the quorum must be one shareholder. The PRC Company Law does not specify the quorum for a shareholders' general meeting, but the Special Regulations and the Mandatory Provisions provide that general meetings may only be convened after replies to the notice of that meeting have been received from shareholders whose shares represent at least 50% of the voting rights at least 20 days before the proposed date of the meeting, or if the replies of shareholders is not reached 50% of the voting rights, the company shall within five days notify its shareholders again by way of a public announcement and the shareholders' general meeting may be held thereafter.

Voting

Under the Companies Ordinance, an ordinary resolution is passed by a simple majority of affirmative votes cast by shareholders present in person, or by proxy, at a general meeting, and a special resolution is passed by not less than three-fourths of affirmative votes casted by shareholders present in person, or by proxy, at a general meeting.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Under the PRC Company Law, the passing of any resolution requires more than one-half of the affirmative votes held by our shareholders present at a shareholders' meeting except in cases such as proposed amendments to our articles of association, increase or decrease of registered capital, merger, division, dissolution or transformation, which require two-thirds of the affirmative votes cast by shareholders present at a shareholders' general meeting.

Financial Disclosure

Under the PRC Company Law, a joint stock limited company is required to make available at the company for inspection by shareholders its financial report 20 days before its shareholders' annual general meeting. In addition, a joint stock limited company of which the shares are publicly issued must publish its financial report. The Companies Ordinance requires a company incorporated in Hong Kong to send to every shareholder a copy of its financial statements, auditors' report and directors' report, which are to be presented before the company's annual general meeting, not less than 21 days before such meeting. A joint stock limited company is required under the PRC law to prepare its financial statements in accordance with the PRC GAAP. In addition, pursuant to the Mandatory Provisions, a company must, in addition to preparing financial statements according to the PRC GAAP, have its financial statements prepared and audited in accordance with international accounting standards or the accounting standards of the oversea place where the shares are listed and its financial statements must also contain a statement of the financial effect of the material differences (if any) from the financial statements prepared in accordance with the PRC GAAP. The lower of the after-tax profits of a specific fiscal year stated in the statements prepared based on the above-mentioned principles shall prevail in the allocation of such profits. The company shall publish its financial reports twice in each accounting year. An interim financial report shall be published within 60 days after the end of the first six months of each accounting year, while an annual financial report shall be published within 120 days after the end of each accounting year.

The Special Regulations require that there should not be any contradiction between the information disclosed within and outside the PRC and that, to the extent that there are differences in the information disclosed in accordance with the relevant PRC and overseas laws, regulations and requirements of the relevant stock exchanges, such differences should also be disclosed simultaneously.

Information on Directors and Shareholders

The PRC Company Law gives shareholders the right to inspect the company's articles of association, minutes of the shareholders' general meetings, share register, counterfoil of company debentures, resolutions of board meetings, resolutions of the board of supervisors and financial and accounting reports, which is similar to the shareholders' rights of Hong Kong companies under Hong Kong law.

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Receiving Agent

Under the PRC Company Law and Hong Kong law, dividends once declared are debts payable to shareholders. The limitation period for debt recovery action under Hong Kong law is six years, while under the PRC laws this limitation period is three years. The Mandatory Provisions require the relevant company to appoint a trust company registered under the Hong Kong Trustee Ordinance (Chapter 29 of the Laws of Hong Kong) as a receiving agent to receive on behalf of holders of shares dividends declared and all other monies owed by the company in respect of its shares.

Corporate Reorganization

Corporate reorganization involving a company incorporated in Hong Kong may be effected in a number of ways, such as a transfer of the whole or part of the business or property of the company in the course of voluntary winding up to another company pursuant to Section 237 of the Companies (Winding Up and Miscellaneous Provisions) Ordinance or a compromise or arrangement between the company and its creditors or between the company and its shareholders under Section 237 and Division 2 of Part 13 of the Companies Ordinance, which requires the sanction of the court. In addition, subject to the shareholders' approval, an intra-group wholly-owned subsidiary company may also be amalgamated horizontally or vertically under the Companies Ordinance.

Under PRC law, merger, division, dissolution or change the form of a joint stock limited company has to be approved by shareholders in general meeting.

Dispute Arbitration

In Hong Kong, disputes between shareholders on the one hand, and a company incorporated in Hong Kong or its directors on the other hand, may be resolved through legal proceedings in the courts. The Mandatory Provisions provide that such disputes should be submitted to arbitration at either the HKIAC or the CIETAC, at the claimant's choice.

Statutory Reserve Fund Withdrawal

Under the PRC Company Law, when a joint stock limited company allocating the after-tax profits of the current year, the Company shall allocate (10) ten percent of its profit to the statutory common reserve fund. There are no corresponding provisions under Hong Kong law.

Remedies of the Company

Under the PRC Company Law, if a director, supervisor or senior management in carrying out his duties infringes any law, administrative regulation or the articles of association of a company, which results in damage to the company, that director, supervisor or senior management should be responsible to the company for such damages. In addition, the Listing Rules require listed companies' articles of association to provide for remedies of the company similar to those available under Hong Kong law (including rescission of the relevant contract and recovery of profits from a director, supervisor or senior management).

APPENDIX V SUMMARY OF PRINCIPAL LAWS AND REGULATIONS

Dividends

The company has the power in certain circumstances to withhold, and pay to the relevant tax authorities, any tax payable under PRC law on any dividends or other distributions payable to a shareholder. Under Hong Kong law, the limitation period for an action to recover a debt (including the recovery of dividends) is six years, whereas under PRC laws, the relevant limitation period is three years. The company must not exercise its powers to forfeit any unclaimed dividend in respect of shares until after the expiry of the applicable limitation period.

Fiduciary Duties

In Hong Kong, directors owe fiduciary duties to the company, including the duty not to act in conflict with the company’s interests. Furthermore, the Companies Ordinance has codified the directors’ statutory duty of care.

Under the PRC Company Law, directors, supervisors and senior management should be loyal and diligent. Under the Mandatory Provisions, directors, supervisors and senior management are not permitted, without the approval of the shareholders’ general meeting, to engage in any activities which compete with or damage the interests of their company.

Closure of Register of Shareholders

The Companies Ordinance requires that the register of shareholders of a company must not generally be closed for the registration of transfers of shares for more than 30 days (extendable to 60 days under certain circumstances) in a year, whereas, as required by the PRC Company Law and the Mandatory Provisions, share transfers shall not be registered within 30 days before the date of a shareholders’ general meeting or within five days before the base date set for the purpose of distribution of dividends.

APPENDIX VI

SUMMARY OF THE ARTICLES OF ASSOCIATION

Set out below is a summary of the principal provisions of the Articles of Association, the objective of which is to provide investors with an overview of the Articles of Association.

As the data contained below is in summary form, it may not contain all the information that may be important to potential investors. Copies of the full English and Chinese texts of the Articles of Association are available for inspection as mentioned in “Appendix VIII – Documents Delivered to the Registrar of Companies and Available for Inspection”.

After the Articles of Association is adopted by the shareholders in the general meeting held on May 27, 2020 and approved by the relevant departments of China, it will become effective on the date that the overseas-listed foreign shares of the Company are listed on the Stock Exchange and replace the Articles of Association at the original registration in Administration for Industry and Commerce.

DIRECTORS AND OTHER SENIOR MANAGEMENT

Power to Allot and Issue Shares

There is no provision in the Articles of Association empowering the directors to allot and issue shares.

To increase the registered capital of the Company, the proposal must be submitted for approval by a special resolution at a general meeting.

Power to Dispose of the Assets of the Company or Any Subsidiary

The Board shall not dispose of or agree to dispose of any fixed assets without approval by the general meeting if the sum of the expected value of the fixed assets to be disposed of and the value derived from the disposal of fixed assets within four months before such proposal to dispose of the fixed assets exceeds 33% of the value of the fixed assets as shown on the latest audited balance sheet considered and approved by the general meeting. Disposals of the fixed assets mentioned herein include transfer of certain asset interests, but do not include guarantee provided by pledge of fixed assets.

The effectiveness of the disposal of the fixed assets shall not be affected by any breach of the above paragraph.

Remunerations and Compensation for Loss of Office

The Company shall enter into a contract in writing with each of the directors or supervisors wherein his emoluments are stipulated, subject to prior approval at a general meeting. The aforesaid emoluments include:

- (a) Emoluments in respect of his service as a director, supervisor or an officer of the Company;

APPENDIX VI

SUMMARY OF THE ARTICLES OF ASSOCIATION

- (b) Emoluments in respect of his service as a director, supervisor or an officer of any subsidiary of the Company;
- (c) Emoluments in respect of the provision of other services in connection with the management of the affairs of the Company or any of its subsidiaries;
- (d) Payment by way of compensation for loss of office, or as consideration for or in connection with his retirement from office.

No proceedings may be brought by a director or supervisor against the Company for anything due to him in respect of matters mentioned above except pursuant to the aforesaid contract.

The Company shall disclose to shareholders the remuneration received by directors, supervisors and senior officers from the Company on a regular basis.

The contracts concerning the emoluments between the Company and its directors or supervisors should provide that in the event that the Company is acquired, the directors and supervisors shall, subject to the prior approval of the general meeting, have the right to receive compensation or other payment in respect of his loss of office or retirement. For the purpose of the paragraph, an acquisition of the Company means either:

- (a) An offer made by any person to all the shareholders;
- (b) An offer made by any person with a view to the offeror becoming a controlling shareholder. See the definition of "Controlling Shareholder" in "-Rights of Minority Shareholders".

If the relevant director or supervisor does not comply with above paragraph, any sum so received by him shall belong to those persons who have sold their shares as a result of such offer. The expenses incurred in distributing that sum pro rata amongst those persons shall be borne by the relevant director or supervisor and not paid out of that sum.

Loans to Directors, Supervisors and Senior Management

The Company shall not directly or indirectly make a loan to, or provide any security in connection with the making of a loan to a director, supervisor, general manager or other officer of the Company or of the Company's parent company or any of their respective associates.

The following circumstances are not subject to above prohibition:

- (a) The provision by the Company of a loan or a guarantee of a loan to a company which is a subsidiary of the Company;

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- (b) The provision by the Company of a loan or a guarantee in connection with the making of a loan or any other funds available to any of its directors, supervisors, general manager and other officers to meet expenditure incurred or to be incurred by him for the purposes of the Company or for the purpose of enabling him to perform his duties properly, in accordance with a service contract approved by the shareholders in general meeting;
- (c) The Company may make a loan to or provide a guarantee in connection with the making of a loan to any of the relevant directors, supervisors, general manager and other officers and their respective associates in the ordinary course of its business on normal commercial terms, provided that the ordinary course of business of the Company includes the lending of money or the giving of guarantees.

A loan made by the Company in breach of the above paragraph shall be forthwith repayable by the recipient of the loan regardless of the terms of the loan.

Any guarantee for a loan provided by the Company in breach of the above paragraph shall be unenforceable against the Company, unless:

- (a) At the time the loan was made to an associate of any of the directors, supervisors, general manager and other officers of the Company or of the Company's parent company, the lender was not aware the relevant circumstances;
- (b) The security provided by the Company has been lawfully disposed of by the lender to a bona fide purchaser.

The guarantee as referred to in the preceding paragraph includes the act of the guarantor to undertake the responsibility or provide property to ensure that the obligor fulfils the obligations.

Financial Assistance to Acquire Shares of the Company

The Company or its subsidiaries (including affiliates of the Company) shall not at any time by way of gift, advance, guarantee, compensation or loans to provide any financial assistance to purchasers or potential purchasers of the Company's shares in any way. The aforesaid purchasers include persons directly or indirectly undertaking obligations because of the purchase of the Company's shares.

The Company or its subsidiaries (including affiliates of the Company) shall not at any time or in any form provide any financial assistance to the aforesaid obligors for the purpose of reducing or discharging their obligations.

Financial assistance referred to in the Articles of Association includes (but is not limited to) the following:

- (a) Gift;
- (b) Guarantee (including the case where the guarantor undertakes liability or provides property to ensure fulfilment of obligations by the obligor), compensation (excluding compensation for the Company's own error), termination or waiver of rights;

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- (c) Provision of loan or execution of contract under which the Company fulfils obligations prior to other parties, change of the said loan and the parties to the contract, and transfer of the said loan and rights under the contract;
- (d) Provision of any other form of financial assistance when the Company is insolvent, has no net assets or its net assets are likely to decrease significantly.

Obligations referred to in the above paragraph include the obligations undertaken by the obligor for entering into a contract or making an arrangement (regardless whether the said contract or arrangement is enforceable or whether it is undertaken by the obligor individually or jointly with others) or for changing his financial position in any form.

the following acts are not deemed as prohibited :

- (a) The Company provides the relevant financial assistance truthfully in the interest of the Company and the said financial assistance is not mainly intended to buy back the Company's shares or the said financial assistance is part of a general plan of the Company;
- (b) The Company distributes its properties as dividends in accordance with the law;
- (c) The Company distributes shares as dividends;
- (d) The Company decreases the registered capital, buys back shares and adjusts the equity structure in accordance with the Articles of Association;
- (e) The Company, within its business scope, provides loan for its normal business operations (but such financial assistance shall not give rise to a decrease of the net assets of the Company, or despite a decrease, such financial assistance is deducted from the distributable profit of the Company);
- (f) The Company provides loan for the employee stock ownership plan (but such financial assistance shall not give rise to a decrease of the net assets of the Company, or despite a decrease, such financial assistance is deducted from the distributable profit of the Company).

Disclosure of Interests in Contracts with the Company

Where a director, supervisor, general manager and other officer of the Company is in any way, directly or indirectly, materially interested in a contract, transaction or arrangement or proposed contract, transaction or arrangement with the Company, (other than his contract of service with the Company), he shall declare the nature and extent of his interests to the Board at the earliest opportunity, whether or not such contract, transaction or arrangement therefor is otherwise subject to the approval of the Board.

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Unless the interested director, supervisor, general manager and other officer discloses his interests in accordance with the requirements of the preceding paragraph of this article and the contract, transaction or arrangement is approved by the Board at a meeting in which the interested director, supervisor, general manager and other officer is not counted in the quorum and refrains from voting, such contract, transaction or arrangement is voidable at the instance of the Company except as against a bona fide party thereto acting without notice of the breach of duty by the interested director, supervisor, general manager and other officer.

A director, supervisor, general manager and other officer of the Company is deemed to be interested in a contract, transaction or arrangement in which an associate of him is interested.

Where a director, supervisor, general manager and other officer of the Company gives to the Board a general notice in writing stating that, by reason of the facts specified in the notice, he is interested in contracts, transactions or arrangements of any description which may subsequently be made by the Company, such notice shall be deemed for the purposes of the above paragraph in the Articles of Association to be a sufficient declaration of his interests, so far as the content stated in such notice is concerned, provided that such general notice shall have been given before the date on which the question of entering into the relevant contract, transaction or arrangement is first taken into consideration on behalf of the Company.

REMUNERATION

The remuneration of Directors must be approved by shareholders at a general meeting. See “–Remunerations and Compensation for Loss of Office” above.

APPOINTMENT, REMOVAL AND RETIREMENT

A person may not serve as a director, supervisor, general manager and other senior management of the Company if any of the following circumstances apply:

- (a) a person without legal or with restricted legal capacity;
- (b) a person who has been found guilty of sentenced for corruption, bribery, infringement of property, misappropriation of property or sabotaging the social economic order where less than a term of 5 years have elapsed since the sentence was served; or a person who has been deprived of his political rights, in each case where less than 5 years have elapsed since the sentence was served;
- (c) a person who is a former director, factory manager or general manager of a company or enterprise which has been entered into insolvent liquidation because of mismanagement and he/she is personally liable for the insolvency of such company or enterprise, where less than 3 years have elapsed since the date of the completion of the insolvency and liquidation of the company or enterprise;
- (d) a person who is a former legal representative of a company or enterprise which had its business licence revoked due to a violation of the law and who incurred personal liability, where less than 3 years has elapsed since the date of the revocation of the business licence;

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- (e) a person who has a relatively large amount of debts due and outstanding;
- (f) a person who is under criminal investigation by judicial organization for the violation of the criminal law which is not yet concluded;
- (g) a person who is not eligible to act as a leader of an enterprise according to laws and administrative regulations;
- (h) a non-natural person;
- (i) currently being barred by the China Securities Regulatory Commission from participating in the securities market;
- (j) a person convicted of the contravention of provisions of relevant securities regulations by a relevant government authority, and such conviction involves a finding that he has acted fraudulently or dishonestly, where less than 5 years has elapsed since the date of the conviction;
- (k) other circumstances as required under laws, administrative regulations, departmental rules, regulatory documents, regulations of relevant regulatory authorities.

Where the Company elects, appoints or employs a director, a supervisor, the general manager and other senior management to which any of the above circumstances applies, such election, appointment or employment shall be null and void. A director, a supervisor, the general manager and other senior management to which any of the above circumstances applies during his/her term of office shall be released of his/her duties by the Company.

The validity of an act of a director, general manager and other senior management on behalf of the Company is not, as against a bona fide third party, affected by any irregularity in his office, election or any defect in his qualification.

CREDIT POWERS

The Articles of Association do not specifically provide for the manner in which borrowing powers may be exercised nor do they contain any specific provision in respect of the manner in which such borrowing powers may be amended, except for:

- (a) provisions which authorize the Board to formulate proposals on the issue and listing of bonds or other securities issued by the Company;
- (b) provisions which provide that the issuing of any class of shares, warrants and other similar securities by the Company shall be passed by the general meeting by a special resolution.

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AMENDMENTS TO THE ARTICLES OF ASSOCIATION OF THE COMPANY

Under any one of the following circumstances, the Company shall amend its Articles of Association:

- (a) after amendment has been made to the Company Law or relevant laws or administrative regulations, the contents of the Articles of Association shall conflict with the amended laws or administrative regulations;
- (b) the changes that the Company have undergone are inconsistent with the records made in the Articles of Association;
- (c) the general meeting decides that the Article of Association should be amended.

The shareholders may authorize the Board of the Company by ordinary resolution at the general meeting:

- (a) in case of increase of registered share capital of the Company, the Board of the Company is entitled to amend the relevant content regarding the registered capital of the Company in the Articles of Association in accordance with the actual circumstances;
- (b) in case of alteration of the text or order of the provisions required by the relevant regulatory authority during the registration, audit and approval of the Articles of Association of the Company approved by the general meeting, the Board of the Company is entitled to make the corresponding amendments according to the requirements of the relevant regulatory authority.

Amendments to the Articles of Association passed by resolutions at the general meeting shall be required to be examined and approved by the competent authorities, and shall be submitted to the competent authorities for approval; where the amendments involve the registered particulars of the Company, procedures for change of registration shall be handled in accordance with the law.

CHANGE OF RIGHTS OF EXISTING SHARES OR CLASSES OF SHARES

Rights conferred on any class of shareholders in the capacity of shareholders may not be varied or abrogated unless approved by a special resolution of a general meeting and by holders of shares of that class at a separate meeting conducted in accordance with stipulated in the Articles of Association.

The following circumstances shall be deemed to be variation or abrogation of the class rights of a class:

- (a) to increase or decrease the number of shares of such class, or increase or decrease the number of shares of class having voting or equity rights or privileges equal or superior to those of the shares of such class;

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- (b) to effect an exchange of all or part of the shares of such class into shares of another class or to effect an exchange or create a right of exchange of all or part of the shares of another class into the shares of such class;
- (c) to remove or reduce rights to accrued dividends or rights to cumulative dividends attached to shares of such class;
- (d) to reduce or remove a dividend preference or a liquidation preference attached to shares of such class;
- (e) to add, remove or reduce conversion privileges, options, voting rights, transfer, pre-emptive rights, or rights to acquire securities of the Company attached to shares of such class;
- (f) to remove or reduce rights to receive payment payable by the Company in particular currencies attached to shares of such class;
- (g) to create a new class having voting or equity right or privileges equal or superior to those of the shares of such class;
- (h) to restrict the transfer or ownership of the shares of such class or add to such restriction;
- (i) to issue rights to subscribe for, or convert into, shares in the Company of such class or another class;
- (j) to increase the rights or privileges of shares of another class;
- (k) to restructure the Company where the proposed restructuring will result in different classes of shareholders bearing a disproportionate burden of such proposed restructuring;
- (l) to vary or abrogate provisions in this section.

Shareholders of the affected class, whether or not otherwise having the right to vote at general meetings, shall nevertheless have the right to vote at class meetings in respect of matter concerning (b) to (h), (k) to (l) of the above Article, but interested shareholder shall not be entitled to vote at class meetings.

The meaning of the foregoing “interested shareholder” is:

- (a) in the case of a repurchase of shares by offers to all shareholders pro rata according to the Articles of Association or public dealing on a stock exchange, a “controlling shareholder” within the meaning of the Articles of Association;
- (b) in the case of a repurchase of shares by an off-market contract according to the Articles of Association, a holder of the shares to which the proposed contract relates;

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- (c) in the case of a restructuring of the Company, a shareholder within a class who bears less than a proportionate burden imposed on that class under the proposed restructuring or who has an interest in the proposed restructuring different from the interest of shareholders of that class.

Resolutions of a class meeting shall be passed by votes representing more than two-thirds of the voting rights of shareholders of that class represented at the relevant meeting who are entitled to vote at class meetings.

When the Company is to hold a class meeting, a written notice shall be issued at least 20 business days (excluding both the date of notice and the date of meeting) prior to the annual general meeting and at least 15 days or 10 business days (whichever is longer, and excluding both the date of notice and the date of meeting) prior to the extraordinary general meeting and shall inform all the registered shareholders of that class of the matters to be considered at the meeting as well as the date and venue of the meeting.

Notice of class meetings need only be served on shareholders entitled to vote thereat.

Except as otherwise provided under the Articles of Association, any class meetings shall be conducted in a manner as similar as possible to that of general meetings. The provisions of the Articles of Association relating to the manner of conducting any general meeting shall apply to any class meeting.

Other than the shareholders of other classes of shares, shareholders of domestic shares and overseas-listed foreign shares shall be deemed as shareholders of different classes.

The special procedures for voting at a class of shareholders shall not apply in the following circumstances:

- (a) where the Company issues domestic shares and overseas-listed foreign invested shares, upon the approval by a special resolution of its general meeting, either separately or concurrently once every 12 months, not exceeding 20% of each of its existing issued;
- (b) where the Company's plan to issue domestic shares and overseas-listed foreign invested shares at the time of its establishment is carried out within 15 months from the date of approval of the securities regulatory authority under the State Council;
- (c) Shares (including domestic and foreign shares) already issued but not listed of the Company, after approval from the securities regulatory authority under the State Council, are converted to overseas-listed shares.

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RESOLUTIONS-MAJORITY REQUIRED

Resolutions of the general meeting shall be divided into ordinary resolutions and special resolutions.

An ordinary resolution of a general meeting shall be passed by more than one half of the voting rights held by the shareholders (including proxies) present at the meeting.

A special resolution of a general meeting shall be passed by two-thirds of the voting rights held by the shareholders (including proxies) present at the meeting.

VOTING RIGHTS

A shareholder (including his/her proxy) shall exercise his/her voting rights based on the number of shares held. Each share shall have one vote. No voting rights shall attach to the shares held by the Company, and such shares shall not be counted among the total number of shares with voting rights present at a general meeting.

If the laws, administrative regulations, regulatory rules of the place where the shares of the Company are listed stipulate that any shareholder shall waive his/her voting right on a certain resolution or limit any shareholder to cast affirmative or negative vote on certain matter, and in case of any violation of such relevant stipulation or limitations, votes casted by such shareholders or proxies thereof shall not be adopted.

Unless the resolutions on relevant procedures of a general meeting or administrative matters which can be decided by the chairman in the spirit of honesty and credibility and shall be voted on by show of hands, voting for a general meeting shall be made by ballot.

At the time of voting, any shareholder who has two or more votes (including the proxies of such shareholders) needs not to use all votes for or against any resolution or to abstain from voting on such resolution.

REQUIREMENT FOR GENERAL MEETINGS

General meetings shall be divided into annual general meetings and extraordinary general meetings. Annual general meetings are held once every year and within 6 months from the end of the preceding accounting year.

The Board shall convene an extraordinary general meeting within two months after the occurrence of any one of the following circumstances:

- (a) where the number of directors falls short of the minimum number required by the Company Law or is no more than two-thirds of the number required by the Articles of Association;
- (b) where the unrecovered losses of the Company amount to one-third of its total paid up share capital;

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- (c) where shareholder(s), individually or jointly, holding 10% or more of the Company's issued and outstanding shares carrying voting rights request(s) in writing the convening of an extraordinary general meeting (the number of shares held shall be calculated as at the date when the shareholder(s) provide(s) the written request);
- (d) where the Board considers it necessary;
- (e) where the board of supervisors proposes to call for such a meeting;
- (f) other circumstances stipulated by laws, administrative regulations, departmental rules, the listing rules of the place where the shares of the Company are listed or the Articles of Association.

The venue of a general meetings of the Company shall be the place where the Company is located or the place specified in the notice of the general meeting.

ACCOUNTS AND AUDIT

The Company shall establish its financial and accounting system in accordance with the laws, administrative regulations and the requirement of relevant regulatory departments of the PRC. Any other requirements as required by the securities regulatory authority at the place where the shares of the Company are listed shall prevail.

The financial statements of the Company shall, in addition to being prepared in accordance with the PRC accounting standards and regulations, be prepared in accordance with either international amounting standards, or that of the overseas listing place. If there is any material difference between the financial statements prepared respectively in accordance with the two accounting standards, such difference shall be stated in an appendix to the financial statements. When the Company is to distribute its after-tax profits, the lower of the after-tax profits as shown in the two financial statements shall be adopted.

The Company shall publish its financial reports twice every fiscal year, that is, the interim financial report shall be published within 60 days after the first 6-month period of each fiscal year and the annual financial report shall be published within 120 days after the expiration of each fiscal year.

Any interim results or financial information published or disclosed by the Company must be prepared and presented in accordance with the PRC accounting standards and regulations, and also in accordance with either international accounting standards or that of the overseas listing place.

The Company's financial reports shall be made available for shareholders' inspection at the Company 20 days before the date of every annual general meeting. Each shareholder of the Company shall be entitled to obtain a copy of the financial reports referred to in this section.

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Unless otherwise specified in the Articles of Association, the Company shall deliver or send to each shareholder of overseas listed shares by prepaid mail at the address registered in the register of shareholders the said reports, the report of directors, together with the balance sheet (including every document to be attached to the balance sheet as required by the law) and statement of profit or loss or the statement of income and expense not later than twenty-one days before the date of every annual general meeting. However, such documents may also be delivered to shareholders of overseas listed shares through the Company's website, the website of the Hong Kong Stock Exchange and other websites as may be provided by the Hong Kong Listing Rules from time to time, provided that the laws, administrative regulations and requirements of the securities regulatory authority at the place where the shares of the Company are listed are observed.

NOTICE OF MEETING AND MATTERS TO BE CONSIDERED

The general meeting is the organ of authority of the Company, which exercises its functions and powers in accordance with laws:

- (a) to decide on operational policies and investment plans of the Company;
- (b) to elect and replace the directors and supervisors who are shareholder representatives, and to decide on matters relevant to remuneration of directors and supervisors;
- (c) to consider and approve reports of the Board;
- (d) to consider and approve reports of the board of supervisors;
- (e) to consider and approve annual financial budget plans and final accounting plans of the Company;
- (f) to consider and approve the profit distribution plan and loss recovery plan of the Company;
- (g) to determine the increases or decrease of the registered capital of the Company;
- (h) to determine the issuance of corporate bonds or other securities by the Company and listing plan;
- (i) to determine matters such as the merger, division, dissolution, liquidation or change;
- (j) to amend the Articles of Association;
- (k) to determine the appointment of, removal of and non-reappointment of an auditor by the Company;
- (l) to consider and approve the provision of guarantees to third parties that shall be approved at a general meeting required by the Articles of Association;

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- (m) to consider matters relating to the purchases and disposals of material assets, which are more than 30% of the latest audited total assets of the Company, within one year;
- (n) to consider and approve the related transactions that shall be considered and approved at a general meeting required by laws, administrative regulations, the listing rules of the place where the shares of the Company are listed and the Articles of Association;
- (o) to consider the formulation, amendment and implementation of share incentive plans;
- (p) to consider and approve the proposal raised by shareholders who, individually or in the aggregate, hold 3% or more of the total number of voting shares of the Company;
- (q) to review other matters which, in accordance with laws, administrative regulations, departmental rules, the listing rules of the places where the shares of the Company are listed, or the provisions of the Articles of Association, shall be approved at a general meeting.

The general meeting can authorize or entrust the Board to handle the matters authorized or entrusted thereby, provided that the laws and regulations, and the mandatory laws and regulations of place where the shares of the Company are listed are not violated.

The following matters shall be approved by ordinary resolution at a general meeting:

- (a) work reports of the Board and the board of supervisors;
- (b) profit distribution plan and loss recovery plan formulated by the Board;
- (c) removal of members of the Board and the board of supervisors, their remuneration and method of payment;
- (d) annual financial budgets and statements of final accounts, balance sheet, income statement and other financial statements of the Company;
- (e) annual report of the Company;
- (f) any matters not otherwise required by the laws, administrative regulations, regulatory rules of the place where the shares of the Company are listed or these Articles of Association to be passed by special resolution.

The following matters shall be approved by special resolution at a general meeting:

- (a) to increase or reduce the registered capital of the Company and issue any type of shares, options and other similar types of securities;

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- (b) to resolve on the issuance of corporate bonds or other securities and listing plan thereof;
- (c) to resolve on the division, merger, dissolution, liquidation or transformation of the Company;
- (d) to make amendments to these Articles of Association;
- (e) to consider purchase or sale of material assets by the Company within one year, or a guarantee amount exceeding 30% of the total assets in the most recent audit period of the Company;
- (f) to formulate, revise and implement a share incentive scheme;
- (g) other matters as stipulated by the laws, administrative regulations, regulatory rules of the place where the shares of the Company are listed or these Articles of Association, and matters deemed by the general meeting by ordinary resolution to have material effect on the Company and necessary for passing by special resolution.

Where the Company convenes an annual general meeting, a written notice shall be issued at least 20 business days (excluding both the date of notice and the date of meeting) prior to the annual general meeting and at least 15 days or 10 business days (whichever is longer, and excluding both the date of notice and the date of meeting) prior to the extraordinary general meeting. If there are other provisions in the laws, regulations and by the securities regulatory authorities of the place where the shares of the Company are listed, such provisions shall prevail.

The notice of the general meeting shall be given in writing and contain the following:

- (a) the date, venue and duration of the meeting;
- (b) matters and proposals submitted for consideration at the meeting;
- (c) an obvious statement that all shareholders are entitled to attend the general meeting in person, or appoint in writing proxies to attend and vote on his or her behalf and that such proxies need not be shareholders of the Company;
- (d) name and telephone number of the permanent contact person;
- (e) such information and explanation as necessary for shareholders to make informed decisions in connection with the matters to be discussed; this principle shall apply (but not be limited to) when proposals are made to merge the Company, to repurchase shares of the Company, to reorganize its share capital or to effect any other reorganization of the Company and specific conditions and contracts (if any) of the proposed transaction together with proper explanations of the causes and consequences of any such proposals;

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- (f) the nature and extent of the material interests of any director, supervisor or senior management members in the transaction to be discussed and the difference in case of the effect of the transaction to be discussed on such director, supervisor or senior management member as shareholders insofar as it differs from the effect on the shareholders of the same class;
- (g) the full text of any special resolution proposed to be passed at the meeting;
- (h) the date and place for serving the power of attorney authorizing the proxy to vote;
- (i) the record date for the determination of the entitlements of shareholders to the general meeting.

The notice and supplementary notice of a general meeting shall adequately and completely disclose the specific contents of all proposals. Where the opinions of the independent directors are required on the issues to be discussed, such opinions and reasons thereof shall be disclosed when the notice or supplementary notice of the general meeting is served.

Unless otherwise stipulated by the laws, regulations and these Articles of Association, the notice of a general meeting shall be delivered by hand or prepaid mail to all shareholders (whether they are entitled to vote at the general meeting or not). The address of the recipient shall be the address registered in the register of members. For holders of domestic shares, the notice of a general meeting may also be in the form of an announcement.

The announcement mentioned above shall be published in one or more newspapers designated by the securities regulatory authorities under the State Council. All holders of domestic shares shall be deemed as having receive the notice of the general meeting once the announcement is published.

The notice of the general meeting sent to holders of H Shares may be published on the designated website of the Hong Kong Stock Exchange and the website of the Company. All holders of overseas listed shares shall be deemed as having receive the notice of the general meeting once the announcement is published.

TRANSFER OF SHARES

Unless otherwise specified in the laws and administrative and by the securities regulatory authorities in the place where the shares of the Company, the paid up shares of the Company can be freely transferred in accordance with laws and are not subject to any lien. Shares of the Company could be granted, inherited and pledged in accordance with relevant laws, administrative regulations and requirement of the Articles of Association. For the transfer of the shares of the Company, registration shall be made in the share registrar authorized by the Company.

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All paid up H shares shall be freely transferable in accordance with the Articles of Association; unless the following conditions are satisfied, the Board may refuse to recognize any transfer documents without giving any reasons:

- (a) The transfer instrument and other documents relating to or likely affecting the ownership of any shares shall be registered, and the payment therefor shall not exceed the maximum payment specified in the Listing Rules by the Hong Kong Stock Exchange from time to time;
- (b) The transfer document only involves H shares;
- (c) The stamp tax payable on the transfer instrument has been paid;
- (d) The relevant share certificate, together with the evidence as reasonably required by the Board showing that the transferor is entitled to transfer the shares are produced;
- (e) If the shares are to be transferred to joint holders, the number of joint holders shall not exceed four;
- (f) No company shall have any lien over the relevant shares; and
- (g) No transfer shall be made to minors or persons of unsound mind or others under legal disability.

If the Board refuses to register the share transfer, the Company shall send a written notice of the transferor and transferee within two months from the date of transfer application. All transfers of H shares shall be effected by transfer document in writing in a general or common form or in any other form acceptable to the Board, including the standard transfer form or form of transfer specified by the Hong Kong Stock Exchange from time to time. The transfer document in writing may be signed by hand or (where the transferor or transferee is a corporation) stamped with the company's seal. If the transferor or transferee is a recognized clearing house as defined by the relevant provisions that come into effect from time to time according to the laws of Hong Kong (hereinafter referred to as the "Recognized Clearing House") or its nominee, the transfer document in writing may be signed by hand or in printed form.

All transfer documents shall be maintained in the legal address of the Company or such places as the Board may designate from time to time.

The Company shall not accept its own shares as pledge subject.

Shares of the Company held by the promoters shall not be transferred within one year after incorporation of the Company. Shares already issued by the Company before [REDACTED] shall not be transferred within one year after the shares of the Company are listed on the stock exchange.

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The directors, supervisors and senior executives shall report to the Company about their shareholdings and changes thereof and shall not transfer more than 25% of their shares per annum during their terms of office; the shares they hold in the Company shall not be transferred within one year after the shares of the Company are listed. The aforesaid persons shall not transfer their shares in the Company within half a year after they terminate service with the Company.

Where the relevant regulations of the securities regulatory authorities of the place where the shares of the Company are listed provide otherwise in respect of any transfer of any overseas listed foreign shares, such regulations shall apply.

POWER FOR THE COMPANY TO REPURCHASE ITS OWN SHARES

The Company may, in the following circumstances, buy back its outstanding shares in accordance with the law, administrative regulations, department rules and requirement of this Articles of Associations:

- (a) When decreasing registered capital of the Company;
- (b) When merging with other companies holding shares of the Company;
- (c) When shares are being used in the employee stock ownership plan or as equity incentive;
- (d) When shareholders objecting to resolutions of the general meeting concerning merger or division of the Company require the Company to buy their shares;
- (e) When shares are being used to satisfy the conversion of corporate bonds convertible into shares issued by the Company;
- (f) When safeguarding corporate value and shareholders' equity as the Company deems necessary;

Except for the abovementioned circumstances, the Company will not conduct any activities buying or selling its shares.

Where the Company repurchases its shares in the circumstances set out in items (a) and (b) above, it shall be subject to approval at the general meeting; where the Company repurchases its shares in the circumstances set out in items (c), (e) and (f) above, it may be resolved by more than two-thirds of directors present at a meeting of the Board in accordance with the authorization of the general meeting.

In the event that the Company repurchases its shares in accordance with the above provisions, such Shares shall be cancelled within 10 days upon such repurchase in the circumstance set out in item (a); shall be transferred or cancelled within 6 months in the

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circumstances set out in items (b) and (d); the aggregate number of shares held by the Company shall not exceed 10% of the total issued shares of the Company, and shall be transferred or cancelled within 3 years in the circumstances set out in items (c), (e) and (f).

Where the Company repurchases its shares, it shall perform its information disclosure obligations in accordance with laws.

The Company may buy back its shares in any of the following ways:

- (a) Issuing a buyback offer to all shareholders according to an equal percentage;
- (b) Buying back through open transaction in the stock exchange;
- (c) Buying back through agreement outside the stock exchange;
- (d) Other methods as permitted by laws and administrative regulations and approved by regulatory authorities.

In buying back shares through agreement outside the stock exchange, the Company shall seek prior approval at a general meeting in accordance with the Articles of Association. With prior approval at the general meeting in the same way, the Company may cancel or change the contract already concluded in the aforesaid manner or waive any right under the contract.

The share buyback contract mentioned in the preceding paragraph includes (but is not limited to) agreement to undertake share buyback obligations and obtain share buyback rights.

The Company shall not transfer the share buyback contract or any right thereunder.

Unless the Company is under liquidation, the Company shall observe the following regulations when buying back its outstanding shares:

- (a) If the Company buys back shares at par value, the payment shall be deducted from the book balance of distributable profit of the Company and the proceeds from issuance of new shares for buying back old shares;
- (b) If the Company buys back shares above par value, the part equivalent to the par value shall be deducted from the book balance of distributable profit of the Company and the proceeds from issuance of new shares for buying back old shares; the part above the par value shall be processed as follows:
 - i. Deducted from the book balance of distributable profit of the Company if the shares bought back were issued at par value;
 - ii. Deducted from the book balance of distributable profit of the Company and the proceeds from issuance of new shares for buying back old shares if the shares bought back were issued above par value; but the amount deducted from the

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proceeds from issuance of new shares shall not exceed the total premium obtained at the time of issuance of the shares bought back and shall not exceed the amount (including premium from issuance of new shares) in the premium account (or capital reserve account) of the Company at the time of buyback;

- (c) The monies paid by the Company for the following purposes shall be deducted from the distributable profits of the Company:
 - i. Acquiring the right to buy back its shares;
 - ii. Changing the share buyback contract;
 - iii. Cancelling its obligations under the share buyback contract.
- (d) After the par value of the cancelled shares is deducted from the registered capital of the Company pursuant to relevant regulations, the amount deducted from the distributable profit for paying the par value of the shares bought back shall be stated in the premium account (or capital reserve account) of the Company.

RIGHT OF THE COMPANY'S SUBSIDIARIES TO OWN SHARES IN THE COMPANY

There are no provisions in the Articles of Association restricting a subsidiary of the Company from owning any of the shares of the Company.

DIVIDENDS AND OTHER METHODS OF PROFIT DISTRIBUTION

The Company may distribute profit in the form of cash or shares.

The Company shall appoint a payment receiving agent for holders of overseas listed foreign shares in Hong Kong. The payment receiving agent shall receive on behalf of such shareholders any dividends or other amounts payable by the Company to them in respect of the overseas listed foreign shares. The payment receiving agent appointed by the Company shall satisfy the requirements under the laws of the place where the Company's shares are listed or the rules of the relevant stock exchange. The payment receiving agent appointed by the Company for holders of overseas listed foreign shares listed on the Hong Kong Stock Exchange shall be a trust company registered under the Trustee Ordinance of Hong Kong.

SHAREHOLDERS' PROXY

Any shareholder who is entitled to attend the general meeting and vote thereat may attend the general meeting in person or appoint one or more proxies (who may not be a shareholder) to attend and vote on its behalf. A shareholder shall authorize his or her proxy in writing and the power of attorney shall be signed by the proxy or the agent authorized in writing by the proxy. Where the proxy is a corporate, the chop of the corporate should be affixed, or the director or the agent officially entrusted shall sign such power of attorney.

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A proxy is entitled to exercise the following rights pursuant to the appointment made by the appointing shareholder:

- (a) the same right as the shareholder to speak at the general meeting;
- (b) authority to demand or join in demanding a poll;
- (c) the right to vote by show of hands or on a poll; however, a proxy of a shareholder who has appointed more than one proxy may only vote on a poll.

The instrument appointing a proxy shall be deposited at the Company's domicile or such other place as specified in the notice of the meeting at least 24 hours before the time appointed for holding the meeting at which the instrument proposes to vote, or 24 hours before the time appointed for taking of poll. Where such instrument is signed by a person under a power of attorney or other authority on behalf of the appointer, that power of attorney or other authority is required to be notarized. A notarized copy of that power of attorney or other authority together with the instrument appointing a proxy is required to be deposited at the Company's domicile or such other place as specified in the notice of the meeting.

If the appointer is a corporation shareholder, the legal representative (person in charge) or such person who is authorized by the resolution of its board or other governing body to act as its representative may attend the general meeting of the Company.

A vote given by a proxy in accordance with the terms of an instrument of proxy shall be valid notwithstanding the previous death or loss of capacity of the appointer or revocation of the proxy or power of authority under which the proxy was executed, or the transfer of the share in respect of which the proxy is given, provided that no notice in writing of such death, insanity, revocation or transfer as aforesaid has been received by the Company before the commencement of the meeting at which the proxy is used.

CALLS ON SHARES AND FORFEITURE OF SHARES

The Company has the power to cease sending dividend warrants by post to a given holder of overseas listed foreign shares, but may exercise such power only if such warrants have been left uncashed on two consecutive occasions. However, the Company may exercise such power after the first occasion on which such a warrant is returned undelivered.

The Company has the power to sell by a method deemed fit by the Board the shares of a holder of overseas listed foreign shares who is untraceable, provided that it complies with the following conditions:

- (a) Dividends on such foreign shares have been distributed at least three times in 12 years, which dividends are not claimed by anybody during the period; and
- (b) upon expiration of the 12-year period, the Company makes an announcement of its intention to sell such shares in one or more newspapers at the place where the shares of the Company are listed, and notify the Hong Kong Stock Exchange.

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RIGHTS OF SHAREHOLDERS (INCLUDING INSPECTION OF REGISTER OF MEMBERS)

Ordinary shareholders of the Company shall enjoy the following rights:

- (a) The rights to receive dividends and other forms of distribution in proportion to the number of shares held by them;
- (b) The rights to request, convene, chair, attend or appoint proxy to attend general meetings and exercise corresponding voting rights in accordance with laws;
- (c) The rights to supervise and manage the operation of the Company and to put forward proposals and raise inquiries;
- (d) The rights to transfer, donate, or pledge shares held by them in accordance with laws, administrative regulations and the Articles of Association;
- (e) The rights to obtain relevant information in accordance with the Articles of Association of the Company, including:
 - i. to obtain a copy of the Articles of Association, subject to payment of the cost of such copy;
 - ii. to inspect and copy, subject to payment of a reasonable charge:
 - (i) all parts of the register of members (the list of all shareholders at the close of trading on the record date of the Company's latest periodic report);
 - (ii) personal particulars of each of the directors, supervisors, general manager and other senior management of the Company, including: a. current and previous names and aliases; b. main address (domicile); c. nationality; d. full-time and all other part-time occupations and duties; e. identification documents and their number;
 - (iii) the status of the Company's share capital;
 - (iv) reports (breakdown by domestic shares and foreign shares (and, if applicable, H Shares)) of the aggregate par value, number of shares, highest and lowest prices paid by the Company in respect of each class of shares bought back by the Company since the end of the last financial year and all the expenses paid by the Company therefor;
 - (v) minutes of general meetings (only available for shareholders' inspection) and copies of the Company's resolutions of general meetings, Board meetings and meeting of Board of Supervisors;

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- (vi) the latest audited financial statements of the Company, and the reports of directors, auditors, and supervisors;
- (vii) copy of the latest annual return filed with the PRC Administration for Industry and Commerce or other competent authorities;
- (viii) special resolutions of the Company.

iii. counterfoils of corporate bonds

Documents of item ii (i), (iii), (iv), (v), (vi), (vii) and (viii) mentioned above shall be made available by the Company, according to the requirements of the Hong Kong Listing Rules, at the Company's address in Hong Kong, for the public and the H shareholders to inspect free of charge (provided that minutes of general meetings are available for inspection by the shareholders only). When a shareholder requests to inspect the relevant information mentioned above or obtain such materials, he/she shall provide the Company with such written documents evidencing the class and amount of shares he/she holds in the Company. The Company may provide such information per the shareholder's request after verifying his/her identity.

- (f) The rights to participate in the distribution of remaining assets of the Company corresponding to the number of shares held in the event of the termination or liquidation of the Company;
- (g) The rights to demand the Company to acquire the shares held by them with respect to shareholders voting against any resolution adopted at the general meeting on the merger or division of the Company;
- (h) Other rights under the laws, administrative regulations, the regulatory rules of the place where the shares of the Company are listed and these Articles of Association.

If any person holding an interest in the shares either directly or indirectly exercises their rights without disclosing their rights to the Company, the Company shall not compromise the rights of such persons by freezing it or in any other manner only on this ground.

QUORUM OF GENERAL MEETINGS

Where the Company convenes an annual general meeting, a written notice shall be issued at least 20 business days (excluding both the date of notice and the date of meeting) prior to the annual general meeting and at least 15 days or 10 business days (whichever is longer, and excluding both the date of notice and the date of meeting) prior to the extraordinary general meeting. If the laws, regulations and the securities regulatory authorities of the place where the shares of the Company are listed provide otherwise, such provisions shall prevail.

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RIGHTS OF MINORITY SHAREHOLDERS

In addition to obligations imposed by the laws, administrative regulations or required by the regulatory rules of the place where the shares of the Company are listed, a controlling shareholder shall not exercise his voting rights in respect of the following matters in a manner prejudicial to the interests the shareholders generally or partially:

- (a) to relieve a Director or Supervisor of his/her duty to act honestly in the best interests of the Company;
- (b) to approve the expropriation by a Director or Supervisor (for his/her own benefit or for the benefit of another person), in any guise, of the Company's property, including (without limitation) opportunities beneficial to the Company; or
- (c) to approve the expropriation by a Director or Supervisor (for his/her own benefit or for the benefit of another person) of the individual rights or interests of other shareholders, including (without limitation) rights to distributions and voting rights save for the Company's restructuring submitted to shareholders for approval and adopted by the general meeting in accordance with the Articles of Association.

The term "controlling shareholder" referred to in the Articles of Association means a person who satisfies any one of the following conditions:

- (a) a person who, acting alone or in concert with others, has the power to elect a majority of the directors;
- (b) a person who, acting alone or in concert with others, has the power to exercise or to control the exercise of 30% (inclusive) or more of the voting rights in the Company;
- (c) a person who, acting alone or in concert with others, holds 30% (inclusive) or more of the issued and outstanding shares of the Company;
- (d) a person who, acting alone or in concert with others, has de facto control over the Company in any other way.

Neither the controlling shareholder nor the de facto controller of the Company may prejudice the interests of the Company by taking advantage of his connected relationship. Anyone who causes any loss to the Company as a result of violating the provisions shall be liable for the compensation.

The controlling shareholder and the de facto controller of the Company owe a fiduciary duty to the Company and its other shareholders. The controlling shareholder shall strictly exercise the rights as a subscriber, and shall not impair the legitimate rights and interests of the Company and its other shareholders in the ways of profit distribution, asset reorganization, external investments, capital use and loans and guarantees and connected transactions and shall not impair the interests of the Company and its other shareholders by using its controlling status in the Company.

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PROCEDURES FOR LIQUIDATION

The Company shall be dissolved and liquidated upon the occurrence of the following events:

- (a) the term of its operations set out in the Articles of Association has expired;
- (b) a resolution for dissolution is passed by shareholders at a general meeting;
- (c) dissolution is necessary due to a merger or division of the Company;
- (d) the Company is legally declared insolvent due to its failure to repay debts as they become due;
- (e) the Company's business license is revoked or the Company is ordered to close down or de-registered according to laws;
- (f) where the Company gets into serious trouble in operation and management and its continuation may cause substantial loss to the interests of shareholders, and no solution can be found through any other channel, shareholders representing more than 10% of the voting rights of all shareholders of the Company may request the People's Court to dissolve the Company.

The Company may continue to exist by amending the Articles of Association in the event of the circumstance as set forth in item (a) of the preceding article.

The amendment to the Articles of Association according to the preceding article shall be passed by 2/3 of the voting rights held by shareholders present at the general meeting.

In the case of dissolution of the Company under items (a), (b), (e) and (f) of the preceding article, a liquidation committee shall be formed to commence liquidation within 15 days from the date of occurrence of events giving rise to dissolution. The members of the liquidation committee shall be determined by the directors or the general meeting. Where a liquidation committee is not established according to schedule, the creditors may apply to the People's Court to designate the relevant personnel to establish a liquidation committee to proceed with the liquidation.

In the case of dissolution of the Company under item (d) of the preceding article, the People's Court shall, according to relevant legal provisions, organize the shareholders, relevant departments and professionals to form a liquidation committee to carry out liquidation.

If the Board decides the Company shall carry out liquidation (except for liquidation resulting from the Company's declaration of bankruptcy), it shall state in the notice of the general meeting convened for this purpose that the Board has conducted comprehensive investigation on the Company's conditions and believes that the Company is able to pay off all its debts within 12 months following the commencement of liquidation.

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The functions and powers of the Board of the Company shall terminate immediately when the general meeting adopts the resolution on liquidation.

The liquidation committee shall follow the directions of the general meeting to report on its income and expenditures, the Company's business and progress of liquidation at least once a year to the general meeting and make a final report to the general meeting at the end of liquidation.

The liquidation committee shall exercise the following functions and powers during the period of liquidation:

- (a) to categorize the Company's assets and prepare a balance sheet and an inventory of assets respectively;
- (b) to inform creditors by a notice or public announcement;
- (c) to dispose of and liquidate any unfinished businesses of the Company;
- (d) to pay all outstanding taxes and the taxes incurred from the process of liquidation;
- (e) to settle claims and debts;
- (f) to deal with the residual assets remaining after repayment by the Company of its debts;
- (g) to represent the Company in any civil proceedings.

The liquidation committee shall, within 10 days of its formation, notify the creditors, and shall, within 60 days, make a public announcement in newspapers at least three times. Creditors shall, within 30 days of the receipt of the notice or within 45 days of the release of the public announcement in the case of failure to receive said notice, file their creditors' rights with the liquidation committee.

Where creditors file their creditors' rights, they shall explain about the matters related to creditors' rights, and shall provide the evidentiary materials. The liquidation committee shall register the creditors' rights. The liquidation committee may not clear off any of the debts of any creditors during the period of filing creditors' rights.

After the liquidation committee has sorted the Company's assets and prepared a balance sheet and an inventory of assets, it shall prepare a liquidation plan and submit it to the general meeting or the People's Court for confirmation.

The remaining assets after paying off the liquidation expenses, wages of employees, social insurance premiums and statutory compensation, the outstanding taxes and the debts of the Company may be distributed in proportion to shareholding of the shareholders.

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During the period of liquidation, the Company continues to exist but may not carry out any business operation that is not related to liquidation. Before the settlement of repayments as provided in the preceding article has been made, the Company's assets shall not be distributed to shareholders.

If the liquidation committee, having sorted the Company's assets and prepared the balance sheet and an inventory of assets, discovers that there are insufficient assets in the Company to pay off its debts, it shall apply to the People's Court immediately for a declaration of bankruptcy of the Company.

Upon the declaration of bankruptcy of the Company by the People's Court, the liquidation committee shall hand over the liquidation matters to the People's Court.

Following the completion of the liquidation, the liquidation committee shall prepare a liquidation report, a statement of income and expenses received and made during the liquidation period and a financial report, which shall be verified by a Chinese registered accountant and submitted the same to the general meeting or the People's Court for confirmation. The liquidation committee shall, within 30 days from the date of said confirmation made by the general meeting or relevant competent authorities, submit the documents referred to in the preceding paragraph to the companies registration authority and apply for cancellation of registration of the Company, and publish a public announcement relating to the termination of the Company.

OTHER IMPORTANT PROVISIONS FOR OUR COMPANY OR THE SHAREHOLDERS

General Provisions

The Company is a joint stock limited company with perpetual existence.

Pursuant to the Articles of Association, the shareholders may pursue actions against other shareholders, the shareholders may pursue actions against the directors, supervisors, general manager and other senior management members of the Company, the shareholders may pursue actions against the Company and the Company may pursue actions against its shareholders, directors, supervisors, general manager and other senior management. The actions, as referred to in the preceding paragraph, include the instituting of legal proceedings with a court or filing with an arbitral authority for arbitration.

After adoption by special resolution on the general meeting of the Company, the Articles of Association shall take effect and put into force from the date on which the H Shares issued by the Company are listed on the main board of the Hong Kong Stock Exchange. Since the effective date of the Articles of Association, the original Articles of Association of the Company shall be automatically invalidated.

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Increase of Capital

The Company may increase capital based on the needs of operation and development and in accordance with the requirements of laws and regulations and resolution on the general meeting, by way of the following:

- (a) Public offering of shares;
- (b) Non-public offering of shares;
- (c) Placement and offer of new shares to existing shareholders;
- (d) Conversion of reserve into share capital;
- (e) Other means stipulated by laws and administrative regulations.

The Company’s increase of capital by issuing new shares shall, after being approved in accordance with the provisions of the Articles of Association, be conducted in accordance with the procedures stipulated by relevant laws and administrative regulations of the State.

Deduction of Capital

The Company may decrease its registered capital. The Company shall decrease its registered capital pursuant to the Company Law, other relevant regulations and the Articles of Association.

A balance sheet and an inventory of assets must be prepared by the Company if it needs to reduce registered capital.

The Company shall notify its creditors within 10 days from the date of the resolution for reduction of registered capital and shall publish a public announcement in newspapers within 30 days thereafter. The creditors are entitled to require the Company to settle the loans or to provide corresponding guarantees within 30 days after the receipt of the written notification, or in the event that no such notification is received, within 45 days after the date of the announcement.

Rights and Obligations of Shareholders

Shareholders shall enjoy rights and have obligations in accordance with the class and amount of shares held by them. Shareholders holding the same class of shares shall be entitled to equal rights and have equal obligations.

Ordinary shareholders of the Company shall enjoy the following rights, please refer to the paragraph headed “– Rights of Shareholders (Including Inspection of Register of members)” above.

APPENDIX VI SUMMARY OF THE ARTICLES OF ASSOCIATION

Shareholders of the Company shall have the following obligations:

- (a) to abide by laws, administrative regulations and the Articles of Association;
- (b) to pay for the shares based on the shares subscribed for and the manners in which they became shareholder;
- (c) not to withdraw their paid share capital except in circumstances allowed by laws and regulations;
- (d) not to abuse shareholder's rights and harm the legal interest of the Company or other shareholders; not to abuse the independent legal person status of the Company and the limited liability of the shareholders to impair the legal interests of creditors of the Company;

Where the shareholder's abuse of its power causes damage to other shareholders, he shall be liable to compensation in accordance with the law;

Where the shareholder has abused the Company's independent legal person status and shareholder's limited liability for debt evasion and caused serious damage to the creditor's interests, it shall bear joint liability for the debts of the Company;

- (e) other obligations imposed by laws, administrative regulations, the regulatory rules of the place where the shares of the Company are listed and the Articles of Association.

Shareholders are not liable for making any further contribution to the share capital other than as agreed by the subscribers of the shares on subscription.

General Meeting

The general meeting is the organ of authority of the Company, which exercises its functions and powers in accordance with laws, please refer to the paragraph headed "-NOTICE OF MEETING AND MATTERS TO BE CONSIDERED" above.

Proposals of General Meetings

Where the Company convenes a general meeting, the Board, the board of supervisors and shareholders individually or jointly holding more than 3% of the shares of the Company shall have the right to put forward proposals to the Company.

Shareholder(s) individually or jointly holding more than 3% of the shares of the Company may submit written provisional proposals to the convener 10 days before the general meeting. The convener shall serve a supplemental notice of the general meeting within two days after receipt of the provisional proposals and notify the contents of the said provisional proposals.

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Save as specified in the preceding paragraph, the convener shall not change the proposals set out in the notice of the general meeting or add any new proposal after the said notice is served.

Proposals not set out in the notice of the general meeting or not complying with the Articles of Association shall not be voted on or resolved at the general meeting.

Board

The Board shall be responsible to the general meeting and shall exercise the following functions and powers in accordance with law:

- (a) to convene general meetings and report to general meetings;
- (b) to implement resolutions of general meetings;
- (c) to resolve on the Company's business plans and investment plans;
- (d) to prepare the annual financial budgets and final accounting plans of the Company;
- (e) to prepare the profit distribution plan and loss makeup plan of the Company;
- (f) to formulate proposals for the Company in respect of increase or reduction of registered capital, issue of bonds or other securities and the listing thereof;
- (g) to formulate plans for material acquisitions, purchase of shares of the Company, merger, division, dissolution or transformation of the Company;
- (h) to determine, within the authority granted by the general meeting, such matters as external investment, acquisition and disposal of assets, asset mortgage, external guarantee, consigned financial management, connected transactions, external financing, etc.;
- (i) to approve the matters in relation to investment, acquisition or disposal of assets, financing and connected transactions as required by the listing rules of the stock exchange where the shares of the Company are listed;
- (j) to decide on the establishment of internal management organizations of the Company;
- (k) to appoint or dismiss the general manager and secretary to the Board of the Company; to appoint or dismiss senior management officers including deputy general manager(s) and the chief finance officer of the Company in accordance with the nominations by general manager, and to determine their remunerations, rewards and penalties;

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- (l) to set up the basic management system of the Company;
- (m) to formulate the proposals for any amendment to the Articles of Association
- (n) to propose to the general meeting the appointment or replacement of the accounting firms which provide audit services to the Company;
- (o) to listen to work reports of the general manager and review his/her work;
- (p) to manage the information disclosure of the Company;
- (q) to exercise other functions and powers as stipulated by laws, administrative regulations, department rules, regulatory rules of the place where the shares of the Company are listed or the Articles of Association.

The Board may resolve on the issues specified in the above paragraphs by approval of more than half of the directors save for the issues specified in (f), (g) and (m), for which approval of more than two-thirds of the directors is required.

Board of Supervisors

The Board shall be responsible to the general meeting and shall exercise the following functions and powers in accordance with law:

- (a) To check the financial condition of the Company and review the periodic reports of the Company prepared by the Board and express its written opinion;
- (b) To monitor the performance of duties in the Company by directors and senior management and propose dismissal of directors and senior management who have violated laws, administrative regulations, the Articles of Association or the resolutions of general meetings;
- (c) To require directors and the senior management to make corrections if their conduct has damaged the interests of the Company;
- (d) To propose the convening of extraordinary general meetings and, in case the Board does not perform the obligations to convene and preside over the general meetings in accordance with Company Law, to convene and preside over the general meetings;
- (e) To propose proposals to the general meetings;
- (f) To initiate legal proceedings against directors and the senior management in accordance with laws;
- (g) To conduct investigation if there is any doubt or any unusual circumstances in the Company's operations; and if necessary, to engage an accounting firm, law firm or other professional institutions to assist in their work at the expenses of the Company;

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- (h) To verify the financial information such as the financial report, business report and plans for distribution of profits to be submitted by the Board to the general meetings and, should any queries arise, to authorize, in the name of the Company, a re-examination by the certified public accountants and practising auditors of the Company for the time being; and
- (i) Other functions and powers specified in the Articles of Association.

Secretary to the Board

The Company shall have a secretary to the Board, who shall be held by a natural person with requisite professional knowledge and experience, shall be appointed by the Board and be the senior management of the Company.

The major duties of the secretary to the Board are:

- (a) to ensure that the Company has complete organization documents and records;
- (b) to ensure that the Company legally prepares and submits reports and documents as required by relevant competent authorities;
- (c) to ensure that register of members of the Company is established appropriately, maintain the registers of the shareholders, directors and senior management and the documents and minutes of the general meeting, board meetings and meetings of special committees under the Board, and ensure that persons who are entitled to obtain the Company's records and documents can timely obtain the relevant records and documents;
- (d) to be responsible for matters pertaining to information disclosure of the Company, and ensure the timeliness, accuracy, lawfulness, authenticity and completeness of the Company's information disclosure;
- (e) such other duties specified by the rules of the stock exchange in the place where the shares of the Company are listed.

A director or other senior management of the Company may also act as the secretary to the Board of the Company. Accountants of the accounting firm appointed by the Company shall not act as the secretary to the Board.

Where the office of secretary to the Board of the Company is held concurrently by a director, and an act is required to be done by a director and the secretary to the Board of the Company separately, the person who holds the office of director and secretary to the Board of the Company may not perform the act in a dual capacity.

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Dispute Resolutions

The Company shall abide by the following principles for dispute resolution:

- (a) Whenever any disputes or claims of rights arise between: holders of the overseas listed foreign shares and the Company; holders of the overseas listed foreign shares and the Company's directors, supervisors, managing directors (president) or other senior management; or holders of the overseas listed foreign shares and holders of domestic shares, in respect of any rights or obligations as provided in the Articles of Association, the Company Law and other relevant laws and administrative regulations concerning the affairs of the Company, such disputes or claims shall be referred by the relevant parties to arbitration.

Where a dispute or claim referred to in the preceding paragraph is referred to arbitration, the entire claim or dispute must be referred to arbitration, and all persons who have a cause of action based on the same facts giving rise to the dispute or claim or whose participation is necessary for the resolution of such dispute or claim, shall, where such person is the Company, the shareholders, directors, supervisors, managing directors (president) or other senior management of the Company, comply with the arbitration.

Disputes in respect of the definition of shareholders and disputes in relation to the register of members need not be resolved by arbitration.

- (b) A claimant may elect for arbitration to be carried out at either the China International Economic and Trade Arbitration Commission in accordance with its Rules or the Hong Kong International Arbitration Centre in accordance with its Securities Arbitration Rules. Once a claimant refers a dispute or claim to arbitration, the other party must submit to the arbitral body elected by the claimant.

If a claimant elects for arbitration to be carried out at Hong Kong International Arbitration Centre, any party to the dispute or claim may apply for a hearing to take place in Shenzhen in accordance with the Securities Arbitration Rules of the Hong Kong International Arbitration Centre.

- (c) If any disputes or claims of rights are settled by way of arbitration in accordance with paragraph (a), the laws of the PRC shall apply, save as otherwise provided in the laws, administrative regulations.
- (d) The award of an arbitral body shall be final and conclusive and binding on all parties.

APPENDIX VII

STATUTORY AND GENERAL INFORMATION

A. FURTHER INFORMATION ABOUT OUR GROUP

1. Incorporation of Our Company

The predecessor of our Company was established as a limited liability company in the PRC on July 4, 2008 with an initial registered capital of US\$2,213,700. On May 12, 2020, our Company was converted to a joint stock company with limited liability under the PRC Company Law. Accordingly, our corporate structure and Articles of Association are subject to the relevant laws and regulations of the PRC. The relevant PRC laws and regulatory provisions and a summary of our Articles of Association are set out in Appendices IV and V to this document, respectively.

Our registered place of business in Hong Kong is at [40th Floor, Sunlight Tower, No. 248 Queen’s Road East, Wanchai, Hong Kong]. We were registered as a non-Hong Kong company under Part 16 of the Companies Ordinance on [●]. Ms. Tam Pak Yu, Vivien of 40th Floor, Sunlight Tower, No. 248 Queen’s Road East, Wanchai, Hong Kong has been appointed as our authorized representative for the acceptance of service of process and notices in Hong Kong.

2. Changes in the Share Capital of Our Company

As of the date of incorporation of the predecessor of our Company, our registered capital was US\$2,213,700, which was fully paid on December 1, 2008. On May 12, 2020, our Company was converted into a joint stock company with limited liability and renamed as RemeGen Co., Ltd. (榮昌生物製藥(煙台)股份有限公司). Our registered capital was RMB401,819,202 divided into 401,819,202 shares with a nominal value of RMB1.00 each.

The following alterations in the total issued share capital of our Company have taken place within the two years immediately preceding the date of this document:

- (a) On June 28, 2019, by way of capitalization of shareholder’s loans provided by RC Pharma to our Company at the amount of RMB600 million, RMB95,912,935 of which was converted into registered capital of our Company and the remaining RMB504,087,065 was converted to capital reserve. The total issued share capital of our Company was increased from RMB70,000,000 to RMB165,912,935 upon registration with the Administration for Industry and Commerce of Yantai Economic and Technological Development Area (煙台經濟技術開發區市場監督管理局) on July 23, 2019;
- (b) On December 13, 2019, our Shareholders resolved to allow PAG’s subscription for 1.6521% of the registered capital of our Company at a consideration on RMB90,000,000. The total issued share capital of our Company was increased from RMB165,912,935 to RMB168,654,052 upon registration with the Administration for Industry and Commerce of Yantai Economic and Technological Development Area on December 16, 2019; and

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- (c) On February 25, 2020, we entered into a capital increase arrangement with the Pre-[REDACTED] Investors, the terms of which are summarized in the paragraph headed “History, Development and Corporate Structure – Pre-[REDACTED] Investments – 2020 Subscription”. The total issued share capital of our Company was increased from RMB168,654,052 to RMB182,645,092 upon registration with the Administration for Industry and Commerce of Yantai Economic and Technological Development Area on February 26, 2020.

Assuming the [REDACTED] is not exercised, upon completion of the [REDACTED], our issued share capital will increase to RMB[REDACTED], made up of [REDACTED] Domestic Shares, [REDACTED] Unlisted Foreign Shares and [REDACTED] H Shares fully paid up or credited as fully paid up, representing [REDACTED]%, [REDACTED]% and [REDACTED]% of our registered share capital, respectively.

For further details, please refer to the section headed “History, Development and Corporate Structure” in this document. Save as disclosed above, there has been no alteration in our share capital within two years immediately preceding the date of this document.

3. Changes in the Share Capital of Our Subsidiaries

A summary of the corporate information and the particulars of our subsidiaries are set out in Note 1 to the Accountants’ Report as set out in Appendix I. There has been no alteration in the share capital of our subsidiaries within two years immediately preceding the date of this document.

4. Resolutions of the Shareholders of our Company Passed on [●]

Pursuant to the resolutions passed at a duly convened general meeting of our Shareholders on [●], the following resolutions, among others, were passed by the Shareholders:

- (a) the issue of H Shares of nominal value of RMB1.00 each by our Company and such H Shares be [REDACTED] on the Stock Exchange be issued;
- (b) subject to the completion of the [REDACTED], the Articles of Association have been approved and adopted, which shall become effective on the [REDACTED], and the Board has been authorized to amend the Articles of Association in accordance with any comments from the Stock Exchange and the relevant PRC regulatory authorities; and
- (c) authorizing our Board to handle all relevant matters relating to, among other things, the implementation of issuance of H Shares and the [REDACTED].

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5. Restrictions on Repurchase

Please refer to Appendices IV and V to this document for details.

B. FURTHER INFORMATION ABOUT THE BUSINESS OF OUR COMPANY

1. Summary of Material Contracts

The following contracts (not being contracts entered into in the ordinary course of business) were entered into by our Group within the two years preceding the date of this document and are or may be material:






(a) [REDACTED].

2. Our Intellectual Property Rights

As of the Latest Practicable Date, our Company has registered, or has applied for the registration of the following intellectual property rights which were material to our Group’s business.

Trademarks

As of the Latest Practicable Date, we have registered the following trademarks in the PRC which we considered to be material to our business:

<u>No.</u>	<u>Owner</u>	<u>Registration No.</u>	<u>Trademark</u>	<u>Class</u>	<u>Validity Period</u>
1.	Our Company	16912861		5 and 44	October 7, 2017 to October 6, 2027
2.	Our Company	21323266		35	October 21, 2018 to October 20, 2028
3.	Our Company	16912862		5 and 44	October 7, 2017 to October 6, 2027
4.	Our Company	21323265		35	June 21, 2018 to June 20, 2028
5.	Our Company	7010164		5	September 14, 2010 to September 13, 2020

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No.	Owner	Registration No.	Trademark	Class	Validity Period
6.	Our Company	7010165		5	April 7, 2012 to April 6, 2022
7.	Our Company	21140928		5	June 21, 2018 to June 20, 2028
8.	Our Company	21141025		5	October 21, 2018 to October 20, 2028
9.	Our Company	21141038		5	June 21, 2018 to June 20, 2028
10.	Our Company	9995960		5	December 28, 2012 to December 27, 2022
11.	Our Company	9995959		5	December 28, 2012 to December 27, 2022
12.	Our Company	27007329		1, 5 and 10	October 21, 2018 to October 20, 2028
13.	Our Company	26992615		5 and 10	October 21, 2018 to October 20, 2028
14.	Our Company	13105683		5	December 21, 2014 to December 20, 2024
15.	Our Company	26743106		1, 5, 35 and 42	January 14, 2020 to January 13, 2030

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As of the Latest Practicable Date, we have applied for the registration of the following trademarks in the PRC and other jurisdictions which have been published to the public and we considered to be material to our business:

No.	Name of Applicant	Application No.	Place of Application	Trademark	Class	Application Date
1.	Our Company	42344636	PRC	泰它西普	5	November 14, 2019
2.	Our Company	42325527	PRC	迪西安	5	November 14, 2019
3.	Our Company	42333858	PRC	纬迪西安	5	November 14, 2019
4.	Our Company	44631336	PRC	泰 立 西 普	5	March 16, 2020
5.	Our Company	44645458	PRC		5, 10, 35, 42 and 44	March 16, 2020
6.	Our Company	44647509	PRC		5, 10, 35 and 42	March 16, 2020
7.	Our Company	44653623	PRC	泰阳伞	5, 10, 35 and 42	March 17, 2020
8.	Our Company	44658171	PRC	TELITACICEPT	5 and 10	March 17, 2020
9.	Our Company	44661127	PRC	泰爱	1, 10 and 35	March 17, 2020
10.	Our Company	44664752	PRC		5, 10, 35, 42 and 44	March 17, 2020
11.	Our Company	44720727	PRC	HiBody	1, 5 and 42	March 19, 2020
12.	Our Company	305232582	Hong Kong		5, 10, 35, 42 and 44	March 27, 2020
13.	Our Company	305230566	Hong Kong	Remegen	5, 10, 35, 42 and 44	March 27, 2020

Patents

For a discussion of the details of the material patents and material patent applications by the Company in connection with our clinical and preclinical drug candidates, please refer to the paragraph headed “Business – IV. Intellectual Property” in this document.

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Save as aforesaid, as of the Latest Practicable Date, there were no other trade or service marks, patents, intellectual or industrial property rights which were material in relation to our Group's business.

Domain Names

As of the Latest Practicable Date, we owned the following domain name which we consider to be material to be or may be material to our business:

No.	Owner	Domain name	Registration Date	End of Validity Period
1.	Our Company	remegen.cn	April 27, 2015	April 27, 2021
2.	Our Company	remegen.com.cn	April 30, 2015	April 30, 2021
3.	Our Company	remegen.net	April 29, 2015	April 29, 2021
4.	Our Company	rcbiotech.cn	April 29, 2015	April 29, 2021
5.	Our Company	rcbiotech.com	October 17, 2011	October 17, 2020
6.	Our Company	榮昌生物.cn	July 28, 2003	July 27, 2020
7.	Our Company	榮昌生物.中國	July 28, 2003	July 27, 2020

C. FURTHER INFORMATION ABOUT DIRECTORS AND SUBSTANTIAL SHAREHOLDERS

1. Disclosure of Interests

(a) *Interests and short positions of our Directors, Supervisors and the chief executive of our Company in the Shares, underlying Shares and debentures of our Company and our associated corporations*

The following table sets out the interests and short positions of our Directors, Supervisors and chief executive of our Company immediately following completion of the [REDACTED] (without taking into account the H Shares which may be allotted and issued pursuant to the exercise of the [REDACTED]) in our Shares, underlying Shares or debentures of our Company or any of our associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions in which they are taken or deemed to have under such provisions of the SFO), or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to us and the Stock Exchange pursuant to the Model Code for Securities Transactions by Directors of Listed Issuers contained in the Listing Rules, once our H Shares are

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[REDACTED]. For this purpose, the relevant provision of the SFO will be interpreted as if they applied to the Supervisors:

Name of Shareholder	Capacity/nature of interest	Number and class of Shares to be held after the [REDACTED]	Approximate percentage of shareholding in the issued share capital of our Company as of the date of this document	Approximate percentage of shareholding in the relevant class of Shares after the [REDACTED] (assuming no exercise of the [REDACTED])	Approximate percentage of Shareholder in the total share capital of our Company after the [REDACTED] (assuming no exercise of the [REDACTED])
Mr. Wang ⁽¹⁾	Interests of controlled corporation; interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	2.91%	[REDACTED]%	[REDACTED]%
	Interests held jointly with another person	[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	9.86%	[REDACTED]%	[REDACTED]%
Dr. Fang ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	2.91%	[REDACTED]%	[REDACTED]%
	Beneficial owner; interests held jointly with another person	[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
		[REDACTED] H Shares	9.86%	[REDACTED]%	[REDACTED]%
Dr. Wang Liqiang ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
	[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%	
Mr. Lin Jian ⁽¹⁾	Interests held jointly with another person	[REDACTED] Domestic Shares	37.05%	[REDACTED]%	[REDACTED]%
		[REDACTED] Unlisted Foreign Shares	6.52%	[REDACTED]%	[REDACTED]%
	[REDACTED] H Shares	12.76%	[REDACTED]%	[REDACTED]%	

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Notes:

- (1) As of the Latest Practicable Date, each of Yantai Rongda Venture Capital Center (Limited Partnership) (煙台榮達創業投資中心(有限合夥)) (“Rongda”), Yantai Rongqian Enterprise Management Center (Limited Partnership) (煙台榮謙企業管理中心(有限合夥)) (“Rongqian”), Yantai Rongshi Enterprise Management Center (Limited Partnership) (煙台榮實企業管理中心(有限合夥)) (“Rongshi”), Yantai Rongyi Enterprise Management Center (Limited Partnership) (煙台榮益企業管理中心(有限合夥)) (“Rongyi”), Yantai Rongjian Enterprise Management Center (Limited Partnership) (煙台榮建企業管理中心(有限合夥)) (“Rongjian”) was a limited partnership established in the PRC. Each of Rongqian, Rongshi, Rongyi and Rongjian is an employee incentive platform and held [REDACTED], [REDACTED], [REDACTED] and [REDACTED] Domestic Shares in our Company, respectively. Mr. Wang is the executive partner of each of Rongda, Rongqian, Rongshi, Rongyi and Rongjian. As such, under the SFO, Mr. Wang is deemed to be interested in the equity interests held by Rongda, Rongqian, Rongshi, Rongyi and Rongjian.

Further, as of the Latest Practicable Date, RongChang Holding Group LTD. was a company incorporated in the British Virgin Islands. Mr. Wang was the sole director of RongChang Holding Group LTD. and RongChang Holding Group LTD. is accustomed to act in accordance with Mr. Wang’s instructions. As such, under the SFO, Mr. Wang is deemed to be interested in the equity interests held by RongChang Holding Group LTD.

As of the Latest Practicable Date, I-NOVA Limited was a company incorporated in the British Virgin Islands and was wholly-owned by Dr. Fang. As such, under the SFO, Dr. Fang is deemed to be interested in the equity interests held by I-NOVA Limited.

On April 16, 2020, Mr. Wang, Dr. Fang, Mr. Lin Jian, Dr. Wang Liqiang, Mr. Wang Xudong, Mr. Deng Yong, Mr. Xiong Xiaobin, Mr. Wen Qingkai, Ms. Yang Minhua, Mr. Wei Jianliang, Rongda, RongChang Holding LTD. and I-NOVA Limited entered into a concert party agreement to confirm that they have acted in concert in the management, decision-making and all major decisions of our Group. As such, each of the Concert Parties are deemed to be interested in the Shares each other is interested in.

(b) Interests of the substantial shareholders in the Shares

Save as disclosed in the section headed “Substantial Shareholders”, immediately following the completion of the [REDACTED] and without taking into account any H Shares which may be issued pursuant to the exercise of the [REDACTED], our Directors are not aware of any other person (not being a Director or chief executive of our Company) who will have an interest or short position in our Shares or the underlying Shares which would fall to be disclosed to us and the Stock Exchange under the provisions of Divisions 2 and 3 of Part XV of the SFO, or who is, directly or indirectly, interested in 10% or more of the issued voting shares of our Company.

(c) Interests of the substantial shareholders in other members of our Group

So far as our Directors are aware and save as disclosed in this document, as of the Latest Practicable Date, no persons are, directly or indirectly, interested in 10% or more of the nominal value of any class of share capital carrying rights to vote in all circumstances at general meetings of any other members of our Group.

2. Particulars of Directors’ and Supervisors’ Service Contracts

Pursuant to Rules 19A.54 and 19A.55 of the Listing Rules, we [have entered] into a contract with each of our Directors and Supervisors in respect of, among other things (i) compliance with relevant laws and regulations, (ii) observance of the Articles of Association, and (iii) provisions on arbitration.

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Save as disclosed in this document, none of our Directors and Supervisors has or is proposed to have entered into any service contract with any member of our Group (excluding agreements expiring or determinable by any member of our Group within one year without payment of compensation other than statutory compensation).

3. Remuneration of Directors and Supervisors

For the two years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, the total remuneration paid to our Directors and Supervisors amounted to RMB2.0 million, RMB3.3 million and RMB0.9 million, respectively.

For the two years ended December 31, 2018 and 2019 and the three months ended March 31, 2020, the total remuneration paid to our five highest paid individuals (excluding Directors and Supervisors) amounted to RMB6.0 million, RMB7.0 million and RMB2.2 million, respectively.

Under the arrangement currently in force, we estimate the total fixed remuneration (before tax) payable to Directors and Supervisors for the year ending December 31, 2020 will be approximately RMB38.1 million.

During the Track Record Period, no fees were paid by our Group to any of our Directors, Supervisors or the five highest paid individuals as an inducement to join us or as compensation for loss of office, and there has been no arrangement under which a Director or Supervisor has waived or agreed to waive any emoluments.

4. Disclaimers

Save as disclosed in this document:

- (a) none of our Directors, Supervisors or our chief executive has any interest or short position in our Shares, underlying Shares or debentures of us or any of our associated corporations (within the meaning of Part XV of the SFO) which will have to be notified to us and the Stock Exchange pursuant to Divisions 7 and 8 of Part XV of the SFO, or which will be required, pursuant to section 352 of the SFO, to be entered in the register referred to therein, or which will be required to be notified to us and the Stock Exchange pursuant to Model Code for Securities Transactions by our Directors of Listed Issuers once the H Shares are [REDACTED] on the Stock Exchange;
- (b) none of our Directors or Supervisors is aware of any person (not being a Director or chief executive of our Company) who will, immediately following completion of the [REDACTED] (without taking into account any H Shares which may be allotted and issued pursuant to the exercise of the [REDACTED]), have an interest or short position in our Shares or underlying Shares which would fall to be disclosed to us under the provisions of Divisions 2 and 3 of Part XV of the SFO or who is interested, directly or indirectly, in 10% or more of the issued voting shares of any member of our Group;

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- (c) so far as is known to our Directors, none of our Directors, their respective close associates (as defined under the Listing Rules) or Shareholders who own more than 5% of the number of issued shares of our Company have any interests in the five largest customers or the five largest suppliers of our Group; and
- (d) save as disclosed in this document, none of our Directors, Supervisors or any of the parties listed in “Qualifications of Experts” of this Appendix is:
 - (i) interested in our promotion, or in any assets which have been, within two years immediately preceding the date of this document, acquired or disposed of by or leased to us, or are proposed to be acquired or disposed of by or leased to any member of our Group;
 - (ii) materially interested in any contract or arrangement subsisting at the date of this document which is significant in relation to our business.

D. OTHER INFORMATION

1. Estate duty

Our Directors have been advised that no material liability for estate duty is likely to fall on our Company or any of our subsidiaries under the laws of the PRC.

2. Litigation

Except as disclosed in this document, as of the Latest Practicable Date, we were not engaged in any litigation, arbitration or claim of material importance and no litigation, arbitration or claim of material importance is known to our Directors to be pending or threatened by or against any member of our Group, that would have a material adverse effect on our Group’s results of operations or financial condition, taken as a whole.

3. Preliminary expenses

As of the Latest Practicable Date, our Company has not incurred material preliminary expenses.

4. Promoters

Save as disclosed in this document, within the two years preceding the date of this document, no cash, securities or other benefit has been paid, allotted or given or is proposed to be paid, allotted or given to any Promoter in connection with the [REDACTED] and the related transactions described in this document.

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5. Taxation of Holders of H Shares

(1) *Hong Kong*

The sale, purchase and transfer of H Shares registered with our Hong Kong branch register of members will be subject to Hong Kong stamp duty. The current rate charged on each of the purchaser and seller is 0.1% of the consideration of or, if higher, of the fair value of our Shares being sold or transferred. For further details in relation to taxation, please refer to Appendix IV to this document.

(2) *Consultation with professional advisers*

Potential investors in the [REDACTED] are urged to consult their professional tax advisers if they are in any doubt as to the taxation implications of subscribing for, purchasing, holding or disposing of or [REDACTED] in our H Shares (or exercising rights attached to them). None of us, the Joint Sponsors, the [REDACTED], the [REDACTED], the [REDACTED], or any other person or party involved in the [REDACTED] accept responsibility for any tax effects on, or liabilities of, any person, resulting from the subscription, purchase, holding or disposal of, [REDACTED] in or the exercise of any rights in relation to our H Shares.

6. Application for [REDACTED]

The Joint Sponsors have made an application on behalf of our Company to the Listing Committee for the [REDACTED] of, and permission to [REDACTED] in, our H Shares. All necessary arrangements have been made to enable the securities to be admitted into CCASS.

7. No Material Adverse Change

Our Directors confirm that, up to the date of this document, there has been no material adverse change in the financial or trading position or prospect of our Group since March 31, 2020 (being the date to which the latest audited consolidated financial statements of our Group were prepared).

8. Qualifications of Experts

The qualifications of the experts (as defined under the Listing Rules and the Companies (Winding Up and Miscellaneous Provisions) Ordinance) who have given their opinion and/or advice in this document are as follows:

<u>Name</u>	<u>Qualifications</u>
Morgan Stanley Asia Limited	Licensed corporation under the SFO to carry on type 1 (dealing in securities), type 4 (advising on securities), type 5 (advising on futures contracts), type 6 (advising on corporate finance) and type 9 (asset management) regulated activities

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Name	Qualifications
Huatai Financial Holdings (Hong Kong) Limited	Licensed corporation under the SFO to conduct type 1 (dealing in securities), type 2 (dealing in futures contracts), type 4 (advising on securities), type 6 (advising on corporate finance) and type 9 (asset management) regulated activities
J.P. Morgan Securities (Far East) Limited	Licensed corporation under the SFO to carry on type 1 (dealing in securities), type 4 (advising on securities) and type 6 (advising on corporate finance) regulated activities as defined under the SFO
Ernst & Young	Certified Public Accountants
King & Wood Mallesons	PRC legal advisor
Frost & Sullivan (Beijing) Inc., Shanghai Branch Co.	Independent industry consultant
Jones Lang LaSalle Corporate Appraisal and Advisory Limited	Independent Property Valuer

As of the Latest Practicable Date, none of the experts named above had any shareholding interest in our Company or any of our subsidiaries or the right (whether legally enforceable or not) to subscribe for or to nominate persons to subscribe for securities in any member of our Group.

9. Consents

Each of the experts as referred to in the paragraph headed “8. Qualifications of Experts” of this Appendix has given and has not withdrawn their respective written consents to the issue of this document with the inclusion of their reports and/or letters (as the case may be) and the references to its name included in the form and context in which it respectively appears.

10. Sponsors’ Independence

All of the Joint Sponsors satisfy the independence criteria applicable to sponsors set out in Rule 3A.07 of the Listing Rules.

The Joint Sponsors’ fees payable by us in respect of the Joint Sponsors’ services as sponsors for the [REDACTED] are US\$[REDACTED].

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11. Binding Effect

This document shall have the effect, if an application is made in pursuance of it, of rendering all persons concerned bound by all of the provisions (other than the penal provisions) of sections 44A and 44B of the Companies (Winding Up and Miscellaneous Provisions) Ordinance so far as applicable.

12. Bilingual Document

The English and Chinese language versions of this document are being published separately, in reliance upon the exemption provided under section 4 of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L of the Laws of Hong Kong).

13. Miscellaneous

Save as otherwise disclosed in this document:

- (a) within the two years preceding the date of this document, our Company has not issued nor agreed to issue any share or loan capital fully or partly paid either for cash or for a consideration other than cash;
- (b) no Share or loan capital of our Company, if any, is under option or is agreed conditionally or unconditionally to be put under option;
- (c) our Company has not issued nor agreed to issue any founder shares, management shares or deferred shares;
- (d) our Company has no outstanding convertible debt securities or debentures;
- (e) with the two years immediately preceding the date of this document, no commission, discount, brokerage or other special term has been granted in connection with the issue or sale of any capital of our Company;
- (f) there is no arrangement under which future dividends are waived or agreed to be waived;
- (g) there has been no interruption in our business which may have or have had a significant effect on the financial position in the last 12 months;
- (h) our Company is not presently listed on any stock exchange or traded on any trading system; and
- (i) our Company is a foreign investment joint stock limited company and is subject to the Foreign Investment Law of the PRC.

**APPENDIX VIII DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES
IN HONG KONG AND AVAILABLE FOR INSPECTION**

DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES

The documents attached to a copy of this document and delivered to the Registrar of Companies in Hong Kong for registration were (i) copies of the [REDACTED]; (ii) copies of each of the material contracts referred to in the paragraph headed “B. Further Information about the Business of our Company—1. Summary of Material Contracts” in Appendix VII to this document; and (iii) the written consents issued by each of the experts and referred to in paragraph headed “D. Other information—8. Qualifications of Experts” in Appendix VII to this document.

DOCUMENTS AVAILABLE FOR INSPECTION

Copies of the following documents will be available for inspection at the office of O’Melveny & Myers at 31/F AIA Central, 1 Connaught Road Central, Hong Kong during normal business hours up to and including the date which is 14 days from the date of this document:

- (a) the Memorandum of Association and Articles of Association;
- (b) the accountants’ report prepared by Ernst & Young, the text of which is set out in Appendix I to this document;
- (c) the audited consolidated financial statements of the Group for the two years ended December 31, 2018 and 2019 and the three months ended March 31, 2020;
- (d) the report received from Ernst & Young on the unaudited pro forma financial information of our Group, the text of which is set out in Appendix II to this document;
- (e) the letter, summary of values and valuation report relating to the property interests of our Group prepared by Jones Lang LaSalle Corporate Appraisal and Advisory Limited, the text of which is set out in Appendix III to this document;
- (f) the industry report prepared by Frost & Sullivan (Beijing) Inc., Shanghai Branch Co. referred to in the section headed “Industry Overview” in this document;
- (g) the PRC legal opinions issued by King & Wood Mallesons, our legal advisors on PRC law, in respect of our general matters and property interests;
- (h) the material contracts referred to in the paragraph headed “B. Further Information about the Business of our Company—1. Summary of Material Contracts” in Appendix VII to this document;

**APPENDIX VIII DOCUMENTS DELIVERED TO THE REGISTRAR OF COMPANIES
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- (i) the service agreements and letters of appointment referred to in “C. Further Information about Directors and Substantial Shareholders—2. Particulars of Directors’ and Supervisors’ Service Contracts” in Appendix VII to this document;
- (j) the written consents referred to in the paragraph headed “D. Other Information— 9. Consents” in Appendix VII to this document; and
- (k) the PRC Company Law, the Special Regulations of the State Council on the Overseas Offering and Listing of Shares by Joint Stock Limited Companies and the Mandatory Provisions for Articles of Association of Companies to be Listed Overseas together with unofficial English translations thereof.