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### Overview

Driven by our innovations across the industry value chain, our mission is to become a leading global pharmaceutical company targeting high-mortality diseases with significant unmet medical needs.

We are a leading China-based pharmaceutical company with global business in pharmaceutical, innovative biotech and CDMO sectors. We ranked the first by both export value and export volume of injectable finished doses in 2018 among China-based pharmaceutical companies, with major sales into the EU market.

Founded by a group of seasoned polysaccharide-chemists with scientific insights and profound understanding of immunology, we have built up a portfolio of both leading drugs in the anticoagulant and antithrombotic therapeutic areas and innovative drug candidates focusing on diseases with an immune system disorder axis, including oncology, autoimmune, metabolic and other areas. These diseases are among the largest unmet medical needs globally and represent the leading causes of morbidity and mortality.

Our leading drugs, Inhixa, Neoparin and Prolongin are three different brands of enoxaparin sodium injection which in total have been approved in 34 countries and sold in 17 countries. We have also supplied enoxaparin sodium injection to our customers in 14 other countries. We are the only China-based pharmaceutical company with cumulative sales of enoxaparin sodium injections in the EU exceeding 100 million doses. Enoxaparin is the “gold standard” anticoagulant and antithrombotic drug for various indications, such as venous thromboembolism (VTE) and pulmonary embolism (PE), with huge market demands and significant growth potential. According to Frost & Sullivan, the global usage of enoxaparin reached 781.9 million syringes/vials in 2019, and is expected to reach 1,068.4 million syringes/vials in 2025. Its usage in China was 52.0 million syringes/vials in 2019, which is expected to increase at a CAGR of 23.6% to 185.5 million syringes/vials in 2025.

We are the largest China-based and third largest global manufacturer and marketer of enoxaparin sodium injection, with a global market share of 6.5%, based on 2019 worldwide sales according to Frost & Sullivan. In China we are the second largest supplier in the enoxaparin injection market with a market share of 10.9% in 2019, second only to the originator firm, according to Frost & Sullivan. We implement localized and differentiated marketing strategies in the three major enoxaparin markets, the EU, China and the U.S. Our marketing strategies incorporate a combination of direct sales, distributor network and supply agreement partnerships. Our effective marketing efforts have resulted in rapid growth of our enoxaparin injection sales. In the EU, sales volume of our enoxaparin sodium injection grew by 164% to 47.8 million syringes/vials in 2018 from 18.1 million syringes/vials in 2017, and grew by 77.0% to 84.6 million syringes/vials in 2019 from 47.8 million syringes/vials in 2018. In China, sales volume of our enoxaparin sodium injection grew by 81% to 5.8 million syringes in 2018 from 3.2 million syringes in 2017, and grew by 15.5% to 6.7 million syringes in 2019 from 5.8 million syringes in 2018. We expect our Prolongin to be the first enoxaparin approved based on Quality Consistency Evaluation (QCE) in China, further solidifying our competitive advantage to capture the fast growth of enoxaparin in the China market.

We are the largest provider of heparin API with a global market share of 40.7%, larger than the second and third market players combined, based on 2018 global revenue according to Frost &

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Sullivan. We also have exclusive access to over 50% of the traceable heparin raw materials in China and 60% in the North America in 2018, which ensures sufficient supply of high quality heparin raw materials. With 91.3% of our revenue generated from markets outside PRC in 2019, we are continuously expanding our strong global footprint to additional overseas markets, such as Southeast Asia, Middle East and South America.

We have established a fully integrated business model covering the heparin industry value chain from supply of raw materials, manufacturing of APIs to the sales of enoxaparin finished doses. Based on such unique business model, we have developed our state-of-the-art supply chain management and facilities with proprietary manufacturing technologies, rigorous quality control standards and large-scale manufacture capability. Through our integrated supply chain management, we have access to a significant portion of the traceable crude heparin globally, which ensures safety, reliability and stability for the supply of our heparin raw materials. Our manufacturing processes and facilities comply with the CGMP requirements in the EU, the U.S. and China, and follow rigorous manufacturing and quality control standards. We have accumulated extensive manufacturing expertise and know-how including our proprietary extraction, purification and virus and bacteria inactivation technologies, which we believe will further solidify our long-term competitiveness in the global enoxaparin market. We are one of the few China-based pharmaceutical companies which are able to produce commercialized biological drugs on a large scale. Our facilities enable us to efficiently manufacture biopharmaceutical products in large volumes while consistently ensure high quality. We believe our unique business model together with state-of-the-art supply chain management and facilities serve as the cornerstones of our leading position in the global enoxaparin market.

Based on our profound understanding of immune response mechanisms, we have strategically constructed a robust portfolio of both exclusive development and commercial rights in Greater China for first-in-class clinical stage drug candidates and self-developed first-in-class drug candidate. These pipeline drugs are being developed to address the significant unmet medical demands in oncology, cardiovascular, inflammation and autoimmune areas. We place great importance in nurturing our partners and provide strong support to them in various areas including clinical development through our CDMO platform and equity investment. For example, Oregovomab, an immune-oncology antibody candidate being developed for first-line treatment of ovarian cancer in combination with chemotherapy, has shown a significant prolongation of median progression-free survival (median PFS 41.8 months vs. 12.2 months in patients treated by chemotherapy-alone,  $p=0.0027$ ) in a phase II trial. It also showed a significant improvement in overall survival (OS) ( $p=0.0043$ ). We own 38.74% equity interest in the developer company of Oregovomab as well as its exclusive development and commercial rights in Greater China.

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As of the Latest Practicable Date, we have exclusive development and commercial rights in Greater China for five drug candidates targeting both oncology and non-oncology indications, among which two are in phase III global clinical trials, namely AR-301 and RVX-208, and two are in phase II global trials, namely Oregovomab and AR-101. We are also developing a self-discovered proprietary oncology drug candidate currently at preclinical stage. We believe we are able to leverage our manufacturing, marketing and distribution capabilities of enoxaparin and industry experience to successfully develop and commercialize our innovative drug pipeline. The following chart summarizes the development status of our pipeline drugs as of the Latest Practicable Date:

Drug Candidate	Target / Mechanism of Action	Indications	Partner Company	Hepalink Shareholding	Development and Commercial Rights Owned by (Regions)	IND	Ph1	Ph2	Ph3	MRCT <sup>1</sup> Participated by Hepalink
Oregovomab	Immunological stimulation after binding to CA125 antigen	Primary late-stage ovarian cancer	OncoQuest	38.74%	OncoVent <sup>2</sup> (Greater China) <sup>4</sup>					☆
		Recurrent late-stage ovarian cancer (Oregovomab+Hiltonol)								☆
		Recurrent late-stage ovarian cancer (Oregovomab+PD-1 Inhibitor nivolumab)								☆
		Recurrent late-stage ovarian cancer (Oregovomab+PARP Inhibitor niraparib)								☆
mAb-AR20.5	Immunological stimulation after binding to MUC1 antigen	Pancreatic cancer								☆
AR-301 (Salvecin)	α-toxin released by Gram-positive staphylococcus aureus	Staphylococcus aureus pneumonia	Aridis	9.86%	Shenzhen Arimab <sup>3</sup> (Greater China)					★
AR-101 (Aerumab)	Gram-negative pseudomonas aeruginosa O11 serum	Pseudomonas aeruginosa pneumonia								☆
RVX-208 (Apabetalone)	BD2 domain of BET family member	Type 2 diabetes with coronary heart disease	Resverlogix	38.60%	Hepalink (Greater China)					
		Chronic Kidney Disease								
H1710	Heparanase (HPA)	Pancreatic cancer	Hepalink (In-house)	100%	Hepalink (Global)					
		New Indication								☆

Hepalink initiated the trials  
 The companies Hepalink invested initiated the clinical trials  
 The company Hepalink invested plans to initiate the clinical trials for new indication based on the ph3 clinical data of Type 2 diabetes with coronary heart disease  
 Hepalink has initiated the China portion MRCT<sup>1</sup>  
 Hepalink plans to initiate the respective China portion MRCTs<sup>1</sup> once entered pivotal phase

<sup>1</sup> MRCT refers to multi-regional clinical trials, which involves more than one independent center in enrolling and following clinical trial participants. It is widely conducted by many global pharmaceutical companies to reduce the time lag of launching innovative drugs in different regions.  
<sup>2</sup> We directly hold 54.00% equity interest in OncoVent and are entitled to additional economic interest through our 38.74% equity interest in OncoQuest and our 14.94% equity interest in Quest Pharma Tech, which together hold 40.00% equity interest in OncoVent. Any profit of OncoVent will be reflected on our financial statement under equity method through our equity interest in OncoVent and Quest Pharma Tech, in addition to our direct holding in OncoVent.  
<sup>3</sup> We directly hold 51.00% equity interest in Shenzhen Arimab and are entitled to additional economic interest through our 9.86% equity interest in Aridis, which holds the remaining 49.00% equity interest in Shenzhen Arimab. Any profit of Shenzhen Arimab will be reflected on our financial statement under equity method through our equity interest in Aridis, in addition to our direct holding in Shenzhen Arimab.  
<sup>4</sup> Greater China region includes PRC, Hong Kong, Macau and Taiwan.

We operate a fast-growing CDMO business through two platforms, Cytovance, a CDMO platform enabling the development and manufacture of recombinant pharmaceutical products and critical non-viral vectors and intermediates for gene therapy, and SPL, a CDMO platform enabling the development and manufacture of pharmaceutical products from natural sources, to capture the growth opportunities in the global biopharmaceutical sector. Our CDMO business ranks among the top three China-owned biologics CDMO operators based on 2018 revenue according to Frost & Sullivan. Our CDMO revenue grew by 69.1% from RMB324.3 million in 2017 to RMB548.5 million in 2018 and grew by 43.4% to RMB786.4 million in 2019. Our customer base ranges from multinational pharmaceutical giants to midsize, small and virtual biotech companies. With continuous investments in capabilities, capacity and innovation, the dual CDMO platform addresses diverse customer needs while leveraging over 45 years of combined experience of Cytovance and SPL in the development and manufacture of large molecule pharmaceutical products for innovative biologically based therapeutics. In addition to supporting a multitude of customer drug pipelines, our own product pipeline is aptly enabled and enhanced by the dual CDMO platform strategy. By addressing the capacity shortage and technological challenge in the CMC process, our CDMO platform empowers our customers to develop drugs from concept to commercial manufacturing stage and ensures CDMO capacities for the development of our own pipeline drugs. Benefiting from the global growth in the biopharmaceutical

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sector, our CDMO business has contributed to our rapid growth and diversified our revenue source. As of the Latest Practicable Date, we had 49 on-going projects and a backlog of US\$64.4 million, which represents the total amount of contracted fees for services yet to be delivered. The following table shows the status of and the backlog from our on-going projects as of the Latest Practicable Date:

<u>Biologics development stage</u>	<u>Number of on-going projects</u>	<u>Backlog (US\$ in million)</u>
<b>Pre-IND</b>		
Drug discovery .....	2	0.1
Preclinical development .....	15	15.3
Subtotal .....	17	15.4
<b>Clinical trial</b>		
Early-phase (phase I & II) clinical development .....	18	8.0
Late-phase (phase III) clinical development .....	7	17.2
Subtotal .....	25	25.2
<b>Commercial manufacturing</b> .....	7	23.8
<b>Total</b> .....	<b>49</b>	<b>64.4</b>

Our revenue increased by 69.7%, from RMB2,828.2 million in 2017 to RMB4,799.8 million in 2018, and decreased by 3.9%, to RMB4,612.1 million in 2019. Our net profit increased by 156.1% from RMB240.9 million in 2017 to RMB617.0 million in 2018, and increased by 69.2% to RMB1,043.9 million in 2019.

### Our Strengths

We believe the following strengths have contributed to our success and differentiated us from our competitors:

#### **Strategic focus on attractive therapeutic areas with both commercialized drugs of significant growth and potential first-in-class pipeline drugs**

We are founded and led by a group of seasoned polysaccharide-chemists with a strategic focus on heparin to address coagulation and thrombosis that cause life-threatening conditions. Through two decades of research, we have also accumulated profound understanding of the immune response mechanisms and engaged in the development of innovative drug candidates for fatal diseases with an immune system disorder axis. Our portfolio includes both commercialized drugs and first-in-class pipeline drugs, which provides us with stable cash flow as well as significant growth potential.

- Enoxaparin. Our own branded enoxaparin sodium injections (Inhixa, Neoparin and Prolongin) have been approved in 34 countries and sold in 17 countries globally with Neoparin targeting Poland, Inhixa targeting the EU market other than Poland and Prolongin targeting China and other emerging markets. We have also supplied enoxaparin sodium injection to our customers in 14 other countries. We had cumulative sales of enoxaparin sodium injections in the EU exceeding 100 million doses since 2016. Enoxaparin is the “gold standard” anticoagulant and antithrombotic drug with huge market demands and significant growth potential. According to Frost & Sullivan, the global market size of enoxaparin was US\$2,735.8 million in 2019, which is expected to increase

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to US\$4,868.8 million in 2025, and the global usage of enoxaparin reached 781.9 million syringes/vials in 2019, which is expected to reach 1,068.4 million syringes/vials in 2025.

- Six first-in-class drug candidates. Our drug candidates are being developed to treat diseases with a weak immune system axis (such as oncology and bacterial inflammation) and diseases with an overactive immune system axis (such as cardiovascular disease, non-infectious inflammation and autoimmune diseases). As of the Latest Practicable Date, we have obtained the clinical development and commercial rights of five of these drug candidates in the Greater China. Two of these drug candidates are in phase III clinical trials and two of them are in phase II clinical trials. We are also developing a self-discovered propriety oncology drug candidate currently at preclinical stage.

### “Gold standard” anticoagulant and antithrombotic drug with outstanding safety profile

Enoxaparin is the “gold standard” anticoagulant and antithrombotic drug for various indications, such as VTE and PE, with significant growth potential, according to the assessment report published by EMA in March 2017. Enoxaparin has been vital in preventing and treating life-threatening conditions caused by coagulation and thrombosis, such as stroke, heart attack and PE. Compared with other general anticoagulant drugs, due to its glycosylated polysaccharide structure, enoxaparin cannot be synthesized *in vitro* at least in the short term, and is neither completely replaceable nor replicable.

Enoxaparin, a type of LMWH, is expected to gradually replace other LMWH drugs. Compared with other LMWH drugs, enoxaparin has wider range of approved indications, more comprehensive delivery routes, longer elimination half-life, higher bioavailability and better anti-Xa and anti-IIa activity ratios. Guidelines published by ACCF/AHA recommend the usage of enoxaparin over other anticoagulant and antithrombotic drugs for the treatment of myocardial infarction. The World Health Organization (WHO) incorporates enoxaparin in the list of essential medicines, highlighting its importance in the anticoagulant and antithrombotic areas and its application as a first option of standard antithrombotic therapy in routine practice in many settings.

Enoxaparin enjoys huge market demand and significant growth potential. According to Frost & Sullivan, the global usage of enoxaparin reached 781.9 million syringes/vials in 2019, and is expected to reach 1,068.4 million syringes/vials in 2025. Its usage in China was 52.0 million syringes/vials in 2019, and is expected to increase at a CAGR of 23.6% to 185.5 million syringes/vials in 2025.

We believe we will benefit from such significant market opportunities by virtue of the outstanding safety profile of our enoxaparin drugs. The outstanding safety profile of our enoxaparin products is demonstrated by its low pharmacovigilance (PV) rate, low batch-to-batch variation, high biological purity (anti-Xa and anti-IIa activity ratio) and high purity level. In 2019, among the 3,042 PV cases relating to enoxaparin reported on the EMA PV system (EudraVigilance), only 139 cases were related to Inhixa and no less than 10 cases were related to Neoparin, amounting to no less than 4.90% being related to Inhixa and Neoparin, while we sold 60.9 million syringes/vials of Inhixa and 23.7 million syringes/vials of Neoparin in the EU in 2019, accounting for 17.8% of the total enoxaparin doses sold in the EU in the same year. Our enoxaparin drugs also demonstrated lower batch-to-batch variation as compared to the originator brand drugs. Percentages of impurities, such as galacturonic acid and sulfate in our enoxaparin sodium product are lower than the originator brand.



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### Fully integrated business model to enhance profitability

We have a fully integrated business model covering the heparin industry value chain from supply of raw materials, manufacturing of APIs to the sales of enoxaparin finished doses. Such unique business model together with state-of-the-art supply chain management, proprietary manufacturing technologies, rigorous quality control standards and large-scale manufacture capability serve as the cornerstones of our leading position in the global enoxaparin market and allow us to secure sufficient supply of high quality raw materials, improve cost efficiency and enhance profitability.

- *State-of-the-art supply chain management:* To ensure sufficient supply of the key heparin raw material, crude heparin, we have built our own crude heparin factories in China and the U.S. The state-of-the-art supply chain network guarantees us exclusive access to over 50% of the traceable heparin raw materials in China and 60% in the North America by volume of the traceable heparin raw materials in 2018. Our state-of-the-art integrated supply chain management ensures safety, reliability, stability and quality for the supply of our heparin raw materials. Our outstanding supply chain management has helped us to establish our leading position in the global heparin industry during the Baxter Incident. In 2008, contamination in the heparin sodium API used in the heparin sodium injections sold by Baxter caused serious acute hypersensitivity reactions in patients. The FDA later confirmed that the heparin sodium API supplied by us did not cause any single event of severe allergic reaction, which made us one of the few major heparin sodium API suppliers unaffected by the Baxter Incident in the U.S. market.
- *Proprietary manufacturing technologies and rigorous quality control:* Our proprietary manufacturing technologies ensure the best-in-class quality of our products. Based on years of experience in manufacturing heparin products, we have developed leading manufacturing technologies and know-how, such as purification technology, virus and bacteria inactivation technology, structural integrity protection and activity release technology and directed compound separation technology. Our leading technologies enable us to effectively preserve the structural integrity and molecular activity to the highest degree while minimize the impurity level of our enoxaparin sodium API. The design of our manufacturing system is rooted in our pursuit for the best-in-class quality standards. Our manufacturing processes and facilities not only comply with the CGMP requirements in the EU, the U.S. and China, but also follow comprehensive and rigorous quality control standards which cover every step of the manufacturing process. Such high quality control standards ensure the outstanding safety profile of our products, which has been proven by our long-term relationships with leading pharmaceutical giants.
- *Scaled production capability:* We are one of the few China-based pharmaceutical companies which are able to produce commercialized biological drugs on a large scale. We have state-of-the-art manufacturing facilities in China and the U.S. As of the Latest Practicable Date, with respect to heparin sodium API, we have an annual production capacity of 10,000,000 mega in China and 3,000,000 mega in the U.S. With respect to enoxaparin sodium API, we have an annual production capacity of 33,350 kg in China. With respect to enoxaparin sodium injection, we have an annual production capacity of 240 million pre-filled syringes, and 80 million vials. Our large-scale manufacturing capability ensures us to meet the huge market demand and capture the significant growth potential of enoxaparin as well as achieve economics of scale.

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We believe our fully integrated business model differentiates us from our competitors and gives us competitive advantages. It ensures sufficient supply of high quality raw materials and enhances our risk resistance profile with respect to price fluctuations and shortage of raw materials. It also improves cost efficiency as it allows us to have better control of the costs on each step throughout the operations of our heparin business and gives us flexibility in making price adjustments for our products in order to enhance our sales. Our powerful supply chain management and cost control capabilities, together with our large-scale manufacturing capability will support our high-volume sales of enoxaparin to capture the huge market demand for enoxaparin globally and continue our growth in enoxaparin business.

### **Well positioned to be the global leader in the enoxaparin market with effective marketing strategies in the major markets worldwide**

We keep abreast of the latest market developments and implement localized and differentiated marketing strategies in the three major enoxaparin markets, the EU, China and the U.S., based on various factors including market size, growth potential, competition and regulatory environment in those markets. We believe we are well positioned to become the leader in the global enoxaparin market by implementing such effective and diversified marketing strategies.

- EU: As the largest enoxaparin market globally, Europe consumed 488.7 million syringes/vials of enoxaparin out of 781.9 million syringes/vials consumed globally in 2019, and total sales of enoxaparin in Europe (including both originator brand and biosimilar drugs) was US\$1,664.9 million in 2019 and is expected to reach US\$2,705.1 million in 2025, according to Frost & Sullivan. In the EU, as the first approved enoxaparin biosimilar drug, Inhixa has been commercialized in the UK and nine EU countries including the top seven enoxaparin country markets (excluding Poland) in the EU in 2019, with the largest market share in the UK and leading market positions in Italy and Austria. In addition, Neoparin has the largest market share in Poland by sales in 2019. Our total sales volume of enoxaparin in the EU reached 84.6 million syringes/vials in 2019, accounting for 17.8% of market share in the EU. As a biosimilar drug, prescription of enoxaparin is based on brand name. To promote our brand name and product awareness, we have established a dedicated in-house sales team in the EU. We also engage distributors and third party promoters to expand our distribution network in various EU countries. As a pioneer in the EU enoxaparin biosimilars market, we believe we have established a strong brand name among leading hospitals and medical professionals.
- China: China enjoys one of the most rapid growth rates for enoxaparin sales globally. Total sales of enoxaparin in China reached US\$307.9 million in 2019, representing a CAGR of 24.5% from 2014 to 2019, and is expected to reach US\$698.0 million by 2025 according to Frost & Sullivan. The per capita use of enoxaparin in China was 0.04 dose while the per capita use was 0.95 dose in the EU in 2019, indicating significant growth potential in China. To further regulate the enoxaparin market and strengthen quality control in China, the NMPA has implemented an approval regime for injectable pharmaceuticals based on QCE in May 2020. We believe enoxaparin products that pass the QCE will gradually replace the low quality LMWH in the market that cannot pass the QCE. To capture the fast growth of enoxaparin market in China, we plan to further promote our current enoxaparin brand Prolongin after it obtains QCE approval. We submitted application for QCE approval of Prolongin to the NMPA in April 2018 and we believe Prolongin will be the first QCE-approved enoxaparin in China.

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- U.S.: U.S. represents a significant enoxaparin market. According to Frost & Sullivan, total sales of enoxaparin in the U.S. is expected to increase from US\$454.8 million in 2019 to US\$837.9 million in 2025, representing a CAGR of 10.7%. In the U.S., as a generic drug, prescription of enoxaparin is based on the generic name. Large scale supply and manufacturing capability is key to capture the significant market demand in the U.S. To take advantage of this market opportunity. We have submitted an ANDA for our enoxaparin sodium injection, which is currently under review by the FDA. In the meantime, we have a supply arrangement with a multinational pharmaceutical company to be its major supplier of enoxaparin sodium injections once launched in the U.S..

### A robust portfolio of first-in-class clinical stage drug candidates for the China market

We have obtained exclusive development and commercial rights in Greater China for five pipeline drugs, among which two are currently in phase III clinical trials and two are in phase II clinical trials. Below are our late clinical stage drug candidates:

- Oregovomab: Oregovomab, an anti-idiotypic murine monoclonal antibody, is an anti-CA125 immunotherapy drug candidate that is being developed by OncoQuest, in which we hold a 38.74% equity interest. It has completed a phase II clinical trial as a first-line treatment combined with chemotherapy in patients with advanced primary ovarian cancer. Phase II clinical trial have proven the safety and efficacy of Oregovomab in such combined treatment regime for advanced primary ovarian cancer patients. The combination of Oregovomab and chemotherapy leverages the effects of chemotherapy without additional toxicity. Phase II clinical results have shown a significant prolongation of median PFS, with a median PFS of 41.8 months, compared with 12.2 months in patients treated by chemotherapy alone ( $p=0.0027$ ). It also showed a significant improvement in OS ( $p=0.0043$ ). OncoQuest is currently in discussion with the FDA regarding a phase III trial plan. We plan to participate in the phase III MRCT of Oregovomab for such combined treatment. Oregovomab has Orphan Drug Designation from the FDA and EMA. Oregovomab is also being evaluated in a phase II clinical trial in combination with an investigational stage immune booster (poly ICLC / Hiltonol) for patients with advanced recurrent ovarian cancer, a phase Ib/IIa clinical trial in combination with PD-1 inhibitor (nivolumab) as a novel combinational immunotherapy treatment for patients with recurrent ovarian cancer, and a phase II clinical trial as a combined treatment with a PARP inhibitor (niraparib) for patients with recurrent ovarian cancer.
- AR-301 (Salvecin): AR-301 is a fully human monoclonal IgG1 antibody (mAb) that specifically targets *S. aureus* alpha-toxin. It is being developed by Aridis (NASDAQ: ARDS) in which we hold a 9.86% equity interest. It is currently being evaluated in a global phase III clinical study as an adjunctive therapy to standard of care antibiotics in patients diagnosed with ventilator associated pneumonia (VAP) caused by *S. aureus*. Results of a Phase I/II trial have shown that patients treated with AR-301 consistently demonstrated less time spent under mechanical ventilation and higher rates of *S. aureus* eradication as compared to those treated with antibiotics alone. AR-301 was granted Fast Track Designation by the FDA and Orphan Drug Designation by the EMA. We have received the NMPA approval for a phase III clinical trial in China as part of the global MRCT of AR-301, and we plan to initiate patient enrollment by the end of 2020.
- RVX-208 (Apabetalone): RVX-208 is an inhibitor of BET transcriptional regulators with selectivity for the second bromodomain. RVX-208 has completed phase III clinical trial



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(BETonMACE) in combination with standard of care to reduce major adverse cardiovascular events among high-risk cardiovascular disease patients with type 2 diabetes mellitus, recent acute coronary syndrome, and low levels of high-density lipoprotein (HDL). It is being developed by Resverlogix (TSE: RVX) in which we held a 38.60% equity interest as of the Latest Practicable Date.

We believe we are able to leverage our industry experience and proven execution capabilities to develop and commercialize these late-stage product candidates in the China market.

### **A fast-growing CDMO business focusing on a vast spectrum of recombinant and naturally derived large molecule and gene therapy products**

We operate a rapidly-growing CDMO business to capture the global growth opportunities in the biopharmaceutical sector and support the clinical development of our pipeline drugs. Our CDMO business ranked among the top three China-owned biologics CDMO operators based on 2018 revenue according to Frost & Sullivan. We offer comprehensive, integrated and highly customizable end-to-end CMC services, including R&D services, manufacturing services, quality assurance, and program management in our state-of-the-art laboratories and CGMP-compliant manufacturing facilities. Through combining the capabilities of our two platforms, Cytovance and SPL, our CDMO business enables the development and manufacture of a wide range of products including naturally derived and recombinant large molecule products and critical non-viral vectors and intermediates for gene therapy, which makes us distinct within the global CDMO industry.

Cytovance is a biopharmaceutical contract manufacturing company specializing in the development and manufacture of recombinant biologic pharmaceuticals from mammalian cell culture and microbial fermentation, and non-viral vectors and intermediates for gene therapy. Cytovance entered the gene therapy sector by developing an innovative platform in October 2019 for critical reagent grade pDNA manufacturing, in order to meet the huge market demand for high-quality pDNA. Cytovance has enabled successful clinical and company milestones for dozens of customers through its CMC services. As a testament to value created by our CDMO platform, several of Cytovance's customers were acquired by large pharmaceutical companies, such as Synageva BioPharma Corp. which was purchased by Alexion Pharmaceuticals, Inc. in 2015, Selexys Pharmaceuticals Corporation which was purchased by Novartis International AG in 2016, ARMO Biosciences, Inc. which was purchased by Eli Lilly and Company in 2018 and Synthorx Inc which was purchased by Sanofi in 2019.

SPL offers a broad spectrum of capabilities in the extraction, isolation and purification of naturally derived pharmaceuticals and extensive expertise in regulatory compliance. Moreover, SPL is able to provide services at scales ranging from laboratory development to CGMP suite production and further to metric-ton, full-scale commercial production.

The breadth of our CDMO services and our on-going innovation to focus on unmet market demands allow us to capitalize on the opportunities offered by different segments of the global biologics outsourcing services market. Our CDMO services address the capacity shortage and technological challenge in the CMC process during clinical development, which empower our customers to develop drugs from concept to commercial manufacturing stage and also help to accelerate the development of our pipeline drugs. Our CDMO business has a global and diversified customer base, consisting of leading global pharmaceutical companies and small- to mid-sized

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biotechnology companies as well as start-up companies. We enjoy a high level of customer loyalty and industry referrals. We provided services to 50, 54 and 52 customers in the years ended December 31, 2017, 2018 and 2019, respectively, including three out of the ten largest pharmaceutical companies in the world.

As of the Latest Practicable Date, we had 49 on-going projects including 17 pre-IND projects, 25 clinical trial projects and 7 commercial manufacturing projects with a total backlog of US\$64.4 million, which represents the total amount of contracted fees for services that we have contracted to perform but have not performed yet. During the Track Record Period, our CDMO services enabled approximately 20 regulatory filing milestones, including INDs, NDAs, BLAs or amendments.

Benefiting from the global growth in the biopharmaceutical sector, our CDMO business experienced rapid growth during the Track Record Period. Revenue from our CDMO business increased from RMB324.3 million in 2017 to RMB548.5 million in 2018, and further increased to RMB786.4 million in 2019. Our CDMO business has contributed to our rapid growth and diversified our revenue sources.

### **Seasoned polysaccharide-chemists founders and experienced management team with strategic insight and proven ability to lead our success**

Our founders are seasoned biochemists with solid scientific background as well as strategic insight. We are led by our founder and chairman of our Board, Mr. Li, who has 27 years of experience in the biopharmaceutical industry. Mr. Li has led the development of our heparin and enoxaparin products and played an instrumental role in our research and development efforts and our overall business growth. Our co-founder and deputy general manager, Ms. Li, and co-founder and general manager, Mr. Shan, have also made significant contributions to the success of our Company. Ms. Li has 27 years and Mr. Shan has 26 years of experience in the biopharmaceutical industry. Since their founding of the Company in 1998, they have worked diligently and passionately to achieve their shared vision to provide high-quality and innovative drugs for treatment of diseases with high mortality to benefit patients globally. With decades of scientific research and industry experience of heparin, we believe our founders are able to replicate our success in the heparin industry to our other businesses and guide us to become a leading pharmaceutical company globally.

Led by our founders, we have assembled a stable senior management team with extensive industry expertise, innovative vision and strong execution capabilities. Members of our senior management team on average have nearly 20 years of experience in the biopharmaceutical industry. Many of them have worked with leading global biopharmaceutical companies. They bring extensive industry experience and in-depth knowledge on the intricacies of managing a biopharmaceutical company. With their exceptional experience in global operations and acquisitions, excellent track record and strong execution capabilities, we believe our management team will continuously deepen our competitive edge and strengthen our integrated global operations and consistently strive to achieve our mission to become a global leader.

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### Our Strategies

To achieve our goal to become a global leading pharmaceutical company, we intend to pursue the following strategies:

#### **Continue to expand our market share of enoxaparin to become the leader in the global heparin industry**

According to Frost & Sullivan, the global enoxaparin market is expected to grow to US\$4,868.8 million in 2025. We aim to achieve significant market share in the global enoxaparin market by deepening penetration in our existing markets as well as expanding into new markets.

- **EU:** We are committed to continuing to increase our sales of enoxaparin in the EU market by implementing differentiated market strategies in various EU countries based on local market conditions and leveraging our experienced in-house sales team supported by our distributors and third-party promoters. As the pioneer of enoxaparin biosimilar in the EU, we plan to further increase our penetration in the major EU countries where we currently have sales and increase our sales to pharmacies, which generally have a higher profit margin than hospitals. In addition, we are considering suitable opportunities to launch our enoxaparin drugs in other European countries, such as Switzerland, primarily by enhancing physician’s awareness through our increased academic marketing efforts and expanding our sales and distribution network.
- **China:** We plan to further promote our Prolongin as the first QCE-approved enoxaparin in China upon NMPA’s approval and cultivate the PRC enoxaparin market.
- **U.S.:** In addition to our supply arrangement with a multinational pharmaceutical company to be its major supplier of enoxaparin sodium injections in the U.S., we are also developing our own generic enoxaparin sodium injection for which we have submitted an ANDA, which is currently under review by the FDA.
- **Other markets:** We aim to expand our sales of enoxaparin in Canada and the emerging markets, such as Southeast Asia, Latin America and Middle East. As of the Latest Practicable Date, our enoxaparin product has received marketing approvals in over 10 countries. Our distributors and we are also in the process of applying for marketing approval in over 15 countries. We believe we are able to become a leader in these markets by leveraging our high product quality, manufacturing and sales experience, customer base and sales network with local agents and pharmaceutical companies.

We will continue to solidify our leadership position in heparin sodium API, which serves as an important entry barrier for the global enoxaparin market, and maintain our position as the key manufacturer and supplier of heparin sodium API for well-known pharmaceutical companies. We plan to further optimize our supply chain management and enhance our quality control of the raw material of heparin API. We plan to expand the production capacity of crude heparin of our two factories in China to reduce our purchase of raw materials from third parties and increase our access to the traceable crude heparin globally. We will continue to invest in the research and development of manufacturing technologies and quality control system to further enhance our competitiveness and distinguish us from our peers.

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### **Maximize the commercial value of our first-in-class pipeline drugs in China by leveraging our local insight and vast experience in global operations**

We have developed a clear road map for the commercialization of our first-in-class pipeline drugs in China to maximize their commercial value. We have established an extensive sales and distribution network and teams in China for our heparin business and we believe we can leverage these resources in China to build specialized in-house sales teams and a distribution channel to hospitals and physicians for the academic marketing of our pipeline drugs. Through years of operations in China and globally, we have accumulated both local insight in China and vast experience in global operations. We believe we are able to leverage our successful experience in the heparin industry and our local insight in China to successfully launch our drug candidates and maximize their commercial value in China.

### **Further expand and develop our CDMO business and build a world-leading CDMO platform**

We plan to further expand and develop our CDMO business to build a world-leading CDMO platform to capture the global growth opportunities in the biopharmaceutical sector and serve as the incubator for our pipeline drugs, by enhancing our production capacity, expanding our customer base and improving our research and development capabilities.

To enhance Cytovance’s drug discovery, development and manufacture capabilities, we intend to double its production capacity of both microbial fermentation and mammalian cell culture. Moreover, we plan to expand rapidly into the gene therapy sector by increasing Cytovance’s current pDNA manufacturing capacity and developing innovative manufacturing platforms for viral vectors, which will differentiate Cytovance from other CDMO service providers with the capability to manufacture both plasmids and viral vectors. We believe the significant unmet market demands for both plasmids and viral vectors will drive the growth of Cytovance. We also plan to enhance Cytovance’s discovery and cell line development capabilities, protein analytics and materials testing services, and establish final dose manufacturing capabilities. Moreover, we plan to further enhance SPL’s development and manufacturing services for large molecule pharmaceutical products extracted from a broader range of natural sources.

To increase our market share in the CDMO industry, we aim to deepen our collaborations with existing clients, such as leading multinational pharmaceutical companies, as well as expand our customer base and promote our CDMO services to new customers in order to secure more projects. Advanced technologies are crucial to become a world-leading CDMO platform. We will continue to invest in innovative technologies to stay at the forefront of the industry. This will enable us to provide the most efficient and effective CDMO solutions to our clients and accelerate their drug development process.

### **Expand our business and strengthen our core competencies through acquisitions and strategic investments**

We intend to expand our business and strengthen our core competencies through selective acquisitions of, or strategic investments in, pharmaceutical or biotech companies. We are primarily interested in companies with robust product portfolios, strong R&D and sales and marketing capabilities that are complementary to ours. We will continue to identify suitable targets leveraging on our scientific insights and extensive industry experience. We take a market-driven approach in assessing potential acquisition targets. We primarily focus on the market potential of a target’s products and pipeline and potential synergies with our existing product pipeline.

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We believe that our strategic vision, vast industry experience and leading CDMO capabilities will make us a desirable acquirer and partner. Our strong business execution capabilities will help us effectively integrate the acquired businesses into our existing platform and achieve synergies with our R&D, manufacturing, sales and marketing capabilities.

Furthermore, we will selectively pursue opportunities to in-license international blockbuster drugs, in particular those targeting therapeutic areas or conditions with significant unmet clinical demands, such as oncology and cardiovascular diseases, as well as those that fall into our main therapeutic areas.

### **Develop our Pingshan Industrial Park into a world-class manufacture base for pharmaceutical products**

Our Pingshan Industrial Park is located within the National Biopharmaceutical Industrial Base in Pingshan, Shenzhen, China, with a total land area of over 200,000 sq.m. and a gross floor area of over 400,000 sq.m. authorized for construction. We have completed the construction and process validation of part of our facilities and product lines in Pingshan Industrial Park, and we are committed to developing our Pingshan Industrial Park into a world-class manufacturing base for pharmaceutical products. We have established 24,000kg annual production capacity of enoxaparin sodium API, and 12,000,000 mega annual production capacity of heparin sodium API. We plan to further expand our production capacity in Pingshan Industrial Park, including the production capacity of pre-filled syringes of enoxaparin sodium injection.

We also plan to make Pingshan Industrial Park as the manufacturing base for our innovative drug candidates in the future. With its leading production design and CGMP-compliant manufacturing system and facilities, we believe it can swiftly and seamlessly undertake the production of our new drug candidates to prepare for their commercialization in the near future.

### **OUR BUSINESS**

We are a global pharmaceutical company with business spanning the manufacture and sale of pharmaceutical products, development of innovative drugs and CDMO services. Our sales of pharmaceutical products consist of (i) finished dose pharmaceutical products which include heparin sodium injection and enoxaparin sodium injection, (ii) API products including heparin sodium API and enoxaparin sodium API and (iii) other products mainly including pancreatin API. We have obtained exclusive development and commercial rights in Greater China for clinical stage innovative drug candidates which are being developed for the treatment of diseases with an immune system axis. We are also developing a self-discovered proprietary drug candidate currently at preclinical stage. We operate a CDMO business that provides R&D, manufacturing, quality management and program management services, through our wholly-owned subsidiary Cytovance, which specializes in the development and manufacture of recombinant pharmaceutical products and critical non-viral vectors and intermediates for gene therapy, and through our wholly owned subsidiary, SPL, which provides services in the development and manufacture of naturally derived pharmaceutical products.



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The following table sets forth a breakdown of our revenue by our products and services during the Track Record Period.

	For the year ended December 31,					
	2017		2018		2019	
	RMB*000	% of Revenue	RMB*000	% of Revenue	RMB*000	% of Revenue
Sales of goods						
Finished dose pharmaceutical products						
Enoxaparin sodium injection . . . . .	311,165	11.0	981,938	20.5	1,230,840	26.7
Heparin sodium injection . . . . .	70,032	2.5	63,705	1.3	—	—
Subtotal . . . . .	381,197	13.5	1,045,643	21.8	1,230,840	26.7
API						
Enoxaparin sodium API . . . . .	171,422	6.0	230,002	4.8	371,714	8.1
Heparin sodium API . . . . .	1,674,707	59.2	2,522,384	52.6	1,902,275	41.2
Subtotal . . . . .	1,846,129	65.2	2,752,386	57.4	2,273,989	49.3
Others <sup>(1)</sup> . . . . .	217,124	7.7	385,403	8.0	287,538	6.2
Subtotal . . . . .	2,444,450	86.4	4,183,432	87.2	3,792,367	82.2
CDMO service . . . . .	324,308	11.5	548,469	11.4	786,401	17.1
Others <sup>(2)</sup> . . . . .	59,467	2.1	67,906	1.4	33,337	0.7
<b>Total</b> . . . . .	<b>2,828,225</b>	<b>100.0</b>	<b>4,799,807</b>	<b>100.0</b>	<b>4,612,105</b>	<b>100.0</b>

Notes:

(1) Other products mainly include pancreatin API.

(2) Other business mainly includes manufacture and marketing service, processing service, technical support service and other services.

### OUR PHARMACEUTICAL PRODUCTS

The sales of our pharmaceutical products accounted for 86.4%, 87.2%, and 82.2% of our revenue in 2017, 2018, and 2019, respectively. We focus primarily on the anticoagulant and antithrombotic finished dose pharmaceutical products, including enoxaparin sodium injection and heparin sodium injection and their relevant APIs. The sales of our finished dose pharmaceuticals accounted for 13.5%, 21.8%, and 26.7% of our revenue in 2017, 2018 and 2019, respectively, and the sales of our API products accounted for 65.2%, 57.4%, and 49.3% of our revenue in the respective years.

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The following table sets forth selective information relating to our products as of the Latest Practicable Date:

<b>PRODUCT TYPE</b>	<b>PRODUCTS</b>	<b>APPROVAL FOR SALES IN CHINA</b>	<b>APPROVAL FOR SALES IN THE EU</b>	<b>APPROVAL FOR SALES IN THE U.S.</b>	<b>APPROVAL FOR SALES IN OTHER MAJOR COUNTRIES*</b>	<b>APPLICATION OF APPROVAL FOR SALES IN OTHER MAJOR COUNTRIES*</b>
<b>FINISHED DOSE PHARMACEUTICAL PRODUCTS</b>	Enoxaparin sodium injection	Prolongin— approved by the NMPA for five strengths in 2005	Inhixa— approved by the EMA in 2016 for five strengths and in 2018 for multi-dose vials and high strengths  Neoparin— approved in Poland in 2016 for five strengths and in 2018 for multi-dose vials and high strengths	Filed an ANDA under the FDA’s review for enoxaparin sodium injection for seven strengths	Colombia, Chile, Paraguay, Madagascar, Jordan, Sri Lanka, Peru, Philippines, United Arab Emirates	Brazil, Canada, Saudi Arabia, Singapore, Malaysia, Switzerland, Israel, El Salvador, Costa Rica, Panama, Vietnam
	Heparin sodium injection	—	—	Four ANDAs approved for nine respective strengths by FDA	—	—
	Heparin sodium API	Approved by the NMPA in 2002	Approved by the EDQM in 2008 and renewed in 2013	Authorized supplier of heparin sodium API for the manufacture of several heparin products	Authorized supplier in Turkey, India, Italy, Brazil, South Korea, Mexico, Canada	Authorized supplier in Russia
<b>API PRODUCTS</b>	Enoxaparin sodium API	Approved by the NMPA in 2005	—	Filed DMF and under the FDA’s review as the manufacturer referenced in a customer’s ANDA for enoxaparin sodium injection  Filed DMF and under the FDA’s review of our ANDA for enoxaparin sodium injection for seven strengths	Authorized supplier in Algeria, Turkey, Brazil, Morocco, Uruguay, South Korea, Bangladesh, Paraguay, Colombia, India, Peru	Authorized supplier in Vietnam, Russia, Saudi Arabia, Mexico, Thailand, Malaysia, Jordan

\* Marketing approvals of our products in these countries are or will be held by third parties, except for Canada and United Arab Emirates.

**Our Finished Dose Pharmaceutical Products**

***Enoxaparin Sodium Injection***

Our finished dose enoxaparin product, enoxaparin sodium injection, a sterile solution of enoxaparin sodium in water for injection, is an injectable anticoagulant and antithrombotic drug that helps prevent blood clots in patients. Our finished dose enoxaparin product is available as solution for injection in both pre-filled syringes and vials. Enoxaparin increases the effect of antithrombin III, a natural substance that controls the blood’s clotting factors and helps prevent blood from clotting inside

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the body, which helps to stop the formation of new blood clots and control existing ones. Our enoxaparin product has been approved for marketing in the EU and China for (i) prevention of venous thromboembolic disease in moderate and high risk surgical patients, in particular those undergoing orthopaedic or general surgery including cancer surgery, (ii) prevention of venous thromboembolic disease in medical patients with an acute illness and reduced mobility at increased risk of venous thromboembolism, (iii) treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), excluding PE likely to require thrombolytic therapy or surgery, (iv) prevention of thrombus formation in extra corporeal circulation during haemodialysis, and (v) treatment of acute coronary syndrome, including unstable angina and certain types of myocardial infarction.

Approved by the EMA, the NMPA and relevant governmental authorities, our enoxaparin product can be administered through all three injection routes, including subcutaneous injection, intravenous (bolus) injection and arterial line injection. In the comparison study with its reference drug Clexane, the fluctuation range of several features of our enoxaparin sodium API, including molecular distribution and molecular weight, the average degree of polymerization, the amount of disaccharide after enzymolysis fall within the range of Clexane, which indicates the high similarity between our enoxaparin product and the reference drug, the outstanding safety profile of our enoxaparin product and the stability of our manufacturing technologies. The post-market safety report retrieved from EudraVigilance that collects incidence of adverse events using enoxaparin sodium injections in 2019 also shows the safety of our enoxaparin sodium injection. In 2019, among the 3,042 PV cases relating to enoxaparin reported on the EMA PV system (EudraVigilance), only 139 cases were related to Inhixa and no less than 10 cases were related to Neoparin, amounting to no less than 4.90% being related to Inhixa and Neoparin, while we sold 60.9 million syringes/vials of Inhixa and 23.7 million syringes/vials of Neoparin in the EU in 2019, accounting for 17.8% of the total enoxaparin doses sold in the EU in the same year.

We are one of the few companies with integrated manufacturing process and manufacturing facilities of enoxaparin sodium injection that are in compliance with the EU, the U.S. and Chinese CGMP standards and have passed multiple inspections by the EMA, the FDA, the NMPA and other relevant governmental authorities. During the Track Record Period, our production of enoxaparin sodium injection was primarily conducted at Techdow Nanshan, which passed the inspection of the EMA in 2015, 2016, 2018 and 2019, the inspection of the FDA in 2018 and 2019 and the inspection of the NMPA in 2011 and 2016. During the Track Record Period, a small portion of our finished dose enoxaparin product was also produced by our OEM, the manufacturing process and facility of which are also in compliance with the EU CGMP requirements.

During the Track Record Period, we sold our enoxaparin finished dose products to over 20 countries either under our own brands or to other pharmaceutical companies for their resale under their own brands. In the EU, our enoxaparin sodium injection products were sold primarily to distributors and wholesalers for their sales to hospitals and pharmacies in the EU. In China, we sold our enoxaparin sodium injection to distributors for their further distribution to hospitals. Revenue generated from the sales of our enoxaparin finished dose products increased from RMB311.2 million in 2017 to RMB981.9 million in 2018 and further to RMB1,230.8 million in 2019, accounted for 11.0%, 20.5%, and 26.7% of our total revenue during the respective years.

### *EU and UK*

Our enoxaparin product is currently marketed under our brand names, Inhixa and Neoparin. Inhixa has been approved by the EMA through the Centralized Authorization Procedure which allows

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it to be sold in all the EU countries without further approval, and Neoparin has been approved for marketing and sales in Poland.

- **Inhixa**

We received the marketing authorization from the EMA for Inhixa in September 2016 for five strengths ranging from 2,000 IU (20 mg)/ 0.2 mL to 10,000 IU (100 mg)/1 mL, based on the consistency evaluation of Inhixa as compared to Clexane in terms of structure, purity and biological activity in a PK/PD study. We also received the marketing authorization from the EMA for Inhixa in multi-dose vials and high-strength pre-filled syringes in September 2018. As of the Latest Practicable Date, Inhixa was covered by the national healthcare programs in ten EU countries and the UK.

- **Neoparin**

Neoparin was approved by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products in Poland in February 2016 for five strengths, primarily based on a randomized, multicenter, parallel, open label clinical study comparing Neoparin with Clexane for the prevention of venous thromboembolism in patients undergoing knee surgery with high venous thromboembolism risk, which proved the safety and effectiveness of Neoparin and its similarity to Clexane. Neoparin in multi-dose vials and high-strength pre-filled syringes were approved in January 2018. Neoparin is covered by the national healthcare program in Poland.

We collaborated with SciencePharma in applying for the marketing authorization of Neoparin in Poland. SciencePharma is a leading service provider in the pharmaceutical industry, specializing in pharmacovigilance and regulatory affairs in the EU. We manufactured and supplied the enoxaparin sodium injections used in the clinical trial for Neoparin. SciencePharma sponsored the clinical trial and, as a result, holds the marketing authorization for Neoparin in Poland. We acquired SciencePharma’s ownership and protective rights of trademark, community designs and domains relating to Neoparin in December 2016. Upon the transfer of the rights, we granted SciencePharma a royalty-free license to use the trademark, community designs and domains for the purpose of its registration and sales of Neoparin. To the knowledge of our Directors, save as disclosed, SciencePharma or its associates do not have any past or present relationships (including, without limitation, business, financial, family or employment relationship) with the Company, its subsidiaries, their shareholders, directors, senior management or their respective associates.

### *China*

- **Prolongin**

Our enoxaparin sodium injection, Prolongin, is the first generic enoxaparin sodium injection approved by the NMPA in China. We received the NMPA approval of our enoxaparin product for five strengths in 2005, which was renewed in 2015. Enoxaparin sodium injection is included as a category II drug in the National Medical Insurance Catalog. We submitted application for QCE approval of Prolongin to the NMPA in April 2018. For details, see “Regulatory Environment — Laws and Regulations Related to Our Business in the PRC — Regulations on Drug Research and Development & Registration Services.” We expect our enoxaparin sodium injection to be the first enoxaparin sodium injection approved by the NMPA based on QCE.

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### *U.S.*

We have entered into a supply agreement with a multinational pharmaceutical company to be its major supplier of enoxaparin sodium injections in the U.S. We are also developing our own generic enoxaparin sodium injection products for which we submitted an ANDA in 2013, which is currently under review by the FDA based on the sameness analysis as the originator brand name drug, Lovenox. Our manufacturing process and facilities in Techdow Nanshan passed the FDA's inspection in 2018 and 2019. We aim to submit our response to the FDA's latest complete response letter by the end of 2020 and we expect that the FDA will approve our ANDA in 2021 at the earliest. When we obtain the ANDA for our own branded enoxaparin sodium injection products in the U.S., we plan to collaborate with a world-leading pharmaceutical distributor, to mainly market and sell our products to pharmacies in the U.S.

### *Other Markets*

During the Track Record Period, we also supplied enoxaparin sodium injections for pharmaceutical companies in the emerging market, including South America and Southeast Asia.

According to Frost & Sullivan, we are the third largest supplier of enoxaparin finished doses globally accounting for 6.5% of the global market share by revenue in 2019, and we are the second largest supplier of enoxaparin finished doses in China accounting for 10.9% of the market share in China by revenue in 2019. We also have a leading market share in the EU and the UK, with the largest market share in the UK and Poland and leading market positions in Italy and Austria accounting for 60.3%, 52.6%, 34.7% and 19.1% of the market shares in those countries, respectively. Enoxaparin finished doses have significant growth potential. As enoxaparin sodium is expected to replace other LMWH preparations, the global usage of enoxaparin sodium will continue to grow from 781.9 million pre-filled syringes/vials in 2019 to 1,068.4 million pre-filled syringes/vials in 2025 according to Frost & Sullivan.

### ***Heparin Sodium Injection***

Our heparin sodium injection is a sterile solution of heparin sodium in water for injection, standardized for anticoagulant activity. It is to be administered by intravenous or deep subcutaneous routes. Heparin inhibits reactions that lead to the clotting of blood and the formation of fibrin clots both *in vitro* and *in vivo*, and it also prevents the formation of a stable fibrin clot by inhibiting the activation of the fibrin stabilizing factor. The approved indications of heparin sodium injection are (i) anticoagulant therapy in prophylaxis and treatment of venous thrombosis and its extension, (ii) low-dose regimen for prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease; (iii) prophylaxis and treatment of pulmonary embolism, (iv) atrial fibrillation with embolization; treatment of acute and chronic consumptive coagulopathies (disseminated intravascular coagulation), (iv) prevention of clotting in arterial and cardiac surgery, (v) prophylaxis and treatment of peripheral arterial embolism and (vi) application as an anticoagulant in blood transfusions, extracorporeal circulation, and dialysis procedures.

We received four ANDAs for generic heparin sodium injection in 2014 for nine strengths in single or multiple dose vials. Before the disposal of our equity interests in Hepatunn in June 2018, we generated revenue from its sales of heparin sodium injection in China, which accounted for 2.5% and 1.3% of our total revenue in 2017 and 2018, respectively. Moreover, we entered into a collaboration



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agreement in 2010 with a world-leading pharmaceutical distributor, under which we granted such distributor with the exclusive distribution right of our generic heparin sodium injection in the U.S. During the Track Record Period, such distributor engaged third-party manufacturers to produce heparin sodium injection with the API we supplied. We plan to change the authorized manufacturer referenced in our ANDAs to Techdow Nanshan.

Primarily driven by the increase in the price of crude heparin, the market size of heparin is projected to grow from US\$668.5 million in 2019 to US\$731.8 million by 2025 at a CAGR of 1.5%, according to Frost & Sullivan. The heparin market is relatively scattered and less concentrated. There are many small market players, the profit margins of which are comparatively low.

### Our API Products

#### *Heparin sodium API*

Heparin sodium is the sodium salt of sulfated glycosaminoglycans present as a mixture of heterogeneous molecules varying in molecular weights that retains a combination of activities against different factors of the blood clotting cascade. Our heparin sodium API product consists of heparin sodium purified from crude heparin, which is separated from the mucosa of porcine small intestines. Our heparin sodium API product is primarily used for the production of heparin sodium preparations and LMWH API.

As of the Latest Practicable Date, our heparin sodium API product was one of the few heparin sodium API products which received NMPA approval, EDQM approval and passed the FDA review. We commenced sales of our heparin sodium API product in the EU in 2000, in the U.S. in 2003 and in China in 2010. Moreover, we are one of the few companies with an integrated manufacturing system compliant with the U.S., EU and Chinese CGMP standards and has passed multiple inspections by the FDA, EMA, NMPA and other relevant governmental authorities. We participated in the revision of the USP heparin sodium standards in 2009, which was primarily in response to the contamination of heparin sodium API used in the Baxter Incident.

Our heparin sodium API was approved by the NMPA in 2002 and by the EDQM in 2008, and we have been authorized by the FDA as the heparin sodium API supplier for several finished dose heparin products. Moreover, our heparin sodium API has received marketing approvals in Canada and India. Our heparin sodium API is produced at our facility in Nanshan, Shenzhen, China (the “**Hepalink Nanshan**”) which complies with the U.S. CGMP requirements, and passed five FDA inspections in 2005, 2008, 2011, 2013 and 2016, including an inspection following the Baxter Incident, where the FDA did not find any deficiencies. In addition, our manufacturing process and facilities of heparin sodium API at Hepalink Nanshan were also certified by BfArm after its inspections in 2006, 2009, 2012, 2014 and 2017, and is in compliance with Chinese CGMP requirements with certificates issued by NMPA after its inspections in 2003, 2008, 2012 and 2017. Our heparin sodium API is also produced at our manufacturing facility in Wisconsin, the U.S., which is in compliance with the U.S. CGMP requirements and has passed multiple inspections by the FDA. Our heparin sodium API business in the U.S. is operated by our wholly-owned subsidiary, SPL, based in the U.S.

Our self-developed proprietary technologies in the separation and purification of heparin sodium API allow us to maximize the yield of highly charged, high molecular weight heparin chains present in the starting material without affecting the material by degradation, such as depolymerization and/or desulfation caused by the applied process conditions. As a result, we are able to maintain a high

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yield of the anti-factor IIa activity of our heparin sodium API. Since we are able to effectively remove impurities, such as lipids, peptides, protein and nuclear impurities, viruses, bacterial endotoxins, related glycosaminoglycans and other neutral and positively charged impurities, our heparin sodium API contains much less impurities per unit, compared with the standards stipulated per CHP, USP and EP. Our product’s high purity and complete structure also led to an anti-factor IIa potency of not less than 200 IU/mg in 80% batches during the Track Record Period, higher than the 180 IU/mg minimum requirement stipulated per USP, EP and CHP. Specifically, our self-developed proprietary technologies include technology of impurities and components separation, technology of virus and bacteria inactivation, technology of genetic integrity protection, technology of the release of active substances and technology of directional components separation, which are protected as our know-how and trade secrets.

We have established an integrated supply chain to secure high quality crude heparin for the manufacturing of our heparin sodium API. Our supply is comprised of crude heparin produced by Independent Third Parties and our wholly-owned subsidiaries, Chengdu Sunrace and Shandong Ruisheng. We require that the crude heparin we purchase or produce are processed from porcine small intestines that can be traced to its supplier. As of the Latest Practicable Date, through our own subsidiaries in China and the U.S. and supply network, we had exclusive supply for over 50% of the traceable crude heparin in China and 60% in the North America by volume of the traceable heparin raw material in 2018.

During the Track Record Period, all of the heparin sodium API products we sold were produced in our facilities in Hepalink Nanshan and SPL, and our heparin sodium API products were sold to over 15 countries and regions. We are able to provide customized heparin sodium API according to our customers’ specifications. Our customers remained relatively stable during the Track Record Period. Revenue generated from the sales of our heparin sodium API increased from RMB1,674.7 million in 2017 to RMB2,522.4 million in 2018 and due to the impact by African swine fever since late 2018, our revenue generated from the sales of heparin sodium API decreased from RMB2,522.4 million in 2018 to RMB1,902.3 million in 2019, accounted for 59.2%, 52.6%, 41.2% of our total revenue for the respective years.

As of the Latest Practicable Date, there were four major suppliers of heparin sodium API based in China and five major suppliers globally, according to Frost & Sullivan. According to Frost & Sullivan, we are the largest heparin sodium API supplier in the global market and our heparin sodium API product had a market share of 40.7% of the global heparin sodium API supply market by revenue in 2018. The global sales revenue of heparin sodium API reached US\$1,262.8 million in 2019, which is expected to increase to US\$3,317.6 million in 2025 at a CAGR of 17.5%, according to Frost & Sullivan. We believe our state-of-the-art supply chain management, rigorous quality control and manufacturing standards and proprietary manufacture technologies serve as the cornerstones of our leading position in the global heparin sodium API market, differentiate us from our competitors and strengthen our competitive advantages.

### ***Enoxaparin sodium API***

Our enoxaparin sodium API is the sodium salt of depolymerized heparin, obtained by alkaline depolymerization of heparin benzyl ester, by chemically breaking up the larger heparin chains into smaller fragments. Heparin sodium API is the primary raw material for our enoxaparin sodium API. Enoxaparin sodium API is used for the production of finished dose enoxaparin sodium pharmaceutical products.

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As of the Latest Practicable Date, our enoxaparin sodium API product was one of the few enoxaparin sodium API approved by the NMPA and other regulatory authorities and qualified for sales in certain countries in Europe, South America, Asia and Africa. Moreover, we are one of the few companies with an integrated manufacturing process in compliance with U.S., EU and Chinese CGMP standards which has passed multiple inspections by the FDA, NMPA and EMA.

Our enoxaparin sodium API was approved by NMPA in 2005. We are currently under the FDA review as the API supplier referenced in a customer’s and Techdow’s enoxaparin ANDA applications. Our enoxaparin sodium API is produced at Techdow’s facility in Nanshan, Shenzhen, China (the “**Techdow Nanshan**”) in compliance with the EU, Chinese and Brazilian CGMP requirements, with the relevant certificate issued by the EMA in 2015 and 2018, NMPA in 2015, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Product of Poland in 2013 and 2018, and ANVISA in 2011. Our production of enoxaparin sodium API at Techdow Nanshan is also in compliance with the U.S. CGMP standards, and passed the inspections by the FDA in 2012, 2015, 2018 and 2019. Moreover, our manufacturing process and facilities of enoxaparin sodium API in Pingshan Industrial Park are designed to be in compliance with the U.S, EU and China CGMP requirements and passed the EMA inspection in 2019, which will further increase our production capacity.

The high quality of our heparin sodium API and our self-developed proprietary technologies in the chemical process of the depolymerization of heparin benzyl ester allow us to maximize the yield of enoxaparin sodium API and ensure the stableness and completeness of its complex chemical features. We developed our proprietary technologies for manufacturing our enoxaparin sodium API which include directed cleavage and structural recombination techniques, targeted component and sequence selective separation techniques, and precise control techniques for purification and impurity removal of synthetic product, and are protected as our know-how and trade secrets. Our design of the manufacturing process and parameters and the technology know-how we apply in the process ensure that the structural integrity and molecular activity of our enoxaparin sodium API is highly consistent with the originator and the impurities of our enoxaparin sodium API are below or at the same level as the originator. In addition, we have established a comprehensive quality management system that guide our operations through our supply chain. We have set stringent quality standards on our enoxaparin sodium API product, which specifies a narrower range of molecular weight, a more stable molecular distribution and a more strict control of impurity than approved standards.

As a result of our proprietary production technologies, integrated supply chain and comprehensive quality management system, our enoxaparin sodium API is able to achieve a higher product quality. Potency of the anti-factor Xa activity of and the impurities contained in our enoxaparin sodium API conform with the respective requirement under the CHP, USP and EP and the potency tested in the API of our reference drug. Our stable manufacturing process also ensures less fluctuation in the product quality among each batch of enoxaparin sodium API we produce.

During the Track Record Period, all of the enoxaparin sodium API products we sold were produced at Techdow Nanshan, which were sold to our distributors and manufacturers of finished dose enoxaparin products in over 10 countries, primarily in the Middle East, Europe, South America and Asia, for the production of enoxaparin sodium injections. Revenue generated from the sales of our enoxaparin sodium API increased from RMB171.4 million in 2017 to RMB230.0 million in 2018 and further to RMB371.7 million in 2019, accounted for 6.0%, 4.8% and 8.1% of our total revenue for the respective years.

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### OUR INNOVATIVE DRUG BUSINESS

Based on our profound understanding of immune response mechanisms, we have engaged in the investment in and development of first-in-class drug candidates that address the significant unmet clinical demands for fatal diseases with an immune system disorder axis. We have strategically invested in a number of biotech companies with first-in-class drug candidates in our focused therapeutic areas and have obtained from them exclusive development and commercial rights of certain drug candidates in the Greater China, including two drug candidates in phase III clinical trials, two drug candidates in phase II clinical trials, and one drug candidate in phase I clinical trial, as of the Latest Practical Date. We are also developing a self-discovered proprietary oncology drug candidate currently at preclinical stage.

For the drug candidates of which we own exclusive development and commercial rights in Greater China, we plan to join the respective MRCTs by opening clinical sites in China, such as phase III trial for Oregovomab and AR-301. The trial for AR-301 has been approved by the NMPA. Data from MRCTs can be submitted to multiple regulatory agencies in International Conference on Harmonization (ICH) and non-ICH countries. Our participation in the MRCTs can reduce the time lag of launching our respective drug candidates in China.

The following chart summarizes the development status of our innovative drug candidates as of the Latest Practicable Date:

Drug Candidate	Target / Mechanism of Action	Indications	Partner Company	Hepalink Shareholding	Development and Commercial Rights Owned by (Regions)	IND	Ph1	Ph2	Ph3	MRCT <sup>1</sup> Participated by Hepalink
Oregovomab	Immunological stimulation after binding to CA125 antigen	Primary late-stage ovarian cancer	OncoQuest	38.74%	OncoVent <sup>2</sup> (Greater China) <sup>4</sup>					☆
		Recurrent late-stage ovarian cancer (Oregovomab+Hiltonol)							☆	
		Recurrent late-stage ovarian cancer (Oregovomab+PD-1 Inhibitor nivolumab)							☆	
		Recurrent late-stage ovarian cancer (Oregovomab+PARP Inhibitor niraparib)							☆	
mAb-AR20.5	Immunological stimulation after binding to MUC1 antigen	Pancreatic cancer								☆
AR-301 (Salvecin)	α-toxin released by Gram-positive staphylococcus aureus	Staphylococcus aureus pneumonia	Aridis	9.86%	Shenzhen Arimab <sup>3</sup> (Greater China)					★
AR-101 (Aerumab)	Gram-negative pseudomonas aeruginosa O11 serum	Pseudomonas aeruginosa pneumonia								☆
RVX-208 (Apabetalone)	BD2 domain of BET family member	Type 2 diabetes with coronary heart disease	Resverlogix	38.60%	Hepalink (Greater China)					
		Chronic Kidney Disease								
H1710	Heparanase (HPA)	Pancreatic cancer	Hepalink (In-house)	100%	Hepalink (Global)					
		New Indication								☆

Hepalink initiated the trials  
 The companies Hepalink invested initiated the clinical trials  
 The company Hepalink invested plans to initiate the clinical trials for new indication based on the ph3 clinical data of Type 2 diabetes with coronary heart disease  
 Hepalink has initiated the China portion MRCT<sup>1</sup>  
 Hepalink plans to initiate the respective China portion MRCTs<sup>1</sup> once entered pivotal phase

<sup>1</sup> MRCT refers to multi-regional clinical trials, which involves more than one independent center in enrolling and following clinical trial participants. It is widely conducted by many global pharmaceutical companies to reduce the time lag of launching innovative drugs in different regions.  
<sup>2</sup> We directly hold 54.00% equity interest in OncoVent and are entitled to additional economic interest through our 38.74% equity interest in OncoQuest and our 14.94% equity interest in Quest Pharma Tech, which together hold 40.00% equity interest in OncoVent. Any profit of OncoVent will be reflected on our financial statement under equity method through our equity interest in OncoVent and Quest Pharma Tech, in addition to our direct holding in OncoVent.  
<sup>3</sup> We directly hold 51.00% equity interest in Shenzhen Arimab and are entitled to additional economic interest through our 9.86% equity interest in Aridis, which holds the remaining 49.00% equity interest in Shenzhen Arimab. Any profit of Shenzhen Arimab will be reflected on our financial statement under equity method through our equity interest in Aridis, in addition to our direct holding in Shenzhen Arimab.  
<sup>4</sup> Greater China region includes PRC, Hong Kong, Macau and Taiwan.

In addition, our portfolio companies are also developing a number of innovative drugs with significant growth potential. As of the Latest Practicable Date, we held 47.02% equity interest in HighTide and 8.60% equity interest in Kymab.

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Based on public information, HighTide is a global clinical-stage biopharmaceutical company focused on discovering and developing novel drugs to treat chronic liver diseases, gastrointestinal diseases and metabolic disorders with high unmet needs. Its leading drug candidate, HTD1801, is a first-in-class oral small molecule drug candidate. The phase II clinical trial for the usage of HTD1801 in treating primary sclerosing cholangitis (PSC) is currently ongoing and the phase II clinical trial for the treatment of nonalcoholic steatohepatitis (NASH) has been completed. The FDA has granted HTD1801 Fast Track Designation in both diseases.

Based on public information, Kymab, based in Cambridge, the UK, is a clinical stage biopharmaceutical company focused on the discovery and development of fully human monoclonal antibody drugs using its proprietary antibody platforms (IntelliSelect®) which contain the entire repertoire of human antibodies. Kymab’s platform has been designed to maximise the diversity of human antibodies produced in response to immunisation with antigens. According to public source, Kymab is using its platforms for a number of internal drug discovery programmes and in partnership with pharmaceutical companies. It has a broad pipeline of therapeutic antibody programmes, with four drug candidates for immune-oncology therapy with significant growth potential.

### **Oregovomab**

Oregovomab is an investigational first-in-class anti-CA125 immunotherapy intended to treat advanced ovarian cancer, including first-line treatment of primary advanced ovarian cancer and recurrent advanced ovarian cancer. Oregovomab is a high affinity murine monoclonal antibody specific for CA125 to induce therapeutic immunity directed against the tumor. OncoVent, a joint venture established by OncoQuest and us, in which we hold 54.0% equity interest, obtained exclusive rights to develop and commercialize Oregovomab in Greater China from OncoQuest, in which we hold 38.74% equity interest. We are entitled to additional economic interest in OncoVent through our investee companies which hold 40.00% of its equity interest in total. Oregovomab has been granted Orphan Drug Designation by the FDA and EMA for its indication in treating primary advanced ovarian cancer, for which, OncoQuest has completed a phase II clinical trial using Oregovomab as first-line therapy combined with first-line chemotherapy. Oregovomab is also undergoing three global clinical trials to evaluate Oregovomab combined with PARP inhibitor or immunotherapy for treating patients with recurrent advanced ovarian cancer. We acquired the exclusive development and commercial right of Oregovomab in Greater China in September 2016.

### ***Market Opportunity and Competition***

There is significant market potential for the treatment of ovarian cancer in China. According to Frost & Sullivan, the incidence of ovarian cancer in China increased from 51.0 thousand in 2014 to 54.1 thousand in 2018, representing a CAGR of 1.5%, which is expected to reach 66.9 thousand by 2028 at a CAGR of 2.2%, and 74.0 thousand by 2035 at a CAGR of 1.4%.

There are three main treatment options for ovarian cancer, including chemotherapy, surgery and hormone therapy. The most adopted first-line treatment for primary ovarian cancer is chemotherapy with carboplatin, docetaxel or paclitaxel, but its effects are not typically long-lasting. More than 80% of ovarian cancer patients treated with chemotherapy experience recurrent disease, and more than 50% of these patients die from the disease in less than five years post-diagnosis. Options of targeted therapy are also limited. There are primarily two kinds of treatment of target therapy, including small molecular targeted drugs, such as PARP inhibitors, and mAbs, such as anti-angiogenesis inhibitors.



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Anti-angiogenesis inhibitors target to block the actions of vascular endothelial growth factor (VEGF), and thereby inhibiting endothelial cell proliferation and vessel formation, which will potentially slow down or stop tumor growth. Bevacizumab is an approved anti-angiogenesis inhibitor, the clinical results of which have shown that bevacizumab has limited efficacy delaying the progression of ovarian cancer. PARP inhibitors target to block the actions of enzyme poly ADP ribose polymerase (PARP) to repair damaged DNA, which will lead to cell death and potentially slow down or stop tumor growth. PARP inhibitor olaparib is approved as first-line maintenance therapy for patients with deleterious BRCA mutations after response to first-line chemotherapy. Only around 10-15% patients with ovarian cancer had BRCA mutations, leaving the rest of patients in urgent need of new first-line treatment.

As of the Latest Practicable Date, according to Frost & Sullivan, there was no approved or commercialized immunotherapy or anti-CA125 monoclonal antibody treatment for ovarian cancer globally, and there were three anti-CA125 antibody candidates under clinical development, as shown in the table below:

<b>Global Pipelines of Anti-CA125 Antibody Treatment for Ovarian Cancer<sup>1</sup></b>				
<b>Pipeline</b>	<b>Indication</b>	<b>Company</b>	<b>Status</b>	<b>Classification</b>
Oregovomab/OvaRex®	• Ovarian Neoplasms	OncoQuest Inc. <sup>2</sup>	Phase II	New Drug
DMUC4064A	• Pancreatic Neoplasms • Ovarian Neoplasms	Genentech, Inc.	Phase I	New Drug
Sofituzumab vedotin	• Pancreatic Neoplasms • Ovarian Neoplasms	Genentech, Inc.	Phase I	New Drug

1. Pre-clinical pipelines are excluded.

2. OncoVent as the exclusive rights to develop and commercialize the drug candidate in Greater China. We directly hold 54.00% equity interest in OncoVent and are entitled to additional economic interest through our investee companies which hold 40.00% of its equity interest in total. We also holds 38.74% of equity interest in OncoQuest.

Source: Frost & Sullivan Report

Oregovomab is being developed as an immunotherapy for ovarian cancer. Using murine mAb, Oregovomab has a novel immunotherapeutic mechanism of action which, in combination with immunomodulating effects of the standard of care chemotherapy, has generated promising evidence. It has demonstrated to prolong life and cause a beneficial immune response which substantially improves standard of care chemotherapy. It does not increase toxicity while having an acceptable and manageable safety profile. The cumulative amount of antibody used is also lower compared to current therapy, with treatment effect achieved with only four infusions. Oregovomab has the potential to be a first-line treatment option for ovarian cancer.

Please refer to the section headed “Industry Overview—Innovative Drug Market—Ovarian Cancer” for more industry related details.

### ***Mechanism of Action***

Oregovomab is a murine monoclonal antibody IgG1 specific for tumor-associated antigen CA125. CA125 is a surface mucin-like glycoprotein antigen that is expressed on more than 95% of all nonmucinous stage III/IV epithelial ovarian carcinomas and occurs at elevated levels in the serum of patients with ovarian cancer. Increased CA125 serum levels have also been observed patients with a variety of malignancies (carcinomas of the pancreas, lung, colon, and other gastrointestinal tumors).

Oregovomab has a unique mechanism of action based on immunological stimulation following its binding to CA125. The non-human antibody, murine mAb, in combination with chemotherapy,

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upon binding to tumor antigen CA125 in patient, will trigger initial human anti-mouse (HAMA) response, which through antigen presentation will stimulate antigen CA125 specific T cells. Current evidence supports that this binding *in vivo* renders the target antigen CA125 more immunogenic or “neoantigen-like” through altered and enhanced recognition, antigen processing and presentation to specific T cells. This induces antigen-antibody uptake and processing using the immunoglobulin Fc $\gamma$  binding via the mannose receptor, Fc $\gamma$ R1, and CCR5, a binding pattern in the human unique to murine IgG1 resulting in cross presentation of CA125 peptides and initiation of local specific immune responses with an IFN- $\gamma$  signature. These properties initiate demonstrable humoral and cellular responses in patients with CA125-positive cancer that are otherwise in a state of relative immune tolerance to their disease, and thus unlikely to mount clinically relevant anti-tumor immune responses. Due to transient changes in relative immune tolerance associated with chemotherapy, clinical activity is particularly enhanced when Oregovomab is given in combination with selected chemotherapeutic agents in a specific schedule in patients with Stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer in the first-line setting.

This application of monoclonal antibody indirect immunization is different from classical active immunization that induces protective immunity, or passive immunization that directly targets disease using mechanisms such as antibody-dependent cell-mediated cytotoxicity (ADCC). Indirect immunization involves transient repeated exposure to a lower dose of specific antibody, avoiding gross antibody excess, and allows immune stimulatory antigen processing in the tumor microenvironment and additional systemic sites. Induced cellular immunity targeting tumor antigen is believed to be the primary mechanism of indirect treatment effect.

### ***Summary of Clinical Trial Data***

#### *Overview*

OncoQuest completed a phase II clinical trial to evaluate the safety and efficacy of Oregovomab as a first-line therapy combined with SOC chemotherapy for treating primary advanced ovarian cancer in February 2019. The trial results have demonstrated that the simultaneous application of Oregovomab and chemotherapy enhances the effects of chemotherapy without additional toxicity.

#### *Trial Design*

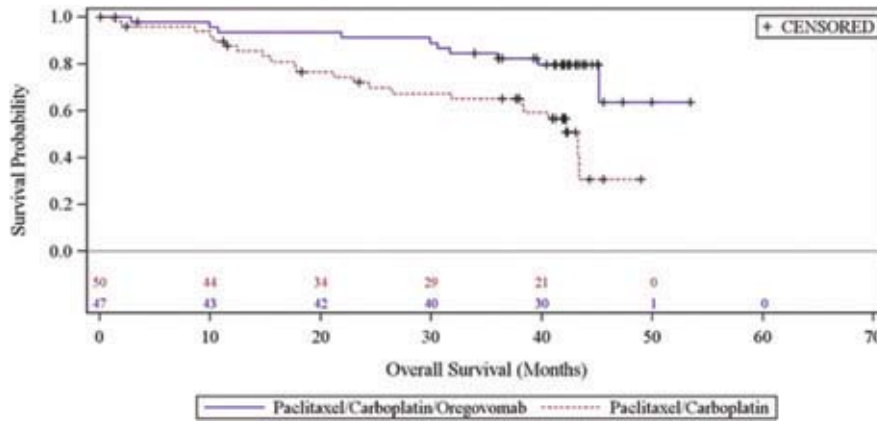
The trial was conducted at 13 centers in Italy and the US, and was a randomized controlled study to evaluate safety and efficacy of first-line chemoimmunotherapy (carboplatin-paclitaxel and Oregovomab) versus chemotherapy SOC (carboplatin and paclitaxel) in this patient population. A 36-month follow-up period was required after the treatment, and a total of 97 patients with newly diagnosed metastatic advanced stage ovarian cancer were enrolled in the study, with 95 patients available for safety assessment. 47 patients were treated with chemotherapy plus Oregovomab and 50 patients were treated with chemotherapy alone. The efficacy endpoints include PFS and OS. The safety endpoint is incidence rate of adverse events.

#### *Efficacy Data*

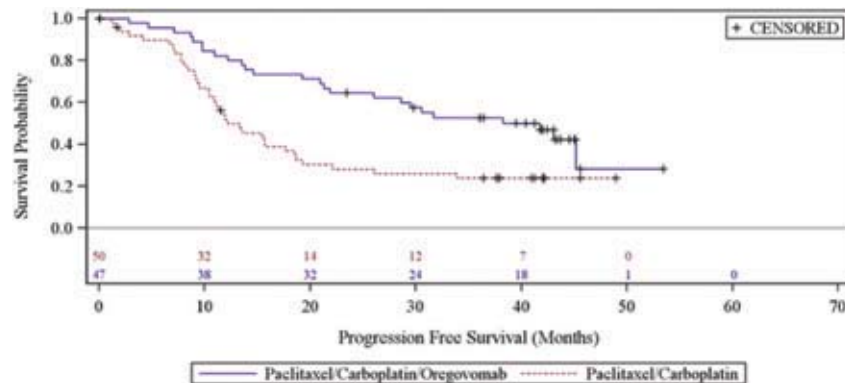
Subjects treated with chemoimmunotherapy had a clinically significant improved OS. There were ten mortality cases among patients treated with chemotherapy plus Oregovomab, lower than the 22 mortality cases among patients treated with chemotherapy alone,  $p=0.0043$ .

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The study included a cohort in which we demonstrated that adding Oregovomab to SOC resulted in increased patient numbers with amplified CA125-specific CD8+ T lymphocytes/ml peripheral blood counts, which might explain the improved therapeutic effect of combined treatment of chemotherapy plus Oregovomab over chemotherapy alone. The diagram below illustrates the Kaplan-Meier curve of OS by treatment group.



The clinical result of phase II shows that subjects treated with chemoimmunotherapy had a clinically significant improvement in PFS, with a median PFS of 41.8 months, compared to subjects treated with chemotherapy alone, with a median PFS of 12.2 months,  $p=0.0027$ . The diagram below illustrates the Kaplan-Meier curve of PFS by treatment group.



Source: Brewer et al., 2020 Front-line chemo-immunotherapy with carboplatin-paclitaxel using Oregovomab indirect immunization in advanced ovarian cancer: A randomized phase II study

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*Safety Data*

Safety analysis carried out in 95 patients showed no significant difference on the incidents of adverse events, related adverse events and serious adverse events between the two groups, as indicated in the table below:

	Patients treated with chemoimmunotherapy (N=46)	Patients treated with chemotherapy (N=49)
At least 1 Treatment Emergent Adverse Event (TEAE) . . . . .	38 (82.6%)	40 (81.6%)
At least 1 related TEAE . . . . .	8 (17.4%)	9 (18.4%)
At least 1 TEAE with grade $\geq 3$ . . . . .	10 (21.7%)	8 (16.3%)
At least 1 related TEAE with grade $\geq 3$ . . . . .	0 (0.0%)	0 (0.0%)
At least 1 serious TEAE . . . . .	24 (52.2%)	28 (57.1%)
At least 1 related serious TEAE . . . . .	2 (4.4%)	4 (8.2%)
At least 1 TEAE leading to study withdrawal . . . . .	3 (6.5%)	1 (2.0%)
At least 1 TEAE leading to death . . . . .	1 (2.2%)	1 (2.0%)

Source: Brewer et al., 2020 Front-line chemo-immunotherapy with carboplatin-paclitaxel using Oregovomab indirect immunization in advanced ovarian cancer: A randomized phase II study

*Clinical Development Plan*

Based on the clinical data of global phase II study, a global phase III pivotal trial will start in 2020. This is a phase 3 double-blind, placebo-controlled, multi-center study to compare the safety and efficacy of Oregovomab versus placebo, administered in combination with specific cycles of a standard six-cycle chemotherapy regimen (paclitaxel—carboplatin), for the treatment of subjects with newly diagnosed advanced ovarian cancer who have undergone optimal debulking surgery. The study is expected to enroll over 500 patients with newly diagnosed, advanced ovarian cancer globally. We plan to join the phase III trial under MRCT by initiating clinical trial in China.

OncoQuest is conducting three other trials evaluating the efficacy of Oregovomab in patients with recurrent ovarian cancer, including a phase II clinical trial that tests the combination of Oregovomab and an investigational stage immune booster Hiltonol, a phase Ib/IIa clinical trial that tests the combination of Oregovomab with a PD-1 checkpoint inhibitor nivolumab, and a phase II clinical trial that tests the combination treatment of Oregovomab with a PARP inhibitor niraparib.

**mAb-AR20.5**

mAb-AR20.5 is a first-in-class immunotherapeutic drug that is being developed by OncoQuest and OncoVent for pancreatic cancer. mAb-AR20.5 is an activated murine monoclonal antibody IgG1 binding with high affinity to the MUC1 antigen. OncoVent acquired the exclusive rights to develop and commercialize mAb-AR20.5 in Greater China in September 2016.

***Market opportunity and competition***

According to Frost & Sullivan, the incidence of pancreatic cancer in China grew from 91.9 thousand in 2014 to 104.9 thousand in 2018, representing a CAGR of 3.4%, which is expected to increase to 143.6 thousand by 2028 at a CAGR of 3.2%, and to 174.5 thousand by 2035 at a CAGR of 2.8%.

The conventional therapeutic options for pancreatic cancer include surgery, radiotherapy, chemotherapy and interventional therapy. Most of the patients taking certain first-line drugs, such as

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gemcitabine, have been found to develop drug resistance. The options of targeted therapy are also limited. Certain targeted therapies have been applied in combination with gemcitabine, nevertheless none of which has shown clinically significant improvement in efficacy. Recently, PARP inhibitor olaparib has been approved in the U.S. as a first-line maintenance treatment of germline BRCA-mutated metastatic pancreatic cancer. However, treatment using olaparib increased the PFS of the patients with BRCA mutation by 3.6 months, and no survival benefit was found in patients treated with olaparib. There has been limited success in the use of immunotherapy in treating pancreatic cancer. Single-agent anti-CTLA-4 ipilimumab was evaluated in a phase II study in patients with advanced pancreatic cancer in 27 patients and showed a delayed response in one patient only, indicating that single-agent ipilimumab was not an effective therapy in advanced pancreatic cancer. Moreover, in a phase I trial of anti-PD-L1 therapy, no patients with pancreatic cancer showed a clinical response. This creates huge unmet medical need for an immunotherapy with novel mechanism of action.

Studies have shown that MUC1 overexpression is associated with tumor progression, invasion and metastasis of pancreatic cancer, and its expression is closely related to the drug resistance. mAb-AR20.5 stimulates or re-activates tumor antigen MUC1-specific T cells, is expected to become a promising treatment method for pancreatic cancer.

As of the Latest Practicable Date, according to Frost & Sullivan, there was no approved or commercialized immunotherapy or anti-MUC1 antibody treatment for pancreatic cancer globally. As of the Latest Practicable Date, there were three anti-MUC1 antibody candidates under clinical development, as shown in the table below:

<b>Global Pipelines of Anti-MUC1 Antibody Treatment for Pancreatic Cancer<sup>1</sup></b>				
<b>Pipeline</b>	<b>Indication</b>	<b>Company</b>	<b>Status</b>	<b>Classification</b>
ETBX-061	Metastatic Pancreatic Cancer	Etubics Corporation	Phase II	New Drug
Anti-CD3-MUC1 Bispecific Antibody	Advanced Pancreatic Cancer	Benhealth Biopharmaceutical	Phase II	New Drug
AR20.5	Pancreatic Cancer	OncoQuest <sup>2</sup>	Phase I	New Drug

1. Preclinical pipelines are excluded.

2. OncoVent has the exclusive rights to develop and commercialize the drug candidate in Greater China. We directly hold 54.00% equity interest in OncoVent and are entitled to additional economic interest through our investee companies which hold 40.00% of its equity interest in total. We also holds 38.74% of equity interest in OncoQuest.

Source: Frost & Sullivan Report

Please refer to the section headed “Industry Overview—Innovative Drug Market—Pancreatic Cancer” for more industry related details.

### ***Mechanism of Action***

mAb-AR20.5 is an activated murine monoclonal antibody IgG1 binding with high affinity to the MUC1 antigen intended for treatment of pancreatic cancer and MUC1 expressing tumors. The MUC1 is aberrantly glycosylated and overexpressed in a variety of epithelial cancers, and plays a crucial role in progression of the disease. The extracellular domain of MUC1 can serve as a ligand for stromal and endothelial cell adhesion receptors, and the cytoplasmic domain engages in several interactions that can result in increased migration and invasion, as well as survival. mAb-AR20.5 binds with high affinity to MUC1, which shed off from tumor cell when patients receive radiotherapy or chemotherapy, recognizing the tandem repeat peptide sequence DTRPAP of MUC1 extracellular domain.



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The mechanism of action of mAb-AR20.5 includes the generation of MUC1-specific immune responses through complex formation of the murine antibody with MUC1 in circulation and/or on MUC1-expressing tumor cells. Dendritic cells that acquire antigenic substances through receptor-mediated endocytosis (FcR, C-type lectins, complement receptors) as compared with macropinocytosis show facilitated uptake and T-cell activation. A "neoantigen-like" immune complex form, taken up by such receptors, have been shown to induce CD4+ and CD8+ T-cell responses. Current evidence shows a stronger CD4+ and CD8+ T-cell induction with dendritic cells pulsed *ex vivo* with MUC1-antibody complexes compared with dendritic cells pulsed with MUC1 alone. Engagement of the activating Fc receptors (CD16, CD64) also induced dendritic cell maturation. The results suggest that effective immunotherapy may be generated in immune complex form. Intravenously administered low-dose antibodies mAb-AR20.5 can target circulating antigen MUC1 and form immune complex *in vivo* that are taken up by antigen-presenting cells and thereby promote a more effective presentation of the antigen to the immune system.

### ***Summary of Clinical Trial Data***

#### *Overview*

A phase I clinical trial was completed in 2004 to evaluate the safety and immunology of mAb-AR20.5 in patients with metastatic cancer at 1, 2 and 4-mg doses. The clinical results demonstrated the bioactivity of mAb-AR20.5 along with a favorable safety profile.

#### *Trial Design*

The phase I clinical trial enrolled 17 patients with MUC1-positive cancers, who received intravenous infusions of the antibody over 30 min on weeks 1, 3, 5, 9, 13 and 17 of treatment. Patients received either a 1-, 2- or 4-mg dose of mAb-AR20.5. The principal objectives of this study were to: (i) characterize the toxicities of mAb-AR20.5 administered as a 30-min intravenous infusion on weeks 1, 3, 5, 9, 13 and 17 in patients with advanced solid malignancies at 1-, 2- and 4-mg doses; (ii) determine the most immunogenic dose with acceptable toxicity and recommend a safe starting dose on this schedule for phase II studies; (iii) characterize the humoral and cellular immunological responses induced by mAb-AR20.5; and (iv) seek preliminary evidence of antitumor activity.

#### *Efficacy Data*

Overall, five of 15 evaluable patients developed human anti-mouse antibodies (HAMA), five developed anti-idiotypic antibodies and seven developed anti-MUC1 antibodies. Immune responses were most prominent in the 2-mg dose cohort for all parameters tested, and treatment-emergent MUC1-specific T-cell responses were detected in five of 10 evaluable patients treated with mAb-AR20.5. 2-mg dose cohort and 4-mg dose cohort generate MUC1 specific T cell response. There were no objective antitumour responses.

#### *Safety Data*

Clinical results show that mAb-AR20.5 was well tolerated at all of the dose levels tested did not induce hypersensitivity reactions, with minimal toxicity being observed during this study. None of the patients discontinued the study due to adverse events, and there was no dose-limiting toxicity. Five patients were reported as having infusion-related adverse events. The majority of reported events were classified as NCI CTC grade 1 or 2. Most adverse events appeared to be transient, non-clinically significant and resolved without medical intervention.

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### ***Summary of PreClinical Data***

A preclinical study was completed in 2016, which investigated the anti-tumor effect of mAb-AR20.5 in combination with anti-PD-L1 and Poly (I:C) in murine models of pancreatic adenocarcinoma using human MUC1 expressing transgenic (hMUC1.Tg) mice, which are immunologically tolerant to MUC1. The therapeutic combination of mAb-AR20.5+anti-PD-L1+Poly (I:C) induced rejection or significant inhibition of tumor growth for two different MUC1 expressing pancreatic tumor cell lines, which was accompanied by persistent MUC1 specific memory immune response, which could be adoptively transferred to other mice and shown to protect against subsequent tumor challenge.

Together, these data support the hypothesis that targeting checkpoint induced immunosuppression (anti-PD-L1) together with the use of toll-like receptor 3 agonist as an adjuvant (poly (I:C) ) enhances the capacity of mAb-AR20.5 to induce specific cell mediated immune responses to MUC1, which in turn provide long lasting anti-tumor response against pancreatic tumors. The study provides a proof of principle that an effective and long-lasting anti-tumor cellular immunity can be achieved in pancreatic tumor-bearing hosts against their own antigen (MUC1), which can be further potentiated using a vaccine adjuvant and an immune checkpoint inhibitor. The results support the rapid translation of this strategy into clinical trials for pancreatic cancer patients.

### ***Clinical Development Plan***

OncoVent is in the process of preparing for phase Ib/II clinical trial to assess the safety and efficacy of using combined treatment of mAb-AR20.5 and chemotherapy (FOLIRINOX) for pancreatic cancer.

### **AR – 301 (Salvecin)**

AR-301 is a first-in-class fully human monoclonal IgG1 antibody (mAb), being developed for the treatment of patients with severe ventilator-associated pneumonia (VAP) or hospital-acquired pneumonia (HAP) caused by *Staphylococcus aureus* (*S. aureus*). AR-301's mode of action is independent of the antibiotic resistance profile of *S. aureus* and it is active against infections caused by both methicillin-resistant staphylococcus aureus (MRSA) and methicillin-sensitive staphylococcus aureus (MSSA). AR-301 is being developed by Aridis in which we hold 9.86% equity interest. Shenzhen Arimab, a joint venture company formed by Aridis and us, in which hold 51% equity interest, acquired the exclusive development and commercial rights of AR-301 in Greater China in February 2018. We are entitled to additional economic interest in Shenzhen Arimab through our investee company which holds the remaining 49.00% of its equity interest. AR-301 has been granted Fast Track Designation by the FDA and Orphan Drug Designation by the EMA.

### ***Market opportunity and competition***

There is significant market potential for the treatment of VAP and HAP caused by *S. aureus* in China. According to Frost & Sullivan, the incidence of VAP and HAP caused by *S. aureus* in China increased from 326.3 thousand in 2014 to 411.1 thousand in 2018, representing a CAGR of 5.9%, which is expected to reach 571.8 thousand by 2028 at a CAGR of 3.4%, and 657.7 thousand by 2035 at a CAGR of 2.0%.

Anti-infection therapy of VAP and HAP includes initial empiric antibiotic therapy with monotherapy or combined antibiotic therapy, that evolves into pathogen-specific antibiotic therapy.

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MRSA is one of the most common drug-resistant pathogens in VAP and HAP. Glycopeptides and linezolid are two antibiotics commonly used for MRSA-specific infections, and development of further drug resistance is a major concern.

Anti-infective mAb is a new class of anti-infective drugs that has the potential to become the standard of care treatment for VAP and HAP due to its superior safety profile, a remarkably long plasma half-life period, and a low possibility of drug resistance. Anti-infective mAbs are typically used as an adjunctive treatment, and applied together with antibiotics, for VAP and HAP.

According to Frost & Sullivan, as of the Latest Practicable Date, there was no approved or commercialized mAb drug and three mAb drug candidates at clinical stage that are indicated to treat HAP or VAP caused by *S. aureus*. There was only one drug candidate with similar mechanism of action as AR-301, which neutralizes the pathogenic effects brought about by *S. aureus* toxins, as shown in the table below:

Global Pipelines of mAb Treatment for HAP and VAP Caused by <i>S. aureus</i>			
Pipeline	Target	Company	Status
AR-301(Salvecin)	<i>S. aureus</i> $\alpha$ Toxin	Aridis Pharmaceuticals <sup>2</sup>	Phase III
MEDI-4893	<i>S. aureus</i> $\alpha$ Toxin	MedImmune LLC	Phase II
514G3	<i>S. aureus</i> Surface protein (SpA)	XBiotech	Phase II&I
DSTA4637	<i>S. aureus</i> Polysaccharide (teichoic acid)	Genentech	Phase I

1. Preclinical pipelines are excluded.

2. Shenzhen Arimab has the exclusive rights to develop and commercialize the drug candidate in Greater China. We directly hold 51.00% equity interest in Shenzhen Arimab and are entitled to additional economic interest through our investee company which holds the remaining 49.00% of its equity interest. We also holds 9.86% of equity interest in Aridis.

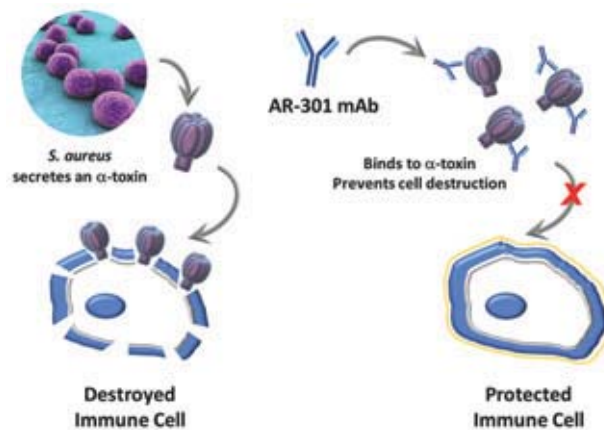
Source: Frost & Sullivan Report

Please refer to the sub-section headed “Industry Overview—Innovative Drug Market—VAP and HAP Caused by *Staphylococcus Aureus*” for more details.

### ***Mechanism of Action***

AR-301 specifically targets *S. aureus* alpha-toxin, an important virulence factor that is secreted by both MRSA and MSSA. AR-301 binds to alphatoxin with high affinity and prevents its assembly into an active complex, which prevents alphatoxin-mediated breakdown of cell membranes, or cell lysis of erythrocytes, human lung cells and immune cells such as lymphocytes. This prevention of killing of host cells, in turn, may protect the patient from further progression of pneumonia disease and systemic spread of infections caused by *S. aureus*. During infection and active proliferation, *S. aureus* is metabolically more virulent, geared toward higher toxin production than during a more sessile colonization stage. In contrast to other programs targeting *S. aureus* colonization, AR-301 targets the active, disease enhancing infection stage. We believe that this mechanism of action complements the bacterial killing properties of multiple conventional antibiotics, essentially neutralizing the bacterial toxins left behind following antibiotic-mediated killing. Additional indications for AR-301 may include other *S. aureus* infections, particularly surgical site infections, blood stream infections (bacteremia and/or endocarditis), septic arthritis and osteomyelitis, skin and soft tissue infections and non-healing wounds such as diabetic ulcers.

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Source: prospectus of Aridis dated August 13, 2018

### Summary of Clinical Trial Data

#### Overview

A double-blind, placebo-controlled, active comparator, ascending dose phase I/II clinical trial of AR-301 was completed in September 2016 to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and explore efficacy of a single intravenous administration of AR-301 plus SOC antibiotics in patients with severe VAP caused by *S. aureus*. The phase I/II clinical results showed that patients treated with AR-301 spent less time on mechanical ventilation and there was a trend toward higher and faster eradication rates of *S. aureus* compared with the placebo group treated with SOC antibiotics alone.

#### Trial Design

The phase I/II clinical trial included 13 sites located across Belgium, France, Spain, the United Kingdom, and the U.S. and was designed primarily to address the safety and pharmacokinetics of AR-301. 48 patients were enrolled in the study. Six patients enrolled in the first cohort (1 mg/kg AR-301 plus SOC), eight in the second cohort (3 mg/kg AR-301 plus SOC), ten in the third cohort (10 mg/kg AR-301 plus SOC) and eight in the fourth cohort (20 mg/kg AR-301 plus SOC). An additional 16 patients received placebo plus SOC as a blind control.

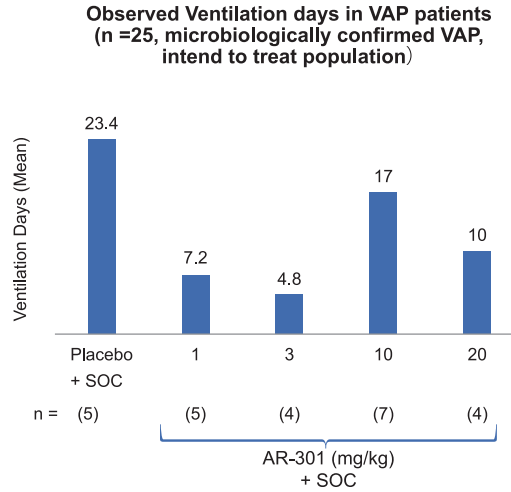
#### Efficacy Data

Multiple efficacy endpoints of clinical improvement were evaluated, including time to extubation, ventilation time and microbiological outcomes. In exploratory analysis of the VAP subgroup of 25 patients, numeric clinical improvement of antibody treated patients over placebo were observed in time to extubation. The clinical results suggest that the addition of AR-301 to SOC treatment may increase the rate of microbiological eradication, and may reduce time to eradication, time on mechanical ventilation and overall duration of hospital stay.

Time intubated to day 28 showed a decrease in the length of time patients who were treated with AR-301 plus SOC remained intubated as compared to those receiving placebo and SOC. When the subset of 25 patients with VAP was assessed, ventilation time was reduced numerically for patients in all four active dose groups receiving AR-301 plus SOC compared to those receiving placebo plus SOC. The lack of dose response could be attributed to high variability associated with a small sample

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size, and/or to the high level of circulating AR-301 mAb as compared to alphatoxin load in infected patients, as even at the lowest dose administered (i.e. one mg/kg), it is estimated that there is more than ten-fold mAbs than the predicted alphatoxin load.



Source: Francois et al., 2018 Safety and tolerability of a single administration of AR-301, a human monoclonal antibody, in ICU patients with severe pneumonia caused by *Staphylococcus aureus*: first-in-human trial

With respect to the microbiological outcomes in the overall study population, eradication or presumed eradication (cured of pneumonia) was observed in 25 (80.6%) of 31 patients treated with AR-301 plus SOC and ten (62.5%) of 16 subjects treated with placebo plus SOC. The mean time to eradication of *S. aureus* bacteria (Day to eradicate) also trended shorter in AR-301 treated cohorts as compared to the placebo cohort.

Details of microbiological outcome by treatment cohort are illustrated below.

	Placebo (Placebo + SOC) n = 16	Cohort 1 (AR301 1 mg/kg + SOC) n = 6	Cohort 2 (AR301 3 mg/kg + SOC) n = 8	Cohort 3 (AR301 10 mg/kg + SOC) n = 9	Cohort 4 (AR301 20 mg/kg + SOC) n = 8	All treated n = 31
Eradicated . . . . .	7 (43.8%)	1 (16.7%)	5 (62.5%)	4 (44.4%)	4 (50.0%)	14 (45.2%)
Day to eradicate . . . . .	10.9±4.4	8.0	9.4±3.1	9.8±3.5	8.8±1.0	9.2±2.5
Presumed eradicated . . . . .	3 (18.8%)	4 (66.7%)	2 (25.0%)	3 (33.3%)	2 (25.0%)	11 (35.5%)
Eradicated or presumed eradicated . . .	62.5%	83.3%	87.5%	77.8%	75.0%	80.6%

Source: Francois et al., 2018 Safety and tolerability of a single administration of AR-301, a human monoclonal antibody, in ICU patients with severe pneumonia caused by *Staphylococcus aureus*: first-in-human trial

When clinical cure was assessed based on the sole judgment of the investigator, there was no statistically significant difference between the groups, and the overall cure rate was high compared to historic published references. Over the first 28 days of the study, the length of stay in the ICU and in the hospital both showed a modest decrease in the AR-301 plus SOC groups as compared to placebo plus SOC-treated subjects, however, this difference did not reach statistical significance.

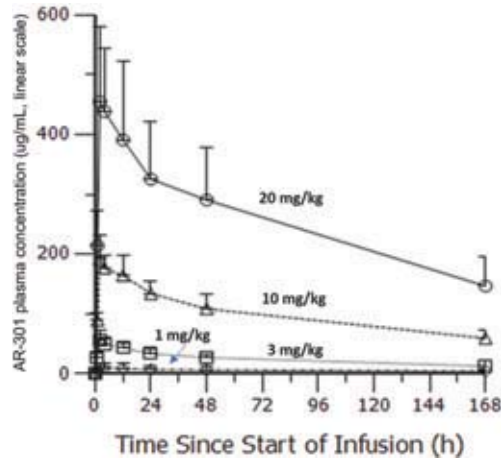
*Safety Data*

Data from the phase I/II clinical trial suggests that AR-301 was well tolerated as adjunctive treatment for severe pneumonia caused by *S. aureus* when used as directed and in addition to antibiotics. Few AEs, with an incidence rate of 2.3% were considered treatment-related by the



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investigators. None of the SAEs were deemed related to AR-301 treatment. Immunogenicity was observed in one subject, with no related adverse event. No significant difference in mortality was observed between groups. There were six deaths in the trial, none of which were deemed related to AR-301. The pharmacokinetic, or PK, profile of AR-301 is consistent with that of a human IgG1mAb, with a plasma half-life of 23 to 31 days, and supports a single-dose administration for the pneumonia indication, as illustrated in the diagram below.



Source: Francois et al., 2018 Safety and tolerability of a single administration of AR-301, a human monoclonal antibody, in ICU patients with severe pneumonia caused by *Staphylococcus aureus*: first-in-human trial

### Clinical Development Plan

A global phase III randomized, double-blind, placebo-controlled clinical trial is currently ongoing, which compares the treatment with active comparator AR-301 (20 mg/kg) plus SOC to treatment with placebo plus SOC. The trial started in May 2019 and targets to enroll approximately 240 patients in over 15 countries. We received the NMPA approval for the phase III clinical trial in China as part of the global MRCT of AR-301 in July 2019. We have engaged an international CRO, for the trial and we plan to initiate patient enrollment by the end of 2020.

### AR—101 (Aerumab)

AR-101 is a first-in class human IgM monoclonal antibody targeting lipopolysaccharide (LPS) on the surface of *P. aeruginosa* serotype O11, being developed by Aridis for treatment of patients with severe VAP or HAP caused by *Pseudomonas aeruginosa* (*P. aeruginosa*). Shenzhen Arimab acquired the exclusive rights to develop and commercialize AR-101 in Greater China in February 2018. It has been granted an Orphan Drug Designation from the FDA and EMA.

### Market opportunity and competition

There is significant market potential for the treatment of HAP and VAP caused by *P. aeruginosa* in China. According to Frost & Sullivan, the incidence of HAP and VAP caused by *P. aeruginosa* in China grew from 446.3 thousand in 2014 to 558.2 thousand in 2018, representing a CAGR of 5.8%, which is expected to increase to 823.2 thousand by 2028 at a CAGR of 4.0%, and to 948.3 thousand by 2035 at a CAGR of 2.0%.

*P. aeruginosa* is a common pathogenic bacteria of HAP and VAP, which can be treated by specific antibiotics such as cephalosporin, carbapenem,  $\beta$ -lactamase inhibitors, aminoglycosides and

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polymyxin. However, anti-microbial resistance in major pathogens of HAP and VAP, such as *P. aeruginosa*, may ultimately result in treatment failure. Anti-infective mAb is a new class of anti-infective drugs that may become the standard of care treatment for HAP and VAP caused by *P. aeruginosa* due to its superior safety profile and a lower possibility of drug resistance. Anti-infective mAbs are typically used as an adjunctive treatment, and applied together with antibiotics, for VAP and HAP.

According to Frost & Sullivan, as of the Latest Practicable Date, there was no approved or commercialized mAb drug and one mAb drug candidate for treating HAP or VAP caused by *P. aureus* at clinical stage. There was no drug candidate with similar mechanism of action as AR101, which is effective against multidrug resistant LPS serotype O11 *P. aureus* clinical isolates.

Global Pipelines of mAb Treatment for HAP and VAP Caused by *P. aeruginosa*

Pipeline	Target	Company	Status
AR-101 (Aerumab)	Pseudomonas aeruginosa lipopolysaccharide(serotype O11)	Aridis Pharmaceuticals <sup>2</sup>	Phase I/II
MEDI3902	Polysaccharide (Psl)	MedImmune LLC	Phase II

1. Preclinical pipelines are excluded.

2. Shenzhen Arimab has the exclusive rights to develop and commercialize the drug candidate in Greater China. We directly hold 51.00% equity interest in Shenzhen Arimab and are entitled to additional economic interest through our investee company which holds the remaining 49.00% of its equity interest. We also holds 9.86% of equity interest in Aridis.

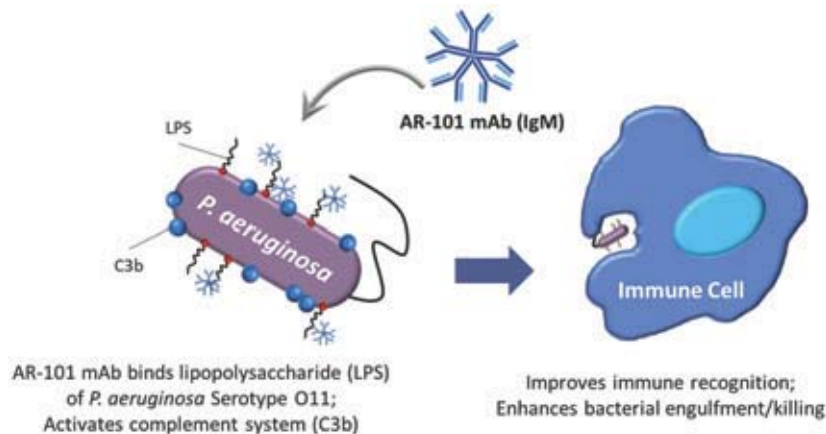
Source: Frost & Sullivan Report

Please refer to the sub-section headed “Industry Overview—Innovative Drug Market—HAP and VAP Caused by *Pseudomonas aeruginosa*” for more details.

### ***Mechanism of Action***

AR-101 targets against *P. aeruginosa* lipopolysaccharide serotype O11. Binding of AR-101 to *P. aeruginosa* pneumonia bacteria facilitates human complement binding and improves immune recognition and destruction by circulating human phagocytes. AR-101’s mechanism of action is distinct from mechanisms of antibiotic resistance, and is effective against multidrug resistant LPS serotype O11 *P. aeruginosa* clinical isolates. Upon binding, AR-101 mediates the deposition of the human complement to the surface of *P. aeruginosa* bacteria. This antibody-complement complex leads to improved recognition by the host immune cells, which results in engulfment and killing of the bacteria. AR-101, like IgM antibodies in general, provides several advantages towards more effective bacterial killing. They possess ten binding sites rather than two for IgG, and they are 100 to 1,000 times more effective than IgG at binding and/or activating key enzymes that facilitate the killing of *P. aeruginosa*. As a result, IgM antibodies are becoming more prevalent as candidates for drug therapies.

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Source: Aridis Prospectus dated August 13, 2018

### Summary of Preclinical Data

AR-101 reacts with a wide range of *P. aeruginosa* serotype O11 clinical isolates from different hospitals, indicating broad application against infections with this serotype. AR-101 is also capable of stimulating phagocytic immune cells to ingest *P. aeruginosa* bacterial cells in a dose dependent manner, thereby killing the pathogen. Passive immunization with murine mAb recognizing O-polysaccharides in LPS of *P. aeruginosa* conferred protection against lethal challenge with live pseudomonas bacteria in several animal models of pneumonia infections. In preclinical studies, AR-101 was found to demonstrate attenuating protection against pulmonary infections caused by *P. aeruginosa* serotype O11 and exhibited a complementary effect with meropenem, a broadspectrum antibiotic.

Additionally, the following observations were found in preclinical studies of AR-101. AR-101 protected mice in a dose-dependent manner from *P. aeruginosa* infection after a burn-wound challenge. Doses of five mg/mouse (corresponding to about 0.2 mg/kg body weight) conferred 70% to 100% protection from systemic *P. aeruginosa* challenge. Administration of decreasing doses resulted in lower survival rates and administration of AR-101 led to rapid clearance of *P. aeruginosa* from the lung in mice and was associated with milder lung pathology six and 24 hours after infection. In addition, AR-101-treated animals had a significantly lower systemic *P. aeruginosa* bacterial load compared to control animals that received saline. To mimic the adjunctive use of AR-101 in humans, AR-101 was administered in combination with meropenem (used clinically to treat pseudomonal infections) in a modified lung challenge model. When meropenem and AR-101 were administered in combination, significant reductions in lung weight (a surrogate marker for injection-induced inflammation), bacterial load and lung inflammation were observed in infected mice compared to each agent given alone.

### Summary of Clinical Trial Data

#### Overview

Two clinical studies of AR-101 were completed, including a phase I safety and tolerability trial of single ascending doses of AR-101 in healthy adults and an open-label phase IIa safety and pharmacokinetics trial of up to three single doses of AR-101 in pneumonia patients. These studies suggested AR-101 to be generally well tolerated in both healthy adults and HAP and VAP patients.

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Also, a contemporaneous control cohort suggested that AR-101 therapy may improve survival, cure rate of the index pneumonia, and time to cure pneumonia.

*Trial Design*

Phase I study was a randomised, double-blind, placebo-controlled study in healthy volunteers to assess the safety and pharmacokinetic characteristics of AR-101. The study enrolled 32 volunteers in four antibody treatment cohorts at doses of 0.1, 0.4, 1.2 and 4.0 mg/kg as well as placebo cohort.

The open-label phase IIa study was the first study performed in the target indication of patients with severe bacterial pneumonia caused by *P. aeruginosa* serotype O11. Patients treated with AR-101 (n=17), including 13 patients receiving the full treatment (three doses of 1.2 mg/kg), were compared to 14 patients who did not receive the antibody. Overall, the 17 patients receiving AR-101 were more ill.

*Phase I Clinical Data*

No SAEs were observed, and no subject was discontinued due to an AE. Reported AEs were mild or moderate in intensity, and all resolved without sequelae, and the incidence of AEs did not increase with the dose. There was no activation of an immune response against AR-101. Pharmacokinetic characteristics that were observed were consistent with the characteristics of a human IgM, with a serum half-life between 70 and 95 hours.

*Phase IIa Clinical Data*

Adjunctive therapy AR-101 resulted in an improved clinical outcome in the group receiving the full three-course AR-101 treatment, with a resolution rate of 85% (11/13) versus 64% (9/14) (p=0.048). The data showed a statistically significantly shorter time to clinical resolution in this group of patients (8.0 versus 18.5 days in those who did not receive the antibody; p=0.004), and more disease-free days (22 versus 12.5 days in those who did not receive the antibody (p=0.028)). Adjunctive therapy AR-101 may improve clinical outcome in a shorter time if patients receive the full treatment (three doses). The mortality rates were not statistically significant between groups.

These preliminary results suggest that AR-101 targeting LPS may be a complementary strategy for the treatment of *P. aeruginosa* pneumonia.

	All patients (n=31)	Not treated with AR-101 (n=14)	AR-101 “intent-to-treat”, ≥1 dose (n=17)	AR-101 “per-protocol”, three doses (n=13)	p-Values: not treated vs. ≥1 dose, not treated vs. three doses
Time (days) to clinical resolution of pneumonia, median (IQR) . . . . .	12.0 (8.0-30)	18.5 (8.0-30)	10.0 (7.0-23)	8.0 (7.0-12)	NS, 0.004
Clinical resolution of pneumonia, n (%) . . . . .	20 (65%)	9 (64%)	11 (65%)	11 (85%)	NS, 0.048
Disease-free days . . . . .	18 (0-22)	12.5 (0-22)	20 (7.5-23)	22 (18.5-23)	NS, 0.028
Relapse within 30 days, n (%) . .	4 (13%)	1 (7%)	3 (18%)	2 (15%)	NS, NS
Survival at day 30, n (%) . . . . .	25 (81%)	11 (79%)	14 (83%)	13 (100%)	NS, NS

IQR interquartile range

Source: Y.-A. Que et al., 2014 Assessment of AR-101 as adjunctive immunotherapy for the treatment of nosocomial *Pseudomonas aeruginosa* pneumonia

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### *Clinical Development Plan*

Aridis plans to announce the clinical development plan of AR-101 in the second half of 2020.

### **RVX—208 (Apabetalone)**

RVX-208 is an investigational first in class oral BET inhibitor that preferentially targets bromodomain 2 (BD2) of BET proteins, indicated for treating type 2 diabetes patients with coronary heart disease (CHD) and patients with chronic kidney disease (CKD). We obtained the exclusive development and commercial rights in Greater China from Resverlogix in July 2015, in which we held 38.60% equity interest as of the Latest Practicable Date.

### ***Market opportunity and competition***

There is significant market potential for the treatment of type 2 diabetes with CHD and CKD in China. According to Frost & Sullivan, the diagnosed patients of type 2 diabetes with CHD in China grew from 5.1 million in 2014 to 6.1 million in 2018, representing a CAGR of 4.6%, and is expected to increase to 10.8 million by 2028 at a CAGR of 5.9%, and to 12.5 million by 2035 at a CAGR of 2.1%. The diagnosed diabetic patients of CKD in China increased from 10.6 million in 2014 to 12.7 million in 2018, representing a CAGR of 4.6%, which is expected to reach 23.4 million by 2028 at a CAGR of 6.3%, and 28.3 million by 2035 at a CAGR of 2.8%.

Although treatment of cardiovascular disease (CVD) includes many therapeutic agents, for example lipid lowering drugs such as statins, heart rate lowering agents such as beta blockers and blood pressure lowering drugs such as ACE inhibitors, there still remains a large residual risk of MACE in patients that receive these treatments. Glucose-lowering agent is currently the major treatment option for preventing major adverse cardiac events in patients with type 2 diabetes mellitus and recent acute coronary syndrome, primarily including metformin, GLP-1 receptor agonist, SGLT2 inhibitors, thiazolidinedione and alpha-glucosidase inhibitors. Metformin decreases blood glucose level by decreasing hepatic glucose production and intestinal absorption of the glucose, and increasing insulin sensitivity by enhancing the uptake and utilization of peripheral glucose. Glucagon-like peptide 1 receptor is a G-protein coupled receptor that catalyzes the conversion of ATP to cAMP upon activation, and as a result, prevents cytosolic cAMP in  $\beta$ -pancreatic cells from leading to insulin secretion. SGLT2 inhibitors function through a novel mechanism blood glucose without stimulating insulin release, by reducing renal tubular glucose reabsorption. Thiazolidinedione can bind PPAR- $\gamma$ , decrease insulin resistance and increase glucose utilization. Alpha-glucosidase inhibitors act as competitive inhibitors of enzymes that are necessary for the digestion of carbohydrates.

RVX-208 has illustrated potential to become an important and differentiated therapeutic for this high-risk population. All BET proteins contain highly-conserved bromodomains that play a key role in epigenetic control of gene expression in many cell types, and RVX-208 functions via inhibition of BET bromodomain binding to chromatin, thereby modulating transcription of particular targets. Moreover, RVX-208 preferentially binds to the second bromodomain of BET family members, including BRD2, BRD3 and BRD4, with a 20-fold or higher selectivity for the second bromodomain versus the first bromodomain. Also, RVX-208 has effects on multiple pathways and biomarkers that function in concert to reduce CVD events, which is highly differentiated from other therapies that focus only on single biological targets, such as increasing HDL or decreasing low-density lipoprotein in plasma.

According to Frost & Sullivan, as of the Latest Practicable Date, RVX-208 was the only selective BET inhibitor in the field of high risk CVD and CKD with no known competitor. Please refer



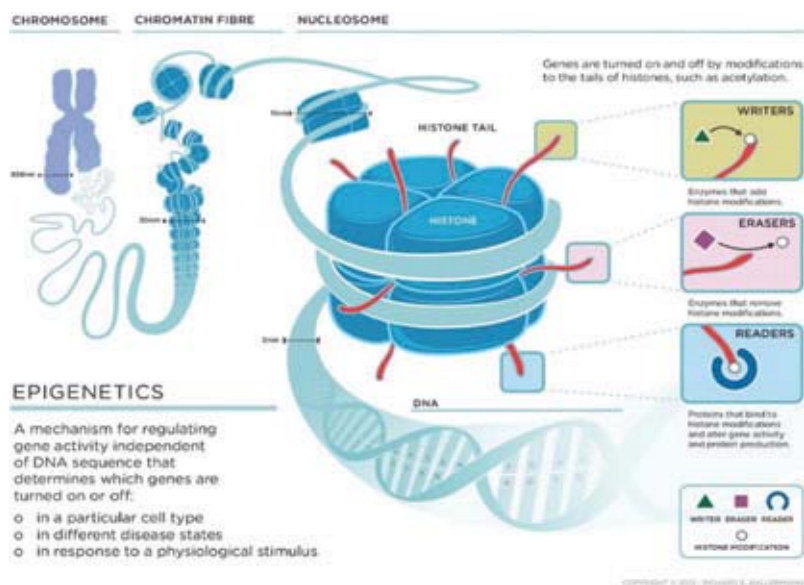
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to the sub-sections headed “Industry Overview—Innovative Drug Market—Type 2 Diabetes with CHD” and “Industry Overview—Innovative Drug Market—Chronic Kidney Disease” for more details.

### *Mechanism of Action*

RVX-208 is the first BET inhibitor in clinical trials for high risk vascular disease. Bromodomains (“BRDs”) are a family of evolutionary conserved protein-interaction modules that play key functions in chromatin organisation and regulation of gene transcription. One recognised family of bromodomain-containing proteins is the BET family. RVX-208’s “Epigenetic Mechanism of Action” illustrates that it functions as an inhibitor of the BET proteins. RVX-208 is the first oral agent in the BET inhibitor class that preferentially targets bromodomain 2 (“BD2”) of BET proteins. In binding to this bromodomain, RVX-208 affects the expression of multiple genes with roles in a variety of cellular processes.

The human body is made up of nearly two hundred different cell types that have cell-specific functions resulting from the selective production of the proteins encoded by human DNA and, more specifically, human genes. Aberrant levels of proteins can contribute to disease progression and disease states. Epigenetics describes the mechanisms by which gene activity is regulated, thereby affecting levels of transcription into messenger RNA (“mRNA”) which is then translated into protein. Epigenetics is the study of modifications to chromatin (DNA associated with proteins) that, without affecting the DNA sequence, result in regulation of gene transcription, the first step in producing the proteins that each gene encodes. Such modifications determine whether a gene is “on” or “off” or whether its activity is high or low in a particular cell type, in different disease states or in response to a physiological stimulus. Chromatin modifications are added by enzymes called “writers” and removed by enzymes called “erasers”. Other proteins, called “readers”, recognize a specific pattern of modifications. In contrast to “writers” and “erasers” that add or remove post-translational modifications, “readers” detect the presence or absence of these modifications and serve as a scaffold for the transcriptional machinery directly responsible for gene expression. BET proteins are “readers”, proteins that recognize a specific pattern of modifications and bind to the chromatin at these sites. The BET proteins then serve as a scaffold, recruiting the necessary transcriptional machinery to the chromatin to drive gene expression and ultimately protein production.



Source: <https://www.resverlogix.com/science-and-programs/epigenetics>

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RVX-208 targets BET proteins to impact several important biological processes that are contributors to the pathophysiology of chronic vascular diseases such as CHD. These pathways include vascular inflammation, vascular calcification, complement and coagulation, reverse cholesterol transport and metabolism.

**Summary of Clinical Trial Data**

*Overview*

A phase III clinical trial was completed in the fourth quarter of 2019 to assess the safety and efficacy in treating type 2 diabetes patients with coronary heart disease. Though the primary endpoint was narrowly missed, as a result of the lower than anticipated placebo event rate due to the application of new drugs, the consistent positive trend in the efficacy data suggests that RVX-208 can further decrease MACE risk on top of best available SOC.

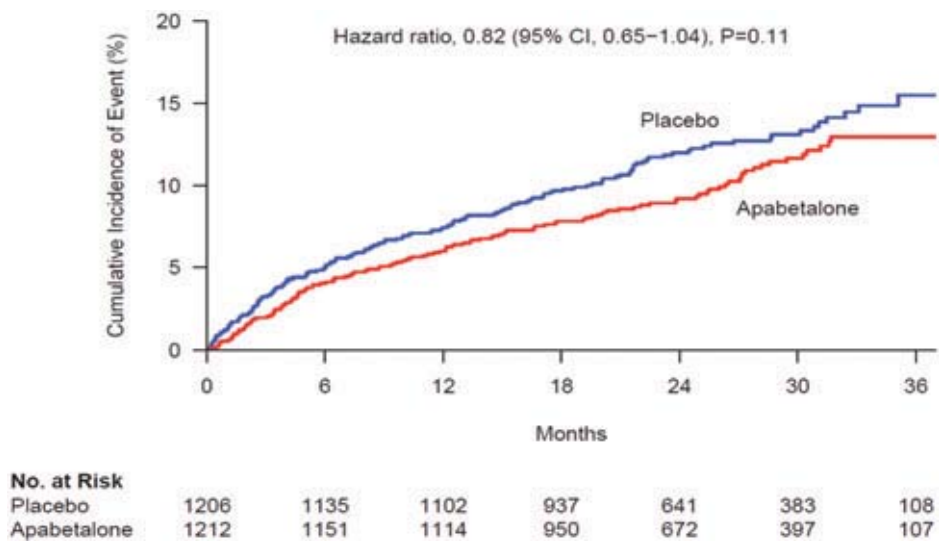
*Trial Design*

The clinical trial enrolled in total 2,425 patients with diabetes and low HDL cholesterol (< 40 mg/dL for men and < 45 mg/dL for women) who had an ACS event within 7-90 days of screening. The trial was approved in 14 countries and was conducted in 220 sites. Patients were randomized to receive standard of care plus 100 mg of RVX-208 twice daily (n = 1,212) or placebo (n = 1,206) until 250 adjudicated primary endpoint events of cardiovascular death or non-fatal myocardial infraction or stroke occurred, which were defined as triple MACE. The primary endpoint was the time to first occurrence of adjudication-confirmed triple MACE.

*Efficacy Data*

The trial results show a narrow miss on the primary endpoint, with an 18% hazard reduction among patients treated with SOC plus RVX-208 compared with patients who received placebo, (p = 0.11).

Kaplan-Meier Estimates of Time to First Occurrence of the Primary Efficacy Endpoint (cardiovascular death or non-fatal myocardial infraction or stroke)

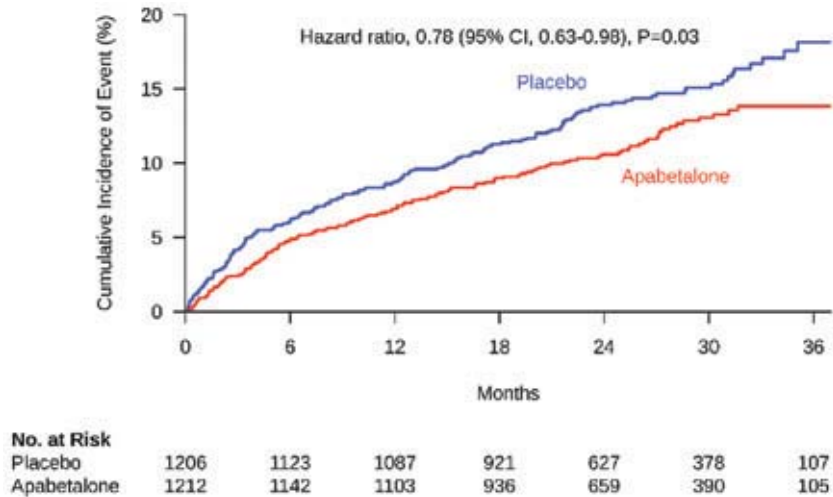


Source: RVX-208 summary report

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Post ACS diabetes patients have a high incidence rate of congestive heart failure (CHF) possibly because lack of collateral vessels and a stunned myocardium. In BETonMACE 77 patients had CHF hospitalization as a first event. When CHF was added to the primary endpoint posthoc as the fourth MACE, a nominally significant reduction of 22% was seen, ( $p = 0.03$ ) as illustrated in the figure below.

Kaplan-Meier Estimates of Time to First Occurrence of the cardiovascular death, non-fatal myocardial infarction, stroke or first hospitalization for congestive heart failure



Source: RVX-208 summary report

Also, RVX-208 improved CVD outcomes in the subgroup of patients with renal impairment, with baseline estimated glomerular filtration (eGFR) below 60mL/min. Especially, there is a 50% hazard reduction in narrowly defined MACE, among patients treated with RVX-208 plus SOC, compared with patients who receive placebo, ( $p = 0.03$ ).

*Safety Data*

RVX-208 was generally well tolerated with an overall incidence of AEs and SAEs similar to that of the placebo group.

*Clinical Development Plan*

The FDA granted Breakthrough Therapy Designation in February 2020 for RVX-208 in combination with top standard of care, including high-intensity statins, for the secondary prevention of major adverse cardiac events in patients with type 2 diabetes mellitus and recent acute coronary syndrome. According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of new drugs to address unmet medical need in the treatment of serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

**H1710**

H1710 is a heparin-like compound that inhibits heparanase activity. The drug candidate is currently at preclinical stage. We are preparing for the IND filing for H1710 in both China and the

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U.S., and we aim to submit the IND application as a biologic drug candidate for oncology with the NMPA and the FDA by the end of 2020.

### *Market Opportunity and Competition*

Heparanase is a heparin sulfate specific endo-β-D glucuronidase. Expression of heparanase is observed in almost all types of cancer examined, including various carcinomas, sarcomas and hematological malignancies and tightly correlates with increased tumor size, angiogenesis, metastasis and poor prognosis.

SST0001 (roneparstat) is one heparanase inhibitor currently under clinical study. Roneparstat is a modified heparin composed of 100% N-acetylated and 25% glycol split. Compared to unmodified heparin, roneparstat is able to inhibit the heparanase enzymatic activity with a decreased ability to release extracellular matrix-bound FGF-2. Roneparstat was well tolerated and safe at all the dose levels tested. Patients are able to consume the drug at the dose levels of 200 and 400 mg/day without showing clinically relevant toxicities. Currently, there is no marketed drugs targeting heparanase. Please refer to the sub-sections headed “Industry Overview—Innovative Drug Market—Heparanase Inhibitors” for more details.

Since heparanase acts on the HS chain of the extracellular matrix (ECM), it plays an important role in tumor metastasis, growth, and regulation of the tumor microenvironment. Different from cytotoxicity or targeting therapeutics, heparanase inhibitors are expected to have a comprehensive inhibitory effect on the growth and metastasis of tumors, and can be combined with cytotoxic drugs, targeting therapeutics or immunotherapy to have a synergistic effect.

As of the Latest Practicable Date, there was no approved or commercialized heparanase inhibitor worldwide, and there were two clinical-stage drug candidates targeting heparanase globally as shown in the table below:

Global Pipelines Targeting Heparanase <sup>1</sup>			
Pipeline	Indication	Company	Status
SST0001	Multiple Myeloma	Sigma Tau	Phase I
PG545	Advanced Solid Tumours	Zucero	Phase I

1. Pre-clinical pipelines are excluded.

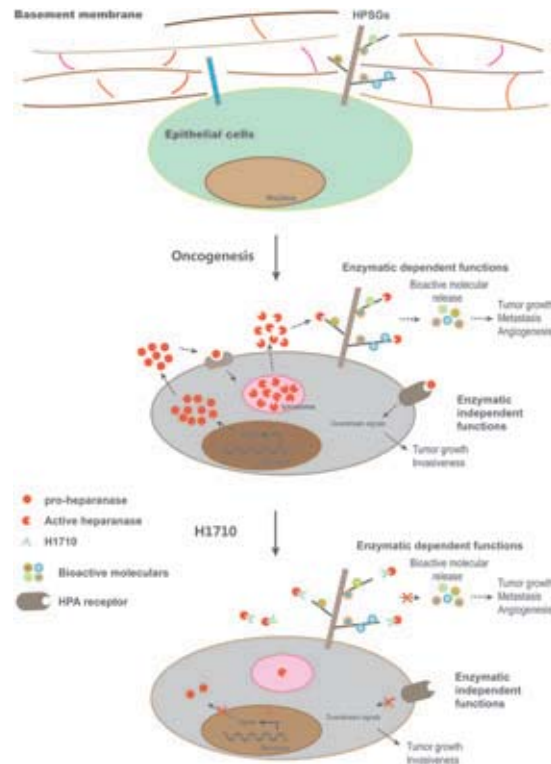
Source: Frost & Sullivan Report

### *Mechanism of Action*

Heparanase is a versatile protein endowed with enzymatic activity dependent and independent functions to play crucial roles in multiple human pathological processes, among them the most attention rendered in tumor biology. Heparanase is the sole endoglycosidase responsible for degrading heparan sulfate (HS) chains in the extracellular matrix (ECM), which function in tumorigenesis via various mechanisms, including promoting the self-assembly, insolubility and structural integrity of ECM, trapping a wide variety of bioactive molecular (i.e., cytokines, chemokines, growth factors, enzymes, protease inhibitors and ECM components) by its abundant negative charge groups. Release of these bioactive molecular by heparanase-mediated HS cleavage will undoubtedly make up a repertoire of fuels for tumor development. Enzymatically inactive heparanase is also recognized as a

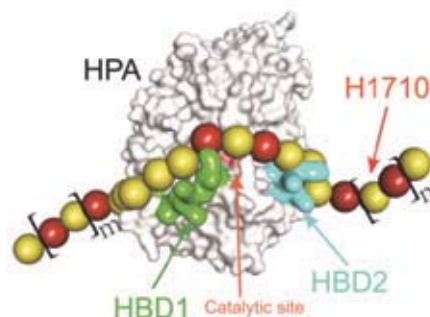
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ligand to interact with an unknown receptor to activate various downstream signal pathways and in turn support tumor growth, invasiveness and chemoresistance, as illustrated in the diagram below.



In addition, numerous mouse model and clinical association studies have consistently demonstrated that enhanced expression of heparanase is observed in almost all types of cancer examined, including various carcinomas, sarcomas and hematological malignancies, and tightly correlates with increased tumor size, angiogenesis, metastasis and poor prognosis.

H1710 is a potent inhibitor of heparanase. It has suitable chain length to bind the two separate heparin-binding domains (HBDs) of heparanase. Its unique flexible chain can dive into the catalytic pocket and keep it from being degraded. In this way, H1710 decreases the pocket's accessibility and degrading ability to the natural substrate HS. The diagram below illustrates the postulated inhibitory mechanisms of H1710 on heparanase.



The unique structure and character of H1710 enable it to efficiently inhibit the activity of heparanase, reduce heparanase expression both *in vitro* in tumor cells and *in vivo* in tumors using pancreatic, lung and breast cancer models, and further demonstrate additive and/or synergistic effect with several cancer drugs including docetaxel, cisplatin and gemcitabine both *in vitro* and *in vivo*.

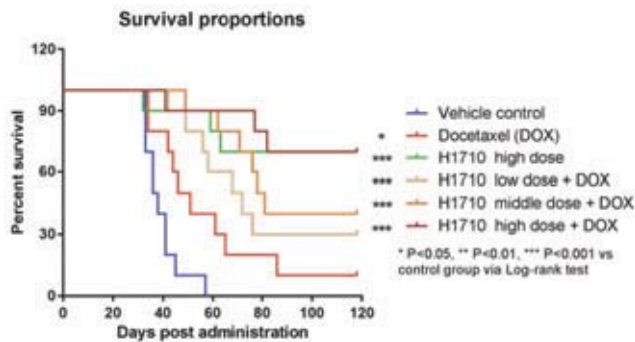


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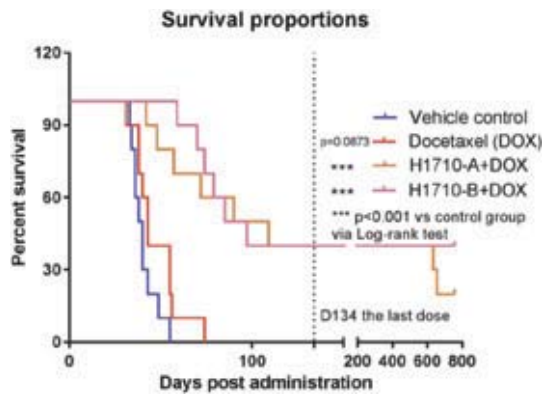
**Summary of PreClinical Data**

In the *in vitro* screening experiment, the inhibitory IC50 value of H1710 on HPA activity was at the nM level, and it was one of the compounds with the best inhibitory activity currently found. A series of tests *in vitro*, including cell scratching, migration and cell growth, have also confirmed that H1710 is effective in inhibiting tumor cell metastasis and growth.

In a preclinical trial, we established a metastasis model by inoculating breast cancer cells 4T1 into mouse mammary fat pad and implementing mastectomy later, to test the efficacy of H1710 in inhibiting tumor metastasis. We found that the application of H1710 alone or application of H1710 combined with docetaxel (DOX) can significantly prolong the survival time of the treated mice ( $p < 0.001$ ), as illustrated in the chart below.

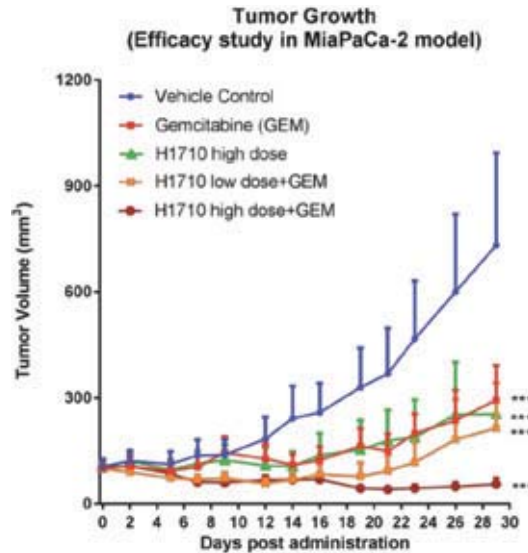


In individual trials of this model, we found that some H1710-treated mice survived more than two years and have achieved the effect of complete tumor healing, as illustrated in the diagram below. We stopped the treatment after 134 days. All the remaining mice survived for 630 days since the beginning of the trial, after which, two died because of aging, and the rest are alive until today, which have survived more than 750 days since the beginning of the trial.



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We also tested H1710's effect in inhibiting tumor growth by inoculating human tumor cells into the left back of immunodeficient mice to establish a human carcinoma xenograft model. We found that H1710 has a good effect on various models such as pancreatic cancer and lung cancer. The results show that the application of H1710 alone or in combination with gemcitabine can significantly inhibit the growth of subcutaneous tumors. Some of the H1710-treated mice even show tumor shrinkage or disappearance. The diagram below is a subcutaneous tumor model of pancreatic cancer Mia PaCa-2.



### Pipeline Drugs of Our Portfolio Companies

We have strategically invested in a number of biotech companies with first-in-class drug candidates in therapeutic areas that address the significant unmet clinical demands.

#### *HighTide's HTD1801*

As of the Latest Practicable Date, we held 47.02% equity interest in HighTide. HighTide's leading drug candidate, HTD1801, is a first-in-class oral small molecule drug candidate. The phase II clinical trial for the usage of HTD1801 in treating PSC is currently ongoing and the phase II clinical trial for the treatment of NASH was completed in March 2020. The FDA has granted HTD1801 Fast Track Designation in both diseases.

#### *NASH*

There is significant market potential for the treatment of NASH in China. According to Frost & Sullivan, the prevalence of NASH in China grew from 32.8 million in 2014 to 36.2 million in 2018, representing a CAGR of 2.5%, which is expected to increase to 43.1 million by 2023 at a CAGR of 3.6%, and to 55.5 million by 2030 at a CAGR of 3.7%.

Currently, the most effective method to control NASH is changes in lifestyle, primarily through diet control and regular exercise. There is no evidence-based approved drug or surgical therapy for the treatment of NASH, suggesting significant unmet medical needs. All the drugs applied are used to treat the complications of NASH, prevent damages to the liver, and control the progression, however, there is no evidence that verifies their effects on treating NASH. Bariatric surgery aims to relieve symptoms and lower the risk of causing cardiovascular diseases, but no evidence has suggested its efficacy in

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treating NASH. Liver transplantation is also not a promising therapeutic option due to the lack of liver source and the high probability of recurrence. Numerous obstacles make drug development for NASH treatment a challenge. The complexity of the pathogenesis of the disease, which involves multiple pathways, requires targeting of more than one pathway or a combination-based therapy. The complex interactions among numerous metabolic pathways, the immune system and the gut prevent the development of a one drug-based therapy that can provide a cure for NASH.

As of the Latest Practicable Date, there was no approved or commercialized targeted therapy drug for NASH globally. The following table shows the current status of small-molecule targeted therapy drug candidates for NASH treatment at clinical stages worldwide:

Global Small-Molecule Targeted Therapy Pipelines for NASH Treatment <sup>1</sup>				
Pipeline	Target	Company	Status	Classification
Obeticholic Acid	FXR	Intercept Pharmaceuticals	NDA for the indication of NASH	New Drug
Resmetirom	THRB	Madrigal Pharmaceuticals	Phase III	New Drug
GS-4997	ASK1	Gilead Sciences	Phase III	New Drug
Aramchol	SCD	Galmed Pharmaceuticals	Phase III	New Drug
GFT-505	PPAR $\alpha$ , PPAR $\delta$	Genfit	Phase III	New Drug
Genicriviroc Mesylate	CCR2, CCR5	Tobira Therapeutics, Inc.	Phase III	New Drug
MSDC-0602K	N/A <sup>3</sup>	Cirius Therapeutics, Inc.	Phase III	New Drug
HTD1801	Multi-target mechanism	HighTide Biopharma <sup>2</sup>	Phase II	New Drug

1. Pre-clinical pipelines are excluded.

2. Shenzhen Hepalink holds 47.02% of equity interest in HighTide Biopharma, in addition to the drug candidate's exclusive rights to develop and commercialize in Greater China.

3. Target not disclosed or multi-target mechanism.

Source: Frost & Sullivan Report

Please refer to the sub-section headed “Industry Overview—Innovative Drug market—Non-Alcoholic Steatohepatitis” for more details.

### PSC

According to Frost & Sullivan, the prevalence of PSC in China increased from 109.4 thousand in 2014 to 115.1 thousand in 2018, representing a CAGR of 1.3%, which is expected to reach 126.1 thousand by 2023 at a CAGR of 1.8%, and 144.9 thousand by 2030 at a CAGR of 2.0%. There are two main therapeutic options for PSC, including drug therapies, which involves ursodeoxycholic acid (“UDCA”) or corticosteroids combined with immunosuppressants, and surgical therapies, such as liver transplantation. Neither of the two conventional drug therapies is proven with superior efficacy in treating classic PSC. While liver transplantation is generally believed to be the most recommended therapy for PSC, it is not commonly available due to the lack of liver source.

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As of the Latest Practicable Date, there was no approved or commercialized targeted therapy drug for PSC globally. The following table shows the current status of small-molecule targeted therapy drug candidates for PSC treatment at clinical stages worldwide:

Global Small-Molecule Targeted Therapy Pipelines for PSC Treatment <sup>1</sup>			
Pipeline	Target	Company	Status
Norursocholic Acid	NA <sup>3</sup>	Dr. Falk Pharma	Phase III
GS-9674	FXR	Gilead Sciences	Phase III
HTD1801	Multi-target mechanism	HighTide Biopharma <sup>2</sup>	Phase II
DUR-928	NA <sup>3</sup>	Durect	Phase II
Cenicriviroc mesylate	CCR2,CCR5	Tobira Therapeutics	Phase II

1. Pre-clinical pipelines are exclude.

2. Shenzhen Hepalink holds 47.02% of equity interest in HighTide Biopharma, in addition to the drug candidate's exclusive rights to develop and commercialize in Greater China.

3. Target not disclosed or multi-target mechanism.

Source: Frost & Sullivan Report

### ***Kymab's drug candidates***

As of the Latest Practicable Date, we held 8.60% equity interest in Kymab. Based on public information, Kymab has a broad pipeline of therapeutic antibody programmes, with the following four leading drug candidates for immune-oncology therapy with significant growth potential:

- KY1005, a Phase IIa OX40L targeting therapy for Atopic Dermatitis
- KY1044, a Phase I/II first-in-class ICOS targeting immune-oncology therapy for solid tumours
- KY1043, a first-in-class PD-L1 targeted immunocytokine therapy for solid tumours
- KY1051, a CXCR4 targeting immuno-oncology therapy for solid tumours

### ***KY1005***

Atopic dermatitis is an inflammatory, pruritus, chronic or chronically relapsing skin disease. Atopic dermatitis is one of the most common non-skin diseases that affects up to 20% of children and 2%-8% of adults in most countries. Atopic dermatitis is often the first step in the development of other atopic diseases. Topical treatment and systemic therapy are the two major treatment options for atopic dermatitis. Topical treatment primarily includes topical glucocorticosteroid and topical calcineurin inhibitor, which are applied directly on inflammatory skin as needed. Systemic therapy includes antihistamine, immunosuppressant, glucocorticosteroid and monoclonal antibody.

Currently, the primary treatment for patients with moderate-to-severe atopic dermatitis is immunosuppressant, which is a broad-spectrum treatment. There is a huge unmet medical need for effective, well-tolerated and narrow-spectrum therapeutics, such as mAbs. Specifically, KY1005 is an mAb that targets OX40L.

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According to Frost & Sullivan, as of the Latest Practicable Date, there was one commercialized mAb drug that treats atopic dermatitis, as set forth in the table below:

Global Marketed mAb Treatment for Atopic Dermatitis		
Drug	Target	Company
Dupilumab	IL-4R $\alpha$	Regeneron & Sanofi

Source: Frost & Sullivan analysis

According to Frost & Sullivan, as of the Latest Practicable Date, there were a few mAb drug candidates that treat atopic dermatitis, none of which has similar mechanism of action as KY1005, as set forth in the table below:

Global Pipelines of mAb Treatment for Atopic Dermatitis			
Pipeline	Target	Company	Status
Tralokinumab	IL-13	AstraZeneca	Phase III
Lebrikizumab	IL-13	Hoffmann-LaRoche	Phase III
Nemolizumab	IL-31RA	Chugai	Phase III
Tezepelumab	TSLP	Medimmune	Phase II
GBR830	OX40	Glenmark	Phase II
Etokimab(ABN020)	IL-33	AnaptyBio	Phase II
Ustekinumab/ Stelara	IL-12/23p40	Janssen	Phase II
Secukinumab/ Cosentyx	IL-17A	Novartis	Phase II
KY-1005	OX40L	Kymab <sup>2</sup>	Phase II
Fevipiprant	CRTH2	Novartis	Phase II
Timapiprant	CRTH2	Atopix Therapeutics	Phase II
Ligelizumab	IgE	Novartis	Phase II

1. Only Phase II and Phase III pipelines are included.
2. We hold 8.60% equity interest in Kymab.

Source: Frost & Sullivan Report

KY1044, KY1043 and KY1051 are either at pre-clinical development or at early-phase clinical development, the specific indications of which have not been determined. Therefore, we are not able to identify the competitors for each of such drug candidates.

## OUR CDMO BUSINESS

### Overview

We operate our CDMO business through two platforms, Cytovance and SPL. The two platforms give our customers access to a truly unique assemblage of CMC services for supporting the vast spectrum of recombinant and naturally derived large molecule pharmaceutical products and critical non-viral vectors and intermediates for gene therapy. Both platforms offer services including R&D services, manufacturing services, quality assurance and program arrangement across the drug development lifecycle from late discovery lead selection to clinical CGMP-compliant manufacture and commercial supply. In addition to dealing with fee-for-service and commercial supply contracts, our CDMO platform also enables us to rapidly develop our own diverse innovative drug pipeline.

Our CDMO business is overseen by Dr. Yan Wang, president of SPL. Dr. Wang holds a Ph.D. degree in chemistry and has more than 20 years of experience in the pharmaceutical industry. Other



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key management members in our CDMO business include Cytovance’s chief executive officer, Dr. Jesse D. McCool, and SPL’s director of specialty product business, Mark Romich. Dr. McCool holds a Ph.D. degree and completed postdoctoral work in microbiology, and he has over 20 years of practice in the biotech field and had served as various management and technical roles in several leading biotech companies prior to joining Cytovance in 2013, such as a world-leading CDMO company Lonza Group AG. Mr. Romich holds master degrees in both civil and environmental engineering and chemical engineering and has more than 20 years of professional engineering experience in industrial process design and biopharmaceutical manufacturing.

Cytovance specializes in the development and manufacture of large molecule pharmaceutical products, with a 12-year track record of working with over 130 different recombinant products, such as monoclonal antibodies, antibody fragments, bispecific antibodies, cytokines, fusion proteins, vaccines and other recombinant proteins. Cytovance has expertise in both mammalian cell culture and microbial fermentation and possesses integrated single-use technologies for production and purification. Cytovance also supports the rapidly growing gene therapy sector by supplying customers with high quality pDNA.

SPL provides services in the development and manufacturing of large molecule pharmaceutical products derived from animal and plant starting materials such as pancreatic enzymes, heparin and heparin analogs. SPL has a 30-year track record of working on naturally derived pharmaceutical products and has developed core competencies such as developing complex and scalable processes for the extraction, isolation and purification of naturally derived materials.

Our CDMO business has a global and diversified customer base, consisting of leading global pharmaceutical companies as well as small- to mid-sized biotechnology companies and start-ups. We enjoy a high level of customer loyalty and industry referrals. We provided CDMO services to three out of the ten largest pharmaceutical companies in the world during the Track Record Period. During the Track Record Period, our CDMO services enabled approximately 20 regulatory filing milestones, including INDs, NDAs, BLAs or amendments. As a further testament to value created by the CDMO platform, several of our customers were acquired by large pharmaceutical companies such as Synageva BioPharma Corp. which was purchased by Alexion Pharmaceuticals, Inc. in 2015, Five Prime Therapeutics, Inc. which was purchased by Bristol-Myers Squibb Company in 2015, Selexys Pharmaceuticals Corporation which was purchased by Novartis International AG in 2016, ARMO Biosciences, Inc. which was purchased by Eli Lilly and Company in 2018 and Synthorx Inc which was purchased by Sanofi in 2019.

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The tables below set forth our ten largest customers and projects for the years indicated. The revenue contribution to our CDMO services from our ten largest customers increased from 70.5% in 2017 to 74.9% in 2018 and further to 81.6% in 2019, primarily because Cytovance’s microbial fermentation capacity increased as a result of the launching of the new facility in August 2018, which enabled us to expand our services to the customers. In particular, the percentage of revenue contribution from customer b increased from 10.8% in 2017 to 30.4% in 2018, primarily attributable to the increase in its estimated clinical demand of the product, and continued to increase to 41.4% in 2019, as a result of the increased estimated clinical demand and our enhanced production capacity. The percentage of revenue contribution from certain customers fluctuated during the Track Record Period, which was primarily associated with the fluctuation of their demand, as the development and commercialization of their product candidates progressed.

Ten Largest Customers for the year ended December 31, 2017	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Years of Collaboration <sup>(2)</sup>	Service Provided	Revenue RMB’ 000	Percentage Contribution to Total Revenue from CDMO Services
Customer a . . . . .	A clinical-stage biotechnology company that develops protein therapies established since 2009	<ul style="list-style-type: none"> <li>• Product candidates primarily at early-phase development</li> <li>• Revenue of over US\$50 million in 2019</li> </ul>	Since 2015	Late-phase (phase III) clinical development	45,267	14.0%
Customer b . . . . .	A biotechnology company that develops immuno-oncology treatments established since 2010	<ul style="list-style-type: none"> <li>• Customer group had over 20 approved drugs</li> <li>• Customer group had revenue of over US\$20 billion in 2019</li> </ul>	Since 2013	Late-phase (phase III) clinical development	34,975	10.8%
Customer c . . . . .	A clinical-stage biotechnology company that focuses on the development of oncology treatments established since 2006	Product candidates primarily at early-phase development	Since 2017	Early-phase (phase I & II) clinical development	27,531	8.5%
Customer d . . . . .	A clinical-stage biopharmaceutical company that focuses on monoclonal antibody immunotherapies established since 2010	Product candidates primarily at early-phase development	Since 2016	Late-phase (phase III) clinical development	25,297	7.8%
Customer e . . . . .	A manufacturer of formulations established since 1977	<ul style="list-style-type: none"> <li>• Customer group had over 130 approved products, 100 validated APIs and sales to the U.S. and other global markets</li> <li>• Customer group had over revenue of over INR100 billion</li> </ul>	Since 2015	Early-phase (phase I & II) clinical development	19,739	6.1%
Customer f . . . . .	A global pharmaceutical company that develops, manufactures and markets various biopharmaceutical products established since 1933	<ul style="list-style-type: none"> <li>• Over 10 approved drugs, over 50 drug candidates, and sales to the U.S. and other global markets</li> <li>• Revenue of over US\$25 billion in 2019</li> </ul>	Since 2016	Early-phase (phase I & II) clinical development	19,450	6.0%
Customer g . . . . .	A company that engages in the development of various drugs and substances established since 2001	Product candidates primarily at early-phase development	Since 2015	Pre-clinical development	17,685	5.5%

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## BUSINESS

Ten Largest Customers for the year ended December 31, 2017	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Years of Collaboration <sup>(2)</sup>	Service Provided	Revenue RMB' 000	Percentage Contribution to Total Revenue from CDMO Services
Customer h . . . . .	A clinical-stage biotechnology company that focuses on overcoming immunogenicity issues established since 2007	Product candidates primarily at early-phase development	Since 2014	Late-phase (phase III) clinical development	15,389	4.7%
Customer i . . . . .	A clinical-stage biopharmaceutical company that develops innovative therapeutics for thrombotic cardiovascular diseases	A clinical-stage biopharmaceutical company	Since 2013	Pre-clinical development	12,172	3.8%
Customer j . . . . .	A pharmaceutical company that develops, manufactures and markets branded and generic prescription pharmaceuticals established since 2001	<ul style="list-style-type: none"> <li>• Over 40 approved drugs and over 100 drug candidates</li> <li>• Net revenue of over US\$200 million in 2019</li> </ul>	Since 2016	Process development	11,036	3.4%
<b>Total . . . . .</b>	—		—		<b><u>228,540</u></b>	<b><u>70.5%</u></b>

Note:

(1) Company background and scale of operation are based on public information.

(2) Years of collaboration refers to the period since we first entered into agreement with the customer.

Ten Largest Customers for the year ended December 31, 2018	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Years of Collaboration <sup>(2)</sup>	Service Provided	Revenue RMB' 000	Percentage Contribution to Total Revenue from CDMO Services
Customer b . . . . .	A biotech company that develops immuno-oncology treatments established since 2010	<ul style="list-style-type: none"> <li>• Customer group had over 20 approved drugs</li> <li>• Customer group had revenue of over US\$20 billion in 2019</li> </ul>	Since 2013	Late-phase (phase III) clinical development	166,618	30.4%
Customer a . . . . .	A clinical-stage biotechnology company that develops protein therapies established since 2009	<ul style="list-style-type: none"> <li>• Product candidates primarily at early-phase development</li> <li>• Revenue of over US\$50 million in 2019</li> </ul>	Since 2015	Late-phase (phase III) clinical development	54,079	9.9%
Customer d . . . . .	A clinical-stage biopharmaceutical company that focuses on monoclonal antibody immunotherapies established since 2010	Product candidates primarily at early-phase development	Since 2016	Late-phase (phase III) clinical development	38,027	6.9%
Customer k . . . . .	A biotechnology company that focuses on the development of antibody therapeutics established since 2014	Product candidates primarily at early-phase development	Since 2017	Early-phase (phase I & II) clinical development	31,502	5.7%

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## BUSINESS

Ten Largest Customers for the year ended December 31, 2018	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Years of Collaboration <sup>(2)</sup>	Service Provided	Revenue RMB' 000	Percentage Contribution to Total Revenue from CDMO Services
Customer l . . . . .	A clinical-stage biotechnology company that develops vaccines treating immune mediated diseases established since 2014	Product candidates primarily at early-phase development	Since 2017	Early-phase (phase I & II) clinical development	25,771	4.7%
Customer j . . . . .	A pharmaceutical company that develops, manufactures and markets branded and generic prescription pharmaceuticals established since 2001	<ul style="list-style-type: none"> <li>• Over 40 approved drugs and over 100 drug candidates</li> <li>• Net revenue of over US\$200 million in 2019</li> </ul>	Since 2016	Process development	24,044	4.4%
Customer c . . . . .	A clinical-stage biotechnology company that focuses on the development of oncology treatments established since 2006	Product candidates primarily at early-phase development	Since 2017	Early-phase (phase I & II) clinical development	20,288	3.7%
Customer m . . . . .	A global biopharmaceutical company that develops and markets advanced therapies established since 2012	<ul style="list-style-type: none"> <li>• Over 30 approved drugs, over 40 drug candidates and sales to the U.S. and other global markets</li> <li>• Net revenue of over US\$30 billion in 2019</li> </ul>	Since 2016	Technical transfer for contract manufacturing	18,440	3.4%
Customer n . . . . .	A pharmaceutical company that focuses on addressing the shortage of transplantable organs established since 1996	<ul style="list-style-type: none"> <li>• Over five approved drugs, over 10 drug candidates and sales to the U.S. and other global markets</li> <li>• Net revenue of over US\$10 billion</li> </ul>	Since 2016	Early-phase (phase I & II) clinical development	17,618	3.2%
Customer o . . . . .	A biotechnology company that focuses on developing oncology treatments established since 2014	<ul style="list-style-type: none"> <li>• Product candidates primarily at early-phase development</li> <li>• Customer group had net sales of over EUR35 billion in 2019</li> </ul>	Since 2018	Early-phase (phase I & II) clinical development	14,645	2.7%
<b>Total . . . . .</b>	—	—	—	—	<b>411,031</b>	<b>74.9%</b>

*Note:*

(1) Company background and scale of operation are based on public information.

(2) Years of collaboration refers to the period since we first entered into agreement with the customer.

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Ten Largest Customers for the year ended December 31, 2019	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Years of Relationship <sup>(2)</sup>	Service Provided	Revenue RMB' 000	Percentage Contribution to Total Revenue from CDMO Services
Customer b . . . .	A biotech company that develops immuno-oncology treatments established since 2010	<ul style="list-style-type: none"> <li>Customer group had over 20 approved drugs</li> <li>Customer group had revenue of over US\$20 billion in 2019</li> </ul>	Since 2013	Late-phase (phase III) clinical development	294,916	37.5%
Customer j . . . .	A pharmaceutical company that develops, manufactures and markets branded and generic prescription pharmaceuticals established since 2001	<ul style="list-style-type: none"> <li>Over 40 approved drugs and over 100 drug candidates</li> <li>Net revenue of over US\$200 million in 2019</li> </ul>	Since 2016	Process development and manufacturing	88,300	11.2%
Customer m . . . .	A global biopharmaceutical company that develops and markets advanced therapies established since 2012	<ul style="list-style-type: none"> <li>Over 30 approved drugs, over 40 drug candidates and sales to the U.S. and other global markets</li> <li>Net revenue over US\$30 billion in 2019</li> </ul>	Since 2016	Commercial manufacturing	75,148	9.6%
Customer o . . . .	A biotechnology company that focuses on developing oncology treatments established since 2014	<ul style="list-style-type: none"> <li>Product candidates primarily at early-phase development</li> <li>Customer group had net sales of over EUR35 billion in 2019</li> </ul>	Since 2018	Early-phase (phase I & II) clinical development	47,189	6.0%
Customer l . . . .	A clinical-stage biotechnology company that develops vaccines treating immune mediated diseases established since 2014	Product candidates primarily at early-phase development	Since 2017	Early-phase (phase I & II) clinical development	39,298	5.0%
Customer p . . . .	A clinical-stage biotechnology company that focese on immuno-modulatory antibodies for the treatment of cancer established since 2015	Product candidates primarily at early-phase development	Since 2016	Late-phase (phase III) clinical development	25,117	3.2%
Customer q . . . .	A biotechnology company that focuses on developing novel products to treat various diseases established since 2014	Product candidate at early-phase development	Since 2018	Early-phase (phase I & II) clinical development	22,305	2.8%
Customer a . . . .	A clinical-stage biotechnology company that develops protein therapies established since 2009	<ul style="list-style-type: none"> <li>Product candidates primarily at early-phase development</li> <li>Revenue of over US\$50 million in 2019</li> </ul>	Since 2015	Late-phase (phase III) clinical development	19,645	2.5%
Customer r . . . .	A biotechnology company that develops vaccines against infectious diseases established since 2017	Lead product candidate at early-phase development	Since 2018	Pre-clinical development	15,825	2.0%



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## BUSINESS

Ten Largest Customers for the year ended December 31, 2019	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Years of Relationship <sup>(2)</sup>	Service Provided	Revenue RMB' 000	Percentage Contribution to Total Revenue from CDMO Services
Customer c . . . .	A clinical-stage biotechnology company that focuses on the development of oncology treatments established since 2006	Product candidates primarily at early-phase development	Since 2017	Early-phase (phase I & II) clinical development	14,090	1.8%
<b>Total</b> . . . . .	—		—		<u><u>641,833</u></u>	<u><u>81.6%</u></u>

Note:

(1) Company background and scale of operation are based on public information.

(2) Years of collaboration refers to the period since we first entered into agreement with the customer.

As of the Latest Practicable Date, we had a backlog of US\$64.4 million, which represents the total amount of contracted fees for services that we have contracted to perform but have not performed yet. Out of such backlog, approximately US\$48.7 million and US\$15.7 million are expected to be generated in 2020 and 2021 onwards, respectively, based on the assumption that the relevant contracts will be performed in accordance with their respective terms and expected timetables. As of the Latest Practicable Date, we had 49 on-going projects. The following table sets forth the status of and the backlog from our on-going projects as of the Latest Practicable Date:

<u>Biologics development stage</u>	<u>Number of on-going projects</u>	<u>Backlog</u> (US\$ in million)
<b>Pre-IND</b>		
Drug discovery . . . . .	2	0.1
Preclinical development . . . . .	15	15.3
Subtotal . . . . .	17	15.4
<b>Clinical trial</b>		
Early-phase (phase I & II) clinical development . . . . .	18	8.0
Late-phase (phase III) clinical development . . . . .	7	17.2
Subtotal . . . . .	25	25.2
<b>Commercial manufacturing</b> . . . . .	7	23.8
<b>Total</b> . . . . .	<u><u>49</u></u>	<u><u>64.4</u></u>

Benefiting from the global growth in the biopharmaceutical sector, our CDMO business experienced rapid growth during the Track Record Period. Revenue from our CDMO business increased from RMB324.3 million in 2017 to RMB548.5 million in 2018, and increased to RMB786.4 million in 2019. Our CDMO business has contributed to our rapid growth and diversified our revenue sources.

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The table below sets forth a breakdown of the revenue from our CDMO business during the Track Record Period, based on the work we performed for our customers. Service fee primarily refers to the payment we collect after completing each work order for product development, and manufacturing fee primarily refers to the payment we receive from the manufacturing and supply of products usually when our customers’ products reach commercial scale.

	<b>For the year ended December 31,</b>		
	<b>2017</b>	<b>2018</b>	<b>2019</b>
	<b>RMB’000</b>	<b>RMB’000</b>	<b>RMB’000</b>
Service fee .....	324,308	530,030	648,782
Manufacturing fee .....	—	18,439	137,619
<b>Total</b> .....	<b>324,308</b>	<b>548,469</b>	<b>786,401</b>

### Our CDMO Services

#### *R&D Services*

We offer comprehensive development services from late discovery to stage 1 of process validation.

For customers with recombinant products at preclinical stage, Cytovance provides development activities including cell line development for mammalian derived proteins, strain development for microbial derived proteins, process development, analytical method development and qualification and pilot process demonstration. The material from the pilot runs may be used by clients for GLP tox studies. The R&D pilot plant features a 200 L single-use bioreactor and a 30 L single-use fermenter. In addition, Cytovance offers bioanalytical testing services for supporting animal and clinical PK/PD studies.

For customers who have advanced drug candidate beyond clinical phase I, both Cytovance and SPL provide development activities including method pre-validation and process characterization. These types of CMC activities are typically referred to as late clinical phase development and our procedures are designed to comply with the FDA guidance for industry on process validation (2011).

In addition to fee-for-service R&D, we are committed to the continual improvements of technologies by organizing industry and academic connections, collaborations and research projects. Such collaborations have helped us to rapidly acquire institutional knowledge, develop new or enhanced services, make publications and obtain intellectual properties. Some of the collaborations have led directly to new client acquisition.

#### *R&D Services for Large Molecule Recombinant Products*

With respect to R&D services for large molecule recombinant products, one of our core competencies is the generation of cell substrates for microbial and mammalian cell line derived recombinants.

For the generation of microbially produced recombinant proteins, we leverage a proprietary protein expression technology, the Keystone Expression System<sup>®</sup>. Keystone Expression System<sup>®</sup> is a microbial strain development toolbox that is used to derive stable, well-characterized cell substrates for intended use in the preparation of biotechnological/biological products. The toolbox was developed by scientists at Cytovance and made accessible to customers in 2014 as a value-add component of a CMC

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service known as strain development. The generation and characterization of the cell substrate are critical CMC activities required prior to establishing the manufacturing process and producing materials in compliance with CGMPs. Our extensive expertise in molecular biology, microbiology, process development, CGMP-compliant manufacturing practices and knowledge of patents help to ensure that the customer is supplied with a productive, robust and scalable cell substrate that is free and clear of intellectual property infringement issues. The parental *E. coli* strains BL21 and K-12 and common derivatives of those form the basis of the Keystone Expression System<sup>®</sup>. These strains have been used extensively in the industry for IND filings and commercial production around the world. Cytovance is actively pursuing continuous improvements to the Keystone Expression System<sup>®</sup> and working to integrate enhanced features into its strain development offering.

For the generation of mammalian produced proteins, we leverage an off-the-shelf, widely-adopted, recombinant protein expression technology, Freedom CHO-S<sup>®</sup> from Thermo Fisher Scientific. Scientists at Cytovance have been using the Freedom CHO-S<sup>®</sup> system to derive well-characterized CHO cell substrates for intended use in the preparation of biotechnological/biological products. On top of the experience with Freedom CHO-S<sup>®</sup>, our cell line experts have decades of experience working with a huge array of mammalian cell lines.

Once a stable cell substrate has been created, Cytovance will advance a customer’s program through key process development milestones such as cell culture process development, microbial fermentation process development, primary recovery development, purification and formulation development, bench scale process demonstration, pilot scale process demonstration and analytical method qualification. Depending on the protein and expression system used, standard processes can be leveraged to save time and cost in CMC development.

### *R&D Services for Naturally Derived Products*

SPL works closely with its customers to transfer their existing process technology at bench scale to SPL’s laboratory. Once transfer is completed, SPL will perform a demonstration batch at bench scale to demonstrate the process and establish the platform for further process development and scale-up. SPL has experience in a wide range of process technologies relating to the extraction and purification of high-value biopharmaceuticals from natural materials.

### *Analytical Testing Capabilities*

Strong analytical testing capabilities, including mass spectrometry, support all of our CMC activities. Such capabilities enable us to develop and qualify analytical test methods that support the process development and quality control for product release. Our core analytical competences of the analytical development team include method development, method transfer, method optimization and robustness testing, pre-qualification, quality control method transfer, pre-formulation development, and product characterization including mass spectrometry. Our experienced scientists will create a product specific testing strategy to measure process performance and confirm product safety and other criteria. In addition to developing product specific methods, our analytical scientists have extensive experience in the transfer and optimization of methods developed at any stage and preparing standard operating procedures, which can be used in a quality control laboratory. We leverage on numerous platform method technologies to evaluate the appropriateness for each new product. Platform methods can decrease method development time and help drive more cost-effective CMC paths.

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### *CGMP-compliant Manufacturing Services*

#### *Manufacturing Sciences*

Once we complete the demonstration batches to establish process robustness limits, the process is then transferred to CGMP-compliant manufacturing through our manufacturing sciences team. Our manufacturing sciences team is responsible for the following:

- completing facility fit evaluation form
- generating the technology transfers
- generating the technology transfers number
- reviewing and approving the technology transfers
- editing the technology transfers
- storing and controlling the technology transfers

#### *Mammalian Cell Banking and Storage*

Cytovance manufactures cryostores of master and working cell banks to support present and future production requirements. Cell banks are cryostored in the vapor phase of liquid nitrogen freezers. We manage and coordinate all required testing per FDA and ICH guidelines.

#### *Mammalian Cell Culture*

Cytovance has installed CGMP-compliant production capacity for recombinant pharmaceutical products, including 250 L, 1000 L and 2000 L single-use disposable bioreactors and a 500 L stainless steel bioreactor. These scales are well matched to meet the majority of demand coming from the customers for products that are in early clinical development. Though Cytovance had not manufactured commercialized large molecule products from mammalian cell culture as of the Latest Practicable Date, Cytovance’s facility can accommodate the installation of additional capacity supporting future commercial demands.

#### *Microbial Fermentation*

Cytovance has installed CGMP-compliant production capacity for recombinant products including 10 L glass fermenter, 200 L and 1000 L stainless steel fermenters and 30 L, 300 L single-use disposable fermenters. These scales are well matched to meet demands from our customers for products that are in early and late clinical development, and Cytovance’s facility can easily accommodate the installation of additional capacity supporting future commercial demands. The microbial fermentation offered by Cytovance is differentiated by its single-use fermentation systems. The Thermo Scientific HyPerforma Single-Use Fermenter (S.U.F.) system is a first-in-class single-use technology delivering unique and rigorous solutions for microbial fermentation applications while offering flexibility, ease of use and efficiency associated with single-use systems. The system delivers an optimal growth environment through powerful agitation with three Rushton impellers and baffles, high gas flow rates, and efficient cooling through a greater vessel surface area. SPL is also equipped with 5L and 30L fermentators and various types of incubators and biosafety cabinets for microbial fermentation.

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### *pDNA manufacture*

The gene therapy market has been growing rapidly and demand for high-quality pDNA is very high. Cytovance launched the pDNA manufacturing service in October 2019. Cytovance’s strong focus on microbial fermentation is highly synergistic with pDNA bioprocessing. The key features of Cytovance’s platform include:

- Industry-leading robust upstream process: HyperGRO™ process, developed by a third party Nature Technology Corporation (Lincoln, NE) is an inducible fed-batch fermentation process consisting of a cell bank and fermentation process that reduce plasmid-mediated metabolic burden, enabling high yield production of optimized plasmids, as well as successful production of previously known unstable or toxic vectors. Due to the controlled addition of nutrients, much higher cell densities can be achieved with a fed-batch process, as opposed to a batch process, and specific growth rates can be reduced, which generally results in increased plasmid copy number.
- S.U.F. equipment: Thermo Scientific HyPerforma S.U.F. system is a first-in-class single-use technology, which allows Cytovance to more rapidly move from one customer process to the next. Cytovance has installed 30 L and 300 L scale S.U.F. system for pDNA manufacture.
- Single-use lysis equipment: Thermo Scientific™ imPULSE™ Single-Use Mixer (S.U.M.) system is a low-shear mixing system used for the lysis step in the pDNA process. It was designed with proven engineering mixer principles and can be used for upstream and downstream mixing applications. The linear-scale design delivers uniform, superior mixing in every model, from 30 L to 5000 L and mixes to empty. The mixer provides consistent scalability. Cytovance has installed 30 L, 500 L, 1500 L SUM system for scalable pDNA production.
- Efficient chromatography technology: BIA Separations’ HiP2 platform, Convective Interaction Media (CIM®) monolith chromatography supports, is designed for the purification of large molecules such as pDNA. Monoliths enable high productivity of pDNA downstream processes due to high dynamic binding capacity, fast operating flow rates and high resolution due to convection-based mass transfer.

### *Natural product extractions*

SPL provides services in the extraction of large molecule products from natural sources, including through processing both animal-derived and plant-derived materials, at scales ranging from laboratory to CGMP development suites to metric ton, full-scale commercial production. SPL operates a flexible multi-product manufacturing facility in Waunakee, Wisconsin, the U.S. in support of its CDMO business. Our team has extensive expertise and experience in sourcing natural materials, establishing complete traceability, extracting high-value products from naturally derived materials, purification, viral inactivation and characterization of complex mixture of large glycoprotein molecules.

### *Purification*

Our teams in Cytovance and SPL have extensive experience with an array of purification capabilities to meet our customers’ CGMP production needs. Our purification suites are segregated and customized with equipment to specifically meet the requirements of each client process. Single-use



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options are available throughout all purification steps with cutting-edge technologies. Our purification personnel are experts with multiple chromatography techniques, tangential flow filtration and bulk drug substance filling.

### *Process validation*

We also offer process validation services in accordance with FDA Industry Guidance (2011) on Process Validation. To ensure that critical parameters are identified and tested, an extensive process characterization (“stage 1” of the 2011 FDA Guidance) is performed. A given process is operated within established parameters in the process performance qualification (“stage 2” of the 2011 FDA Guidance).

### *Quality Assurance*

All of our manufacturing and support operations in Cytovance and SPL are built on the framework of a quality management system, including quality control testing, quality assurance, stability testing and regulatory support.

Our CDMO quality management systems are driven by three organizational functions including validations, quality control, and quality assurance. Quality assurance is further organized into four functional departments, including incoming materials, quality assurance operations, quality systems and regulatory affairs. The department of incoming materials is responsible for the incoming material sampling, inspection and testing, non-conforming material oversight and supplier management. The department of quality assurance operations is responsible for customer project oversight, deviation management, investigation review and approvals, batch record review and lot disposition. The department of quality systems is responsible for document control, training coordination, CAPA and audit management, and metrics and trending. The department of regulatory affairs is responsible for regulatory reporting, pharmacovigilance, complaint and change management and policy-level compliance oversight.

### *Quality control testing*

Quality control testing is to ensure that the product strictly meets the FDA and USP guidelines. Our team has relevant experience in CGMP compliance and microbial root cause investigations.

### *Quality assurance*

We ensure quality of the products by following established systems that are compliant with domestic and international regulations. Our quality systems provide planned and systematic quality requirements for our services. The established systems ensure traceability of materials from receipt through final disposition and storage and ensure the products’ compliance with quality requirements from the clinical stage through commercialization. These systems also provide feedback to ensure robust monitoring and continuous improvement.

### *Stability testing*

ICH stability testing is a critical aspect to any early-stage manufacturing project. We provide state-of-the-art services to screen excipients, determine an optimum formulation and get the product on its stability regimen as quickly as possible. We provide stability chamber storage and analysis that are compliant with the ICH guidelines and suit the properties of each product.

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### *Regulatory support*

Every stage of the manufacturing process has regulatory implications. Initially, we advise on meetings with regulatory authorities. Production processes and manufacturing strategies are specifically designed for optimal regulatory outcomes. We are a critical partner for CMC section preparation, assisting clients throughout the production process to target regulatory success. We believe we are poised to successfully complete regulatory inspections such as a PAI and general CGMP audits. We host numerous customer quality audits each year in addition to our internal auditing program.

### *Program Management*

Both Cytovance and SPL provide professional CMC program management services for their customers, including project planning, resource management, sample shipment coordination, batch scheduling and project team communications. Customers are assigned a dedicated program manager who plays a central communications role while leading the coordination of project milestones, project resources and the working project plan. The program manager is responsible for escalation processes and other business processes enabling the most efficient timeline achievable.

### **Marketing of Our CDMO Services**

We directly market our services to pharmaceutical and biotechnology companies by actively participating in trade conferences and trade shows. During these conferences, we set up booth to introduce our integrated CDMO platform and our technical staffs will also give presentations that highlight the advantages of our end-to-end CMC services. We have also established active online presence through our corporate websites. We provide extensive information about our integrated services and our technology platforms, our competitive and technical advantages, training and education resources as well as announcements of our most recent project development on our corporate websites. After we have established contact with our target customers, we market our services through regular meetings with their representatives and senior management, where we present how we can expedite the customers’ product development process. In light of our broad customer base, customer referrals and word-of-mouth marketing have also significantly contributed to new customer acquisition.

We have a team of experienced business development specialists, consisting of 13 people, who are dedicated to understanding the demands of existing and potential customers and work closely with our technical experts to prepare quotes and to secure customer orders. Three of the members of our sales and marketing team have attained a master’s or higher degree in biologics-related disciplines as of the Latest Practicable Date.

### **Our CDMO Fee Model**

We enter into long-term service agreements with our major customers. Services for each project under a long-term service agreement are provided pursuant to separate and distinct work orders. A work order typically comprises a number of tasks, each in turn including several steps.

According to our contractual arrangements with our customers, we typically bill our customers after we complete a task. A task is deemed to be completed after all the steps within such task are completed. Our contracts with customers and work orders include specifications about the services to

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be rendered at each step and the deliverables that we should send to the customer upon completion of such step. Our project team also interacts with each customer’s project-management team through daily emails, bi-weekly reports and regular conference calls to give the customer timely updates of the progress of its projects. We are typically required to deliver a technical laboratory report, product/samples and/or other deliverables and transfer the relevant data and rights to the customer after all the services have been rendered for a step. A particular step is deemed to be completed upon the customer’s acceptance of the deliverables in relation to such step, which indicates that the customer is satisfied with the services provided by us at such step and would like us to proceed.

### **SALES AND MARKETING**

We implement differentiated and localized sales and marketing strategies which are suitable for our various pharmaceutical products in different markets. We use a combination of academic marketing by our in-house sales and marketing team and collaboration with a network of independent distributors and third-party promoters to generate market demands for our products. We have not engaged in any sales and marketing activity for innovative drug candidates as they are currently at development stage. We directly market our CDMO services to pharmaceutical and biotechnology companies by actively participating in trade conferences, trade shows and scientific conferences. For the marketing of our CDMO services, please refer to “—Our CDMO Business—Marketing of Our CDMO Services.”

#### **Our Sales of Enoxaparin Sodium Injection**

We use a combination of academic marketing by our in-house sales and marketing team and collaboration with a network of independent distributors and third-party promoters to generate market demands for our products. Specifically, our marketing for enoxaparin sodium injection can be categorized into three models, depending on our marketing efforts, including in-house marketing model, co-marketing model and outsourced marketing model. The table below sets forth the percentage of each marketing model’s revenue contribution to our total revenue generated from the sales of enoxaparin sodium injection in the years indicated:

	For the year ended December 31,		
	2017	2018	2019
	%	%	%
In-house marketing model .....	70.7	73.2	74.1
Co-marketing model .....	25.8	19.8	19.1
Outsourced marketing model .....	3.5	7.0	6.8
<b>Total</b> .....	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>

#### ***In-House Marketing Model***

The in-house marketing model is currently applied only in certain EU countries and the UK. Under our in-house marketing model, all market demands are generated directly by our sales and marketing team. Our sales and marketing team directly market our products and develop relationships with physicians, hospitals and pharmacies, participate in the bidding process to create sales to hospitals and further through the prescription of physicians promote sales of our products to pharmacies. We sell our products either through distributors or directly to hospitals in these countries.

In 2017, 2018 and 2019, out of our total revenue from the sales of enoxaparin sodium injection under the in-house marketing model, direct sales accounted for 0.0%, 11.3% and 18.5%, respectively.

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Our sales to distributors not through logistics providers accounted for 98.2%, 81.3% and 46.8%, respectively, of such total revenue in the same years, and our sales through logistics providers in the UK, Germany and Spain, either to distributors or to hospitals, amounted to 1.8%, 7.5% and 34.7% of such total revenue in the respective years.

### *Sales through Distributors*

In Germany, UK, Spain and Italy, during the Track Record Period, we primarily sold our enoxaparin sodium injection under the brand name Inhixa to distributors. Our products are sold to distributors at a fixed price set by relevant regulatory authorities based on retail price. We do not enter into any sales agreement with our distributors. In Germany, UK and Spain, distributors place purchase orders to our appointed logistics providers on an as-needed basis, depending on the orders they receive from customers. We generally enter into a services agreement with each logistics provider, under which, such logistics provider is responsible for providing integrated logistics services, including storage, secondary packaging and final shipment. The logistic providers are responsible for accepting and processing orders from distributors, issuing sales invoices to the distributors, collecting payment from the distributors on our behalf and settling payment with us within 30 days upon payment by the distributors to them. We are responsible for delivering our products to the logistics providers, and pay service fee in consideration of the services they provided. The ownership of the products will not be transferred to the logistics provider at any time. In Italy, distributors directly place orders and settle payment with us. We typically grant credit terms of one to two months to the distributors in Italy.

We also sell enoxaparin sodium injection under our brand name Neoparin to SciencePharma in Poland. As SciencePharma owns the marketing authorization of Neoparin, we are not able to directly sell Neoparin in Poland. SciencePharma is our exclusive distributor of the product in Poland. We have not prohibited SciencePharma from appointing sub-distributors of Neoparin and we have not limited the amount or price of its sales to sub-distributors. In line with the market practice in the EU, SciencePharma also sold Neoparin through sub-distributors, aside from its direct sales, to pharmacies and hospitals, during the Track Record Period. We have entered into a supply agreement with SciencePharma, which will remain in force as long as SciencePharma is the holder of the marketing authorization of Neoparin. Under the supply agreement, SciencePharma purchases Neoparin from us on an as-needed basis by placing purchase orders from time to time, and we deliver the products to its designated subcontractor who is responsible for certain importation activities. We are obligated to reserve an agreed production capacity in accordance with the amount of products SciencePharma declares to the government for reimbursement application. Our Neoparin is sold pursuant to a price schedule in the supply agreement which sets a per unit price for each strength subject to periodic renewal, and we grant SciencePharma credit term of 180 days. Separately, for the technical and quality aspects concerning the manufacturing and importation of enoxaparin sodium injection, our OEM partner and we, have each concluded a quality manufacturing agreement with SciencePharma and its designated subcontractor, to ensure the compliance with relevant EU laws and regulations. We have also entered into a separate service agreement with SciencePharma, under which, we have acted as a marketing service provider to assist SciencePharma in selling Neoparin with our sales and marketing team in Poland. Pursuant to the medical communication services agreement, we are responsible for organizing communication and meetings with customers, conducting market analysis and developing communication strategies, completing post-sale analysis and reporting our activities on a monthly basis to SciencePharma. The monthly remuneration for our services is our actual costs plus an agreed profit margin, limited by the amount equal to SciencePharma's profit margin achieved in the same month, which shall be paid within 60 business days following our invoice.

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### *Direct Sales*

During the Track Record Period, we sold enoxaparin sodium injection under the brand name Inhixa directly to hospitals and pharmacies in certain countries in the EU, such as Italy. We deliver our products to hospitals pursuant to the purchase orders we receive at the price set during the bidding process.

### *Co-Marketing Model*

Under co-marketing model, besides our in-house academic marketing, we also rely on third-party promoters and distributors to market our products, especially enoxaparin sodium injection, by leveraging their local connection and marketing network. Each of our distributors and third-party promoters has its own sales force that focuses on marketing in its designated territory, which expands our marketing coverage and deepens our marketing penetration while allowing us to maintain operational flexibility and optimize our resource allocation.

### *EU*

In certain EU countries such as Croatia, we enter into consignment arrangements with our distributors, where we issue invoice to our distributor upon its sales to the customers. The distributor assists us to market and sell our products in its designated region. Pursuant to the agreement, we are responsible for delivering our products to the distributor, while the legal ownership of the products is only transferred to the distributor when the product is withdrawn from the consignment stock and delivered to its customers. We provide typically three months of credit terms for the distributors.

### *China*

We collaborate with our third-party promoters for the marketing of our enoxaparin sodium injection in China. For our sales in China, we generally enter into a standard agreement with a third-party promotor in each province with a term of one year. We work with our third-party promoters to design marketing strategies in respective regions, participate in academic conferences and engage in patient education to increase the awareness of our brand and product. Pursuant to our agreement, each third-party promotor is also responsible for introducing and promoting our product to target hospitals and physicians in the designated province, as well as assisting with the bidding process of our product through submitting bidding materials and communicating with local authorities. Each third-party promotor is assigned with a quarterly and annual marketing plan in each target hospital within its designated province, the failure to comply with which may lead to termination of the agreement at our discretion. Our third-party promotor will generally appoint a CSO in their covered region, with whom we enter into a standard one-year CSO agreement. Each CSO is required to assist with the marketing and promotion of our product by organizing or attending various events and leveraging their connection with local hospitals. Each of our CSOs is prohibited from marketing or selling our products outside its designated province, and is generally not allowed to promote other products that directly compete with ours.

We rely on an extensive network of distributors to distribute our enoxaparin sodium injection under the brand name Prolongin in China. Generally, there are multiple distributors in each province, each covering the hospitals that it has access to. The Distributor is responsible for processing orders and delivering our products to the designated hospitals. For each sale, we will enter into a sales agreement with the distributor that specifies the product, purchase amount and price. Pursuant to our



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agreement, each distributor will pay us the fixed price set in the agreement when placing the order. We typically do not provide any credit term for the distributors. We believe that our existing distribution model is consistent with customary industry practice and serves to ensure efficient coverage of our sales network while controlling our cost of distribution and account receivables.

### *Outsourced Marketing Model*

For our sales of enoxaparin sodium injection in certain countries in the EU and other overseas regions, we rely on our local distributors' marketing efforts and resources for the promotion of our product in respective regions.

#### *EU*

We rely on exclusive distribution arrangement to market and sell our enoxaparin sodium injection in certain countries, such as France, Austria and the Republic of Cyprus. Our distribution agreement with each distributor generally has a term of three to five years, subject to renewal at the end of each term. Each distributor is responsible for using its best efforts to promote and sell our products in the designated region. Pursuant to the agreement, the distributor is obligated to purchase a minimum amount of products at the prices set in the agreement applicable to respective purchase amount. We are responsible for delivering our products to the distributor under the agreement, and the legal ownership of products is transferred to the distributor upon delivery. The distributor is responsible for delivering products to its customers within the designated region. The credit terms we grant to the distributors vary depending on market conditions, and is typically less than two months.

#### *U.S.*

We have entered into a supply agreement of enoxaparin sodium injection with a multinational pharmaceutical company as its major supplier of enoxaparin sodium injection in the U.S. As of the Latest Practicable Date, we have not supplied our enoxaparin sodium injection to this customer pursuant to the supply agreement.

#### *Other markets*

We sell enoxaparin sodium injection through distributors in other markets. In certain countries, such as Peru and Sri Lanka, we sell enoxaparin sodium injection under our brand name Prolongin, or under the brand name Inhixa, in countries such as United Arab Emirates. In other countries such as Brazil, Colombia and Vietnam, we supply enoxaparin sodium injection to our customers for them to sell under their own brand names. We generally enter into a supply agreement with our major distributors for a term of five years, under which, we manufacture and deliver enoxaparin sodium injection as requested. Our distributors are responsible for registering the enoxaparin sodium injection and applying for marketing approval in the designated regions, and we will assist them in obtaining the marketing approval by providing materials and product samples as requested by the regulatory authority. Our distributors will purchase our products at a set price pursuant to the agreement and are committed to purchase a minimum amount. We generally grant credit terms of one month to two months to our distributors.

### **Our Sales of Heparin Sodium Injection**

We have established and maintained a cooperative relationship with a world-leading pharmaceutical distributor for the promotion and distribution of heparin sodium in the U.S. We have

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granted the company with exclusive rights to use our ANDAs to market, sell and distribute heparin sodium injection in the U.S. that are manufactured, packaged and labeled by authorized manufacturers. We have also granted the company with exclusive rights to use our label in connection with its marketing, sale and distribution of the heparin sodium products. Pursuant to the agreement with such distributor, we are responsible for supplying heparin sodium API for the manufacturing and production of heparin sodium injection. In addition to the payments for purchasing heparin sodium APIs, the company agrees to pay a licensing fee to access and use our certain intellectual properties, ANDAs, ANDSs and applicable product specifications in connection with the sourcing, manufacturing, packaging and labeling of the heparin sodium injection.

Moreover, we sold heparin sodium injection to distributors in China through Hepatunn in 2017 and 2018, before we disposed our equity interests in Hepatunn in June 2018. We applied marketing and distribution model similar to our sales of enoxaparin sodium injection, through collaborating with third-party promoters and CSOs for marketing and appointing distributors for delivery to hospitals.

### **Our Sales of API Products**

#### ***Heparin Sodium API***

We primarily sell heparin sodium API directly to pharmaceutical companies for their production of heparin sodium injection or LMWH products. During the Track Record Period, our major customers included Techdow before it became our wholly-owned subsidiary in 2018, with whom we conducted the transactions on an arm’s length basis, and international suppliers of heparin products, with whom we have established and maintained a long-term business relationship. Our customers are global leading manufacturers of heparin products or the leading manufacturers in their respective regional markets.

We also sell to distributors in certain regions, who are designated as the exclusive distributors in their covered regions to further sell our heparin sodium API to pharmaceutical companies for their production of heparin products.

We generally enter into a supply agreement with our major purchasers of heparin sodium API for a term of three to five years subject to renewal. Under the agreement, we are responsible for delivering the products pursuant to each order, and our direct customers and distributors are generally required to make payment within 30 to 60 days at the price set in the supply agreements. Our products are generally sold according to a schedule in each supply agreement that sets a price for different periods during the term of the agreement, based on our estimates of the market conditions that may affect the cost of sales or our estimates of the effect on our costs of sales of certain events that have occurred. For example, the price of our raw materials may fluctuate as a result of the outbreak of swine fever or certain crisis such as Baxter Incident. The price may also vary with discounts applicable to respective purchase amount. The price schedule of our products are generally subject to renewal each year or upon certain unexpected market changes, subject to adjustment in each order based on parties’ negotiation.

#### ***Enoxaparin Sodium API***

We primarily sell enoxaparin sodium API directly to manufacturers of enoxaparin products. The regions where we sell our enoxaparin sodium API generally do not overlap with regions where we sell our enoxaparin sodium injection. For the major markets, we generally enter into supply agreements with regional leading manufacturers of enoxaparin products.

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We also sell our enoxaparin sodium API through distributors which have extensive and long-term connections with local manufacturers of enoxaparin products in their covered regions.

We generally enter into a supply agreement with our major purchasers of enoxaparin sodium API for a term of two to five years subject to renewal. The purchase orders generally set credit terms of 30 to 60 days with our major direct customers or distributors. Our products are sold at a price subject to parties' negotiation for each order based on changes in the raw materials market or certain unexpected market changes.

### **Our Sales and Marketing Team**

We have an experienced and specialized in-house sales and marketing team with international exposure. As of the Latest Practicable Date, our sales and marketing team consisted of 105 staff in total, with 52 people in the EU and the UK, 40 people in China and 13 people in the U.S. Our overseas sales and marketing team is led by Wen Shi, vice president of business development, who has vast experience in the pharmaceutical industry, and our sales and marketing team in China is led by Guanhua Cao, who has over 20 years of practice in the field.

### ***Our Sales and Marketing Team for Enoxaparin Sodium Injection***

#### *Our Regional Sales and Marketing Team*

We have a dedicated sales and marketing team for enoxaparin sodium injection, divided into three sub-teams by market, including China, the EU and other regions, each led by a director, who reports on a regular basis to our management. As of the Latest Practicable Date, our sales and marketing team for enoxaparin sodium injection consisted of 86 people in total, including 52 people in the EU and UK and 34 people in China, among whom, five people had over 20 years of experience in pharmaceutical sales. To penetrate into local markets in the EU, we have formed a sales and marketing team in each major market, each led by a regional manager. We do not maintain a local office for the sales of enoxaparin sodium injection in each province in China or in other overseas markets. We divide the China market into seven major regions, including East China, North China, Central China, South China, Northeast China, Northwest China and Southwest China, each with a designated sales and marketing team. Our respective sales and marketing teams for the U.S. market and other regions are based in China and are primarily responsible for coordinating with our major clients for the sales and distribution of our products in relevant markets.

Our penetration into local market and broad market exposure allow our sales and market team for enoxaparin sodium injection to design marketing strategies and engage in promotion activities in each region, based on respective market conditions, such as competitive landscape and regulatory environment. Specifically, each team is responsible for establishing and maintaining relationships with hospitals and other health institutions and increasing the awareness and recognition of our products among physicians in the covered region, through academic marketing activities and other promotional efforts. They also collect feedback on our products for further improvement. Besides, our sales team also coordinates with third-party promoters and distributors in the promotion and distribution of our products. Our management closely oversees the sales activities and results in the major markets and determine the sales and pricing policies in each market.

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### *Academic Marketing*

Our sales and marketing efforts are characterized by a strong emphasis on academic promotion, in order to promote and strengthen the awareness and recognition of our products and our brand among medical professionals. We have adopted different academic marketing strategies for our enoxaparin sodium injection products targeting different markets. In the EU, where in most countries, prescription of biosimilar enoxaparin sodium injection is based on brands, we need to proactively market our products to enhance the awareness of our brand names among physicians. To enter into each new market, we generally promote our brand-name products through introducing the advantages in quality, supply and price to physicians. We present Inhixa as the first EMA-approved enoxaparin biosimilar drug to demonstrate its outstanding quality and safety profile. SciencPharma has also published the comparative clinical trial results of Neoparin to prove the bioequivalence of Neoparin and the reference drug and the non-inferiority of the safety of Neoparin versus the reference drug in the prophylaxis of VTE in patients submitted to high VTE risk surgery. Additionally, we also demonstrate our capacity to fulfill the orders from hospitals and pharmacies by presenting our state-of-the-art manufacturing facilities and integrated supply chain. In China, different from the EU, the prescription of enoxaparin as an anticoagulant and antithrombotic drug has not been widely recognized and applied by physicians. Considering that the per capita use of enoxaparin in China was 0.04 dose, compared to the per capita use of 0.95 dose in the EU in 2019, academic promotion to raise physician’s awareness of enoxaparin sodium injection may enable us to take advantage of the significant growth potential. Other than introducing the advantages of our product, we explain to physicians from a pharmacology perspective, the safety and efficacy of enoxaparin sodium injection in treating various indications, as well as its advantages over other anticoagulant and antithrombotic drugs including other LWMH products. We also introduce to physicians that our manufacturing process and facilities have passed the GMP inspection of the NMPA, the EMA and the FDA.

We regularly organize and participate in various academic conferences, seminars and symposia, as well as smaller events tailored for specific cities and hospital departments. We invite leading experts in relevant therapeutic areas to speak on the latest developments and share their experience in the academic conferences, such as the latest application of enoxaparin sodium injection, their experience in using enoxaparin sodium injection as the anticoagulant in practice and its effect in treating different indications. We also set up exhibitions at large-scale academic conferences to present our products’ innovative and advantageous features.

We conduct academic marketing activities to establish and maintain relationships with key opinion leaders (“KOLs”), as well as department heads and senior physicians in our target hospitals. We provide these experts with detailed information on our products and help them make independent comparisons among competing products in the market. We depend on KOLs to introduce and recommend our products to physicians and hospitals. We have maintained regular contact with various KOLs, who are generally medical experts with substantial national or regional influence, especially in the anticoagulant field, and some hold leadership positions in national medical associations. Our sales and marketing team is responsible for establishing relationships with KOLs and introduce them the features of our products. We maintain lists of national and regional KOLs. We select KOLs primarily based on the therapeutic areas they specialize in, their professional qualifications and their reputation

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in the medical community. We also consider whether they have participated in clinical studies or published academic articles related to our products. Prescription of our products is not a criterion for our selection of KOLs. We provide KOLs with assistance in organizing high profile domestic and international academic conferences and seminars and conducting clinical studies. We maintain regular communication with the KOLs regarding the application of our products, and we also invite them to visit our facilities, where we present our integrated quality control management throughout the production process. We believe that KOLs’ independent reviews and studies of our products, which may be published in academic journals or shared in conferences and seminars, help increase the recognition of our products among the wider medical community. We do not pay KOLs for their promotion of our products, however, we may reimburse them for expenses incurred by their attendance of academic conferences, such as related travel expenses.

We target to establish relationships with department heads and senior physicians in the therapeutic areas targeted by our products. We generally provide them with assistance in organizing and attending regional academic conferences and conducting clinical studies in our targeted therapeutic areas. We sponsor the education of physicians by encouraging them to attend academic conferences pertaining to their specialization to learn about the latest medical advances and develop their professional skills. For conferences sponsored by us, we may reimburse these physicians for registration fees and traveling expenses through the academic associations that organize these conferences. We also organize communication among the physicians to discuss the latest development in relevant therapeutic fields.

### ***Our Sales and Marketing Team for API Products***

We have a dedicated sales and marketing team for each API product. We generally have long-term supply arrangement with our existing major customers, and potential purchasers tend to approach us directly in reliance on the high quality of our API products, and therefore, we tend to keep a lean and efficient sales and marketing team for our API products.

The team process purchase orders, arrange for delivery and engage in constant communication with our customers to assist with the sales of our products. Moreover, they are responsible for the marketing and promotion of our API products in conferences and exhibitions such as the Convention on Pharmaceutical Ingredients (CPhI). When we enter into a new market, our team will conduct research and connect with the leading regional manufacturers of heparin products and LMWH products to create sales and penetrate into the local market.

### **Our Distributors**

We sell a significant portion of our enoxaparin sodium injection to distributors, and we also sell some of our API products to distributors for their sales to pharmaceutical manufacturers. All of our CDMO services are directly offered to our customers. We believe that our sales arrangement is in line with market practice. In 2017, 2018 and 2019, our direct sales (including CDMO and other services) accounted for 82.2%, 75.5% and 69.3%, respectively, of our total revenue, our sales to distributors not through logistics providers accounted for 17.7%, 23.4% and 23.8%, respectively, of our total revenue, and a small portion of our sales were through logistics providers in the UK, Germany and Spain, either to distributors or to hospitals, which amounted to 0.1%, 1.1% and 6.9% of our total revenue in the respective years. For our sales of enoxaparin sodium injections through logistics providers, the logistics providers will assist us in transactions with customers in the respective regions, including



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distributors and hospitals. We will settle payments directly with logistics providers, and accordingly, our accounting system will record payment received from each logistics provider, rather than a breakdown of revenue from the sale to each customer. As a result, the revenue generated from our sales through logistics providers include both sales to distributors and sales to hospitals.

The following table sets forth a breakdown of revenue generated from our sales of both finished dose pharmaceutical products and API products to distributors not through logistics providers by region for the years indicated. Revenue from our sales of enoxaparin sodium injections to distributors through logistics providers is not included in the breakdown below.

	For the year ended December 31,					
	2017		2018		2019	
	RMB'000	%	RMB'000	%	RMB'000	%
Europe .....	253,766	50.6	749,738	66.7	661,567	60.3
China .....	180,704	36.0	313,317	27.9	306,381	27.9
U.S. ....	7,006	1.4	12,204	1.1	36,928	3.4
Other countries/regions .....	60,112	12.0	48,696	4.3	92,931	8.4
<b>Total</b> .....	<b>501,588</b>	<b>100.0</b>	<b>1,123,955</b>	<b>100.0</b>	<b>1,097,267</b>	<b>100.0</b>

The following table sets forth a breakdown of revenue generated from our sales of both finished dose pharmaceutical products and API products to distributors not through logistics providers by product for the years indicated. Revenue from our sales of enoxaparin sodium injections to distributors through logistics providers is not included in the breakdown below.

	For the year ended December 31,					
	2017		2018		2019	
	RMB'000	%	RMB'000	%	RMB'000	%
Finished dose pharmaceutical products						
Enoxaparin sodium injection .....	314,294	62.6	842,323	74.9	744,974	67.9
Heparin sodium injection .....	70,032	14.0	63,705	5.7	—	—
Subtotal .....	384,326	76.6	906,028	80.6	744,974	67.9
API						
Heparin sodium API .....	117,262	23.4	205,871	18.3	324,887	29.6
Enoxaparin sodium API .....	—	—	12,056	1.1	27,406	2.5
Subtotal .....	117,262	23.4	217,927	19.4	352,294	32.1
<b>Total</b> .....	<b>501,588</b>	<b>100.0</b>	<b>1,123,955</b>	<b>100.0</b>	<b>1,097,267</b>	<b>100.0</b>

Sales to distributors are material to our sales and distribution of enoxaparin sodium injections in China, Europe and other regions, since we rely on distributors’ extensive network of hospitals and pharmacies and logistics for distribution or in certain markets for promotion of our products. Additionally, in certain regions in China, we are required under the applicable PRC law to sell our enoxaparin sodium injections to hospitals through selected distributors. Sales to distributors are not material to our sales and distribution of API products, and did not constitute a substantial portion of our sales of API during the Track Record Period, accounting for 6.4%, 7.9% and 15.5% of our total revenue generated from sales of API in 2017, 2018 and 2019, respectively.

### *Selection of Distributors*

We select our distributors based on their qualifications, reputation, market coverage and sales experience. All of our distributors are independent third parties. To distribute our products, a



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distributor must maintain relevant licenses and permits, as well as extensive customer coverage in the designated region. For distributors who are responsible for the storage and delivery of our product, they should also have the capacity to store and deliver the product at appropriate conditions. We also conduct credit assessments of each of our distributors before we enter into a distribution agreement. We typically tend to terminate our relationships with distributors if their collaboration with the customers they cover is ended, or there are material non-compliance with the terms in the agreement, such as their failure to acquire or maintain marketing approval for the product, failure to fulfill the purchase or sales target or marketing or distribution of our competing products within the market assigned in the distribution agreement.

As of December 31, 2017, 2018 and 2019, we had a total of 407, 668 and 779 distributors for the sales of our products, respectively. The following table sets forth the changes in the number of our distributors for the years indicated:

	For the year ended December 31,		
	2017	2018	2019
As of the beginning of the year . . . . .	122	407	668
Additions of new distributors . . . . .	303	401	227
Termination of existing distributors . . . . .	18	140	116
Net increase in distributors . . . . .	285	261	111
As of the end of the year . . . . .	407	668	779

The table below sets forth the number of distributors by regions as of the dates indicated:

	As of December 31,		
	2017	2018	2019
EU . . . . .	138	258	310
China . . . . .	254	392	450
Countries other than the EU and China . . . . .	15	18	19
<b>Total</b> . . . . .	<b>407</b>	<b>668</b>	<b>779</b>

The increased number of distributors during the Track Record Period was primarily attributable to the increased number of distributors for enoxaparin sodium injection. The increased number of distributors in 2017 was primarily because we further increased our sales of our enoxaparin sodium injection in China and launched Inhixa in Italy, Germany and the UK in 2017. The increased number of distributors in 2018 was primarily because we further increased our sales of enoxaparin sodium injection in China and Germany and launched Inhixa in Spain in 2018. The increased number of distributors in 2019 was mainly because we further increased our sales of enoxaparin sodium injection in China, Germany and Italy in 2019. We terminated the distribution arrangement with 140 distributors in 2018, primarily because we replaced certain distributors in China, after their cooperation with the hospitals they were designated to cover ended, and we disposed our equity interests in Hepatunn in June 2018 and therefore terminated our relationship with distributors who distributed heparin sodium injections sold by Hepatunn. We terminated the distribution arrangement with 116 distributors in 2019, primarily because we replaced certain distributors in China, after their cooperation with the hospitals they were designated to cover ended. In general, the fluctuation of our additions of new distributors and termination of existing distributors during the Track Record Period was primarily in line with the market practice in both China and the EU, since each of our distributors only works with a limited number of hospitals or pharmacies, which requires us to appoint a substantial number of new distributors to expand our sales in the EU and China markets, and accordingly, replace a number of

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existing distributors when their sales to the designated hospitals or pharmacies were terminated. During the Track Record Period, among the distributor relationships that ended, the average length of our relationship before the termination was around 15 months, without taking into account of the termination unrelated to our sales and marketing activities, namely, as a result of our disposal of Hepatunn.

***Management of Distributors***

Our arrangement with each distributor varies for different products and in different markets, however, we generally keep a few principal terms, which are summarized in the table below:

Designated geographical regions and hospitals . . . . .	The geographical area within which a distributor is permitted to promote and distribute our products. Distributors with such territorial restriction cannot market or sell our products outside the designated region, and some may only sell our products to the assigned hospitals in the region. Such distributor is also prohibited from promoting and selling competing products in the designated region.
Transportation . . . . .	We are responsible for transporting our products to each distributor, and bear the costs and risk of loss of the transportation.
Product returns . . . . .	Generally, the purchaser may not return or exchange our products except for product quality issues at our fault. We should replace the defective products at our own costs within an agreed period.
Obsolete stock return . . . . .	None.
Termination . . . . .	If either of the parties breaches or defaults on any of its obligations under the agreement, and the breaching or defaulting party does not cure the breach or default within the period of time specified, then the non-breaching or non-defaulting party has the right to terminate the agreement.
Regulatory compliance . . . . .	The distributor is required to comply with all applicable laws and regulations, including, among other things, anti-bribery and anti-kickback laws and regulations. The distributor is also required to obtain relevant permits to sell and distribute medical devices and maintain storage facilities compliant with regulatory standards on medical device storage, and provide us with copies of the relevant licenses, permits and certificates.
Intellectual property rights . . . . .	The distributor shall have a non-sublicensable, nontransferable, non-assignable and non-exclusive right to use our trademark for selling our products in the designated area during the term of our distribution agreement. Our distributor shall not use the trademark for any other product and shall use the trademark only for the purpose of selling our products in accordance with the agreement.

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During the Track Record Period, our distributors of API products did not have any sub-distributor arrangement. With respect to the sale of our enoxaparin sodium injection, sub-distributor arrangement varies in different markets. In China, sub-distribution is prohibited by law. In the EU, in line with market practice, our distributors tend to sell some of our products to sub-distributors. We generally do not prohibit our distributors from engaging sub-distributors and we do not control their sales amount or price in such arrangement. In markets other than the EU, China and the U.S., the practice is similar to the EU market. Moreover, since we only sold heparin sodium injection in China during the Track Record Period, sub-distribution was prohibited by law.

During the Track Record Period, we generally maintained effective management and control over our distributors. We regularly communicate and conduct review with our distributors primarily regarding their inventory level, sales amount and marketing activities, as applicable. We have adopted various measures in place in order to avoid channel stuffing. With respect to our sales to distributors under the co-marketing model, in certain EU countries under consignment arrangement, since the title of the product is only transferred to the distributor when the product is withdrawn from the consignment stock for delivery to its customers, we generally do not encounter channel stuffing issues in relevant markets. In China, our distributors are typically required to provide monthly reports on their inventory volumes, which allow us to reduce the risk of channel stuffing and also review the performance of respective third-party promoters. With respect to our sales to distributors under the outsourced marketing model, some of the distributors are required to provide us with quarterly or yearly supply forecasts, which allow us to reserve capacity, plan our manufacturing activities and prepare for the supply to our distributors based on market demand, and thereby reducing the risk of channel stuffing. With respect to our sales to distributors under the in-house marketing model, although we do not directly monitor the inventory and sales volume of each distributor, if a logistics provider is involved, we generally receive a weekly or a monthly product flow report, which sets forth, among others, date of sale, customer name, unit price and sales volume, relating to that logistics provider. In addition, under the in-house marketing model, we also review the volume of products we sold to distributors in the respective country, against the sales volume of our products in the respective country, through our access to the IQVIA or local databases. The communication with logistics providers and review of sales volume can assist us with detecting the existence of channel stuffing. Our monitor of distributors' activities allows us to reasonably allocate and transfer our products among the distributors and us, which helps to avoid product stock-up and ensure sufficient supply and circulation of our products in the local market. For example, in 2019, we purchased certain amount of enoxaparin sodium injection from one distributor in Italy at the same price they purchased from us, in order to meet the demand from local tender process.

During the Track Record Period, our distributors did not materially breach our contract terms, and we did not have any material disputes with our distributors relating to the settlement of trade receivables. As of the Latest Practicable Date, we were not aware of any potential abuse or improper use of our name by our distributors, which could adversely affect our reputation, business operation or financial contribution.

## **PRICING**

### ***Pricing of Enoxaparin Sodium Injection***

In certain major markets of our enoxaparin sodium injection, including the EU and China, we negotiate with relevant government for the ceiling price of our product's retail price or allowable reimbursement under national medical insurance. To ensure our profitability, we generally target to set

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a price near the high end as allowed by the pricing policies. In markets where there is a ceiling price of our product, we are able to take advantage of our integrated supply chain that covers raw material supply to manufacturing of APIs to the sales of enoxaparin sodium injections, to improve our cost efficiency and thereby securing or enhancing our profitability. Moreover, we believe our first-mover position in the EU market can be advantageous to us during our pricing negotiation with relevant government. We do not expect that in the immediate or mid-terms, the current pricing policies and practice in countries where our enoxaparin sodium injection is marketed will have any material adverse impact on our sales and pricing in the respective markets.

### *EU and UK*

Our enoxaparin sodium injections are covered by national medical insurance in 11 EU countries and the UK. Suppliers need to negotiate with local governmental authorities for the listing price of their pharmaceutical products, which will be the ceiling price at which such pharmaceutical products can be sold in the market. Each country may have its own policy regarding the listing price of biosimilar drugs in comparison with their reference drugs. In some major markets such as Poland, Spain and Italy, the listing price or the reimbursement price for the biosimilar drug is required by relevant laws or regulations to be lower than the price of the respective reference drug. In other major markets including UK and Germany, though the regulatory authority does not set a ceiling price for the biosimilar drug, its listing price or reimbursement price is generally not higher than the price of the respective reference drug in the market. For the sales to the pharmacies, the price generally follows the listing price.

For the sales to hospitals, suppliers are generally required to go through a public bidding process to be selected as the supplier for hospitals in the respective regions. Selection of bidders and drugs primarily takes into consideration of several factors, including the drug's offer price, potential effect and quality and the supplier's capacity to provide the amount of drugs requested by the hospitals. If we win the bids in the bidding process, our enoxaparin sodium injection will be sold to hospitals at the bid prices, which primarily determines the prices at which we sell our product to our distributors. For the sales to some hospitals in certain markets, the sales price are determined based on our negotiation with each hospital.

For our sales to distributors pursuant to a distribution agreement between the distributor and us, our enoxaparin sodium injection is sold at a fixed price set in the agreement, which may vary depending on the market conditions in different regions, taking into account of our cost of sales, our target gross profit margin, the margin for our distributor, the distributor's purchase amount and services provided by the distributor, such as marketing and promotion efforts. The fixed purchase price is negotiated and determined, based on the retail price at which the products will be sold to the distributor's customers. We are mindful of keeping a reasonable gap between the retail price, and our average selling price to the distributor. For our sales to some of our distributors, mainly wholesalers with which we do not enter into distribution agreement, our products are sold at a wholesale price set by relevant laws and regulations based on the retail price of our enoxaparin sodium injection.

### *China*

During the Track Record Period, we sold enoxaparin sodium injection in China to our distributors who then sold to public hospitals and other public medical institutions. In May 2015, seven state agencies in China including the NDRC and the NMPA issued a notice regarding pharmaceutical

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price reform, pursuant to which government price controls on pharmaceutical products (other than narcotic drugs and Class I psychiatric drugs) were lifted starting June 1, 2015, allowing for a more market-based drug pricing system. Meanwhile, the PRC government continues to regulate prices mainly through a centralized tender process, medical insurance reimbursement standards and regulation of medical and pricing practices. During the Track Record Period, the NDRC price adjustments, the centralized tender process or the inclusion in the NRDL did not have a material negative impact on our results of operations.

Our enoxaparin sodium injection, Prolongin, has been included in the NRDL since 2015, with a tender price based on the negotiation with the government, as the ceiling price of allowable reimbursement under the national medical insurance. Each public medical institution must make substantially all of their purchases of pharmaceutical products through a centralized tender process. The centralized tender process is held in different provinces and cities across China with varying terms, procedures and preferences and is usually organized at the national, provincial or city levels. The frequency that a drug is required to resubmit a tender under the centralized tender process varies across different provinces, which generally ranges from two to three years. Please refer to “Regulatory Overview—PRC Laws and Regulations in Relation to the National Medical Insurance and Price of Pharmaceutical Products—Drug Purchase by Hospitals” for further details of the centralized tender process in China. The selection of the winning bidder is based on a number of criteria, including bid price, product quality, clinical effectiveness, qualifications and reputation of the manufacturer and after-sale services. The successful bid price in the centralized tender process dictates the price at which distributors sell the relevant product to the relevant public medical institutions. If we are successful in winning bids in the centralized tender process, our enoxaparin sodium injection under the brand name Prolongin will be sold to public medical institutions at the bid prices, which primarily determines the prices at which we sell our product to our distributors. Our bidding strategy generally focuses on differentiating our product instead of competing solely based on pricing.

Our sales and marketing department and our third-party promoters work closely to monitor new policies affecting the pricing of pharmaceutical products in China, and formulate strategies to stay competitive and profitable. Our sales and marketing team designated for different regions actively communicates with the local authorities in charge of the public tendering process, studies the tendering proposals, including minimum bidding requirements, if any, pricing trends for each strength and format of our product and of our competitor products on a province-by-province basis to form a bid. Our sales and marketing department also creates and executes a master plan to cope with competition in different provinces, with the goal of maintaining the price levels of our product and maximizing our overall sales in China.

There have been certain changes in regulatory policies that may affect the price of our Prolongin enoxaparin sodium injection. The PRC government launched the national pilot scheme for tendering with minimum procurement quantities in November 2018, which is aimed at reducing drug prices. Please refer to “Regulatory Environment—Other Related Regulations in the PRC Pharmaceutical Industry—The Drug Centralized Procurement in ‘4+7 Cities’ and Wider Areas.” Although it is a pilot program, this scheme for tendering with minimum procurement quantities has resulted in increased pricing pressure on us. Please refer to “Risk Factors—Risks Relating to Our Business and Industry—The retail prices of certain of our products are subject to price control or downward adjustment by the government authorities or other pricing pressure.” for further details of risks associated with pricing regulation. Moreover, the NMPA requires existing generic drugs to undergo QCE. See “Regulatory Environment—Laws and Regulations Related to Our Business in the

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PRC—Regulations on Drug Research and Development & Registration Services—Drug Registration.” Generic drugs that have passed QCE are afforded certain advantages, including preferential treatment in centralized tender process. We have submitted application for QCE approval of Prolongin in April 2018. Once Prolongin obtains the QCE approval, it is expected to significantly increase our product’s sales potential.

### *U.S.*

We have entered into a supply agreement with a multinational pharmaceutical company for its sale of enoxaparin sodium injection in the U.S. The purchase price for each strength as stipulated in the agreement is subject to adjustments on a semi-annual basis having regard to, among other things, our costs for crude heparin sodium and comparable prices of other third-party suppliers.

### *Other Markets*

For our sales of enoxaparin sodium injection in other regions, the price may vary depending on the market conditions in each local market, taking into account of our cost of sales, our target gross profit margin and the customer’s purchase amount, and subject to periodic renewal or based on parties’ mutual agreement.

### *Pricing of API products*

Governments generally do not set a controlling price on the API products and there will not be a listing price or ceiling price for the API products in the market, as the API products are not directly applied to patients and are not covered by any medical insurance. We sell our API products to our customers at the prices set in the supply agreements, which generally take into consideration of the market price, our cost of sales, our target profit margin, term of the agreement and the purchase amount. We generally build in the agreement a price schedule that lays out the price for each month or year under normal market conditions during the term of the agreement and ensure that the price can be periodically re-negotiated or changed based on parties’ mutual consent, so that we can adjust our sales price as a prompt response to events such as outbreak of swine fever that may significantly affect the costs of our raw materials.

## CUSTOMERS

For the years ended December 31, 2017, 2018 and 2019, the aggregate sales to our five largest customers were approximately RMB1,707.8 million, RMB2,873.8 million and RMB2,218.3 million, representing approximately 60.4%, 59.9%, and 48.2% of our revenue for the same years, respectively. Sales to our largest customer for the same years were approximately RMB1,126.9 million, RMB1,804.7 million and RMB1,036.6 million, representing 39.8%, 37.6% and 22.5% of our revenue for the same years, respectively.



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One of our five largest customers in 2017, 2018 and 2019 was a distributor. Please see below a summary of the sales to our five largest customers for the years indicated:

Five Largest Customers for the year ended December 31, 2017	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Our Products	Sales Amount RMB'000	Percentage of Revenue
Customer A . . . . .	A public multinational pharmaceutical company that engages in the development, production and sales of pharmaceutical products in various therapeutic areas, with its principal place of business in France	<ul style="list-style-type: none"> <li>• A multinational company with offices and facilities in over 100 countries and sales in over 150 countries</li> <li>• Customer group had net sales of over EUR35 billion in 2019</li> </ul>	Heparin sodium API	1,126,899	39.8%
SciencePharma Sp. z o.o.Sp.k . . . . .	A professional service provider for pharmaceutical industry in the fields of CMC, non-clinical and clinical development, pharmacovigilance and regulatory affairs, with its principal place of business in Poland	Specializing in the EU regulations on medical industry and requirements of local health authorities in Poland	Enoxaparin sodium injection, medical communication service	214,547	7.6%
Customer C . . . . .	A pharmaceutical company with its principal place of business in Singapore	<ul style="list-style-type: none"> <li>• A subsidiary of a leading American multinational pharmaceutical company with sales in over 120 countries</li> <li>• Customer group had a total revenue of over US\$50 billion in 2019</li> </ul>	Heparin sodium product	166,987	5.9%
Chemi S.p.A . . . . .	A pharmaceutical manufacturer that specializes in the manufacturing of API and injectable products, with its principal place of business in Italy	<ul style="list-style-type: none"> <li>• Sales to major global markets</li> <li>• A subsidiary of a leading Italian pharmaceutical company with sales in over 10 countries</li> </ul>	Heparin sodium API	114,731	4.1%
Customer E . . . . .	An API pharmaceutical manufacturer with its principal place of business in Turkey	Sales and services primarily in the Middle Eastern market and the EU market, with exports to over 20 countries	Heparin sodium API, enoxaparin sodium API	84,589	3.0%
<b>Total . . . . .</b>				<b><u>1,707,753</u></b>	<b><u>60.4%</u></b>

Note:

(1) Company background and scale of operation are based on public information.

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**Five Largest Customers for the year ended December 31, 2018**

	<b>Company Background<sup>(1)</sup></b>	<b>Scale of Operation<sup>(1)</sup></b>	<b>Our Products</b>	<b>Sales Amount</b> RMB'000	<b>Percentage of Revenue</b>
Customer A . . .	A public multinational pharmaceutical company that engages in the development, production and sales of pharmaceutical products in various therapeutic areas, with its principal place of business in France	<ul style="list-style-type: none"> <li>A multinational company with offices and facilities in over 100 countries and sales in over 150 countries</li> <li>Customer group had net sales of over EUR35 billion in 2019</li> </ul>	Heparin sodium API	1,804,652	37.6%
SciencePharma Sp. z o.o.Sp.k . . .	A professional service provider for pharmaceutical industry in the fields of CMC, non-clinical and clinical development, pharmacovigilance and regulatory affairs, with its principal place of business in Poland	Specializing in the EU regulations on medical industry and requirements of local health authorities in Poland	Enoxaparin sodium injection, medical communication service	471,461	9.8%
Customer C . . .	A pharmaceutical company with its principal place of business in Singapore	<ul style="list-style-type: none"> <li>A subsidiary of a leading American multinational pharmaceutical company with sales in over 120 countries</li> <li>Customer group had total revenue of over US\$50 billion in 2019</li> </ul>	Heparin sodium product	226,402	4.7%
Customer F . . .	A biotech company that focuses on the development of novel therapies for treating neurological disorders, with its principal place of business in New York, U.S.	Major product candidate at late-clinical stage	Pancreatin API	204,675	4.3%
Customer G . . .	A biotech company that develops immuno-oncology treatments, with principal place of business in California, U.S.	<ul style="list-style-type: none"> <li>Major product candidates at early development stage</li> <li>A subsidiary of an American multinational pharmaceutical company with products marketed in over 120 countries</li> <li>Customer group had total revenue of over US\$20 billion in 2019</li> </ul>	CDMO service	166,618	3.5%
<b>Total . . . . .</b>				<b>2,873,808</b>	<b>59.9%</b>

Note:

(1) Company background and scale of operation are based on public information.

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Five Largest Customers for the year ended December 31, 2019	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Our Products	Sales Amount RMB*000	Percentage of Revenue
Customer A . . . .	A public multinational pharmaceutical company that engages in the development, production and sales of pharmaceutical products in various therapeutic areas, with its principal place of business in France	<ul style="list-style-type: none"> <li>A multinational company with offices and facilities in over 100 countries and sales in over 150 countries</li> <li>Customer group had net sales of over EUR35 billion in 2019</li> </ul>	Heparin sodium API	1,036,608	22.5%
SciencePharma Sp. z o.o.Sp.k . . . .	A professional service provider for pharmaceutical industry in the fields of CMC, non-clinical and clinical development, pharmacovigilance and regulatory affairs, with its principal place of business in Poland	Specializing in the EU regulations on medical industry and requirements of local health authorities in Poland	Enoxaparin sodium injection, medical communication service	386,723	8.4%
Customer G . . . .	A biotech company that develops immuno-oncology treatments, with principal place of business in California, U.S.	<ul style="list-style-type: none"> <li>Major product candidates at early development stage</li> <li>A subsidiary of an American multinational pharmaceutical company with products marketed in over 120 countries</li> <li>Customer group had total revenue of over US\$20 billion in 2019</li> </ul>	CDMO service	294,916	6.4%
Customer E . . . .	An API pharmaceutical manufacturer with its principal place of business in Turkey	Sales and services primarily in the Middle Eastern market and the EU market, with exports to over 20 countries	Enoxaparin sodium API	257,437	5.6%
Customer C . . . .	A pharmaceutical company with its principal place of business in Singapore	<ul style="list-style-type: none"> <li>A subsidiary of a leading American multinational pharmaceutical company with sales in over 120 countries</li> <li>Customer group had total revenue of over US\$50 billion in 2019</li> </ul>	Heparin sodium product	242,640	5.3%
<b>Total . . . . .</b>				<b><u>2,218,324</u></b>	<b><u>48.2%</u></b>

**Note:**

(1) Company background and scale of operation are based on public information.

## **BUSINESS**

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During the Track Record Period, none of our Directors or any Shareholders, who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following the completion of the [REDACTED] (but without taking into account the exercise of the [REDACTED]) nor any of their respective associates had any interest in any of our five largest customers.

### **RESEARCH AND DEVELOPMENT**

Our R&D activities primarily include the improvement of the technologies relating to our existing products, and the R&D of our innovative pipeline drugs, through a combination of investing and licensing in drug candidates with significant market potential, collaboration with CROs and involving our CDMO team in the R&D of our drug candidates from preclinical stage to commercialization stage. We plan to continue to diversify and expand our product pipeline through both in-house research and development, investment and collaboration with CROs and our own CDMO team.

We employ a clinical-demand-oriented and market-driven approach to our R&D efforts. Our experienced R&D team identifies innovative product candidates with significant market potential, conducts preclinical development and clinical trials, and ultimately assists with the commercialization of these products. We carefully select drug development programs by balancing the commercial potential of each drug candidate and its likelihood of successful development, its potential competition and market size.

As of the Latest Practicable Date, our R&D team consisted of 335 employees. Our R&D team in China is led by Dr. Lige Ren, who holds a Ph.D degree in chemistry, and has over 10 years in the field of biotechnology, including the R&D of heparin and enoxaparin products and innovative drugs. 273 of our employees are holders of bachelor or above degrees, including 34 Ph.Ds, most of whom have extensive working experience in the healthcare and biotechnology research fields.

#### **R&D Center**

In order to enhance our capacity in technology innovation and cultivate our core competitiveness, we founded our R&D center in 2008, primarily focusing on development of innovative drugs and providing technology support to our commercialized pharmaceutical products. The R&D center consists of major groups, including R&D service, operation support and overall management.

Our R&D center’s operation support group primarily includes the administration of R&D projects through establishing development management system, providing technology and professional support for the team’s R&D services and the training of R&D personnel. The management group focuses on the administration and allocation of R&D resources. The R&D service group primarily takes responsibilities listed below, including R&D information technology, early-stage R&D, preclinical R&D, pharmaceutical R&D and technology support to the commercialized pharmaceutical products.

- R&D information technology: The team provides technology evaluation of the projects we invested during the stages of project selection and due diligence, based on which the team provides suggestions regarding investment decision-making.
- Early-stage R&D: The team explores new R&D opportunities, conducts feasibility research and provides evaluation opinion for the opportunities. The team also designs and

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prepares new types of chemical compounds, conducts systematic research regarding the manufacturing process and quality management of the new drugs, and develops technology platforms to support, manage and supervise the related technologies.

- Preclinical R&D: The team coordinates and accomplishes preclinical R&D activities in relation to pharmacology, efficacy, toxicology, and safety. The team also assists in the registration process of the new drugs by collecting and preparing the required information and materials.
- Pharmaceutical R&D: The team conducts extensive early-stage investigation on drug candidates. The team also develops and optimizes our proprietary technologies in the manufacturing process and quality control of our API products and enoxaparin sodium injection products in accordance with the ICH guidelines and QbD principles, after which the team will assist in the transfer of manufacturing technology to our manufacturing department.
- Technology support to the commercialized pharmaceutical products: The team stipulates specific activity plans and provides technology support at each stage of the products’ commercialization, in order to accommodate the continuing improvement of our supply chains, production and operation, quality management requirements, and our customers’ and market demands. Such improvement will help enhance our technology levels and ensure the quality consistency of our products.

### Collaboration with Third Parties

During the Track Record Period, our portfolio companies primarily conducted the R&D of our drug candidates that we obtained exclusive development and commercial rights in Greater China from them. We plan to gradually participate in the clinical trial for our drug candidates in China as part of their global trial under the MRCT. For AR-301, our subsidiary, Shenzhen Arimab, is in charge of employing the principal investigators for the clinical trial of AR-301 in China. Shenzhen Arimab has entered into a master service agreement with an international CRO, under which, we provide separate work order with detailed specification and schedule that the CRO should follow in providing services for each clinical trial, such as the clinical trial for AR-301 to be conducted in China. Pursuant to the agreement, the CRO is required to perform its services in accordance with the standard operating procedures as set out in each work order that specifies the tasks and responsibilities of the CRO with respect to each project, which are designed based on the applicable regulatory authority requirements defined by the ICH-GCP guidelines.

With respect to our self-developed drug candidate, our in-house R&D team plays a leading role in the design and management of the R&D projects, and outsources the execution work to leading CROs.

### R&D in CDMO Business

We provide various R&D services for our clients. For details, see “—Our CDMO Business—R&D Services.” Our R&D team for CDMO services is led by Dr. Jesse D. McCool, Cytovance’s chief executive officer, who has over 20 years of practice in the biotech field. As of the Latest Practicable Date, we had an experienced R&D team consisting of 144 people, among which, 24 possessed a doctorate degree and 23 had a master degree.

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In addition, Cytovance currently participates as a fee-for-service CDMO vendor in the development of certain of our drug candidates. OncoQuest has been a customer of Cytovance since 2016 for the development of Oregovomab, and OncoVent has been a customer since 2019 for the development of mAb-AR20.5. The work completed for Oregovomab includes process development and one scale-up manufacturing batch for phase III clinical supply. The work completed for mAb-AR20.5 includes process development.

## MANUFACTURING

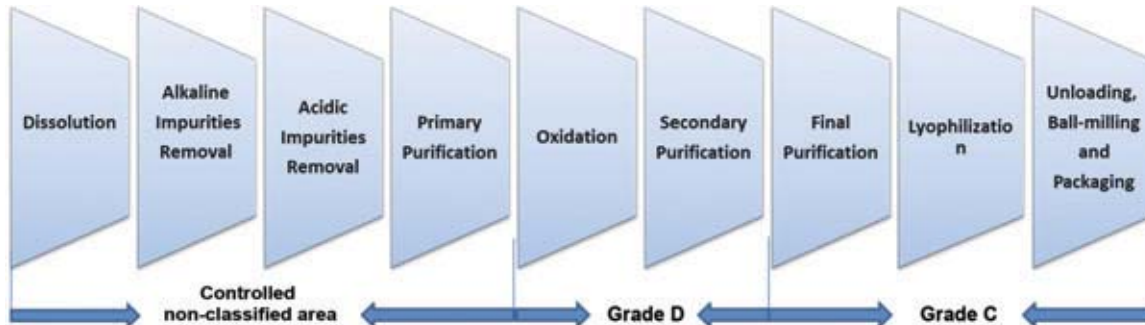
We currently manufacture most of our biopharmaceuticals at our production facilities in Shenzhen, China and SPL's production facilities in Waunakee, Wisconsin, the U.S. We also outsource a small portion of the manufacturing of enoxaparin sodium injection to our OEM partner. Substantially all packaging activities in relation to these products in the PRC are conducted at our Shenzhen facilities.

We generally manufacture our products based on quarterly and monthly order forecasts. We expect that our existing manufacturing facilities and our OEMs will allow us to meet manufacturing needs for our biopharmaceuticals and product candidates that are in clinical trials in the near future.

### Manufacture of Our Products

#### *Manufacturing Process*

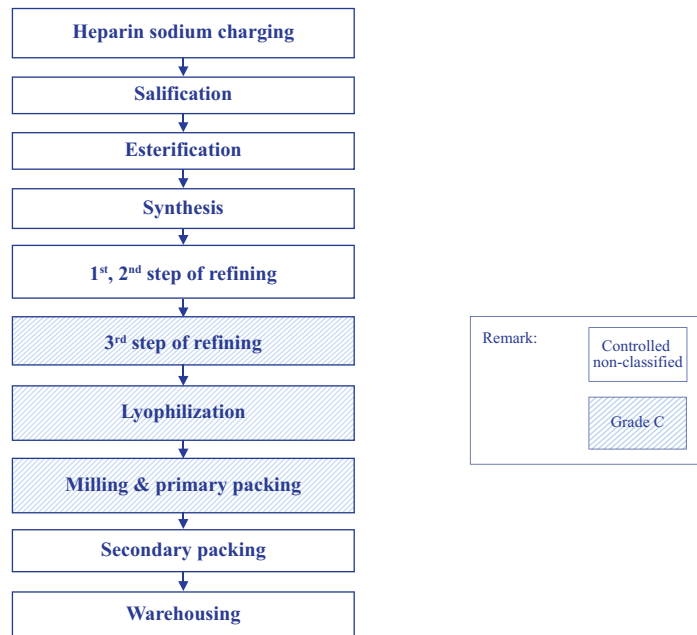
The following diagram summarizes the manufacturing process for our heparin sodium API:



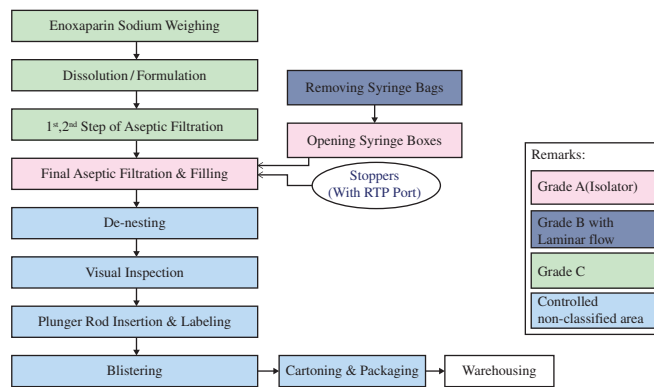


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The following diagram summarizes the manufacturing process for our enoxaparin sodium API:



The following diagram summarizes the manufacturing process for our enoxaparin sodium injection in the format of pre-filled syringes:



***Our In-House Manufacturing Activities***

Most of our production activities are currently carried out at our Techdow Nanshan, Hepalink Nanshan and SPL facility. We have also completed the construction and process validation of our Pingshan Industrial Park located in Shenzhen, China, which is expected to significantly enhance our manufacturing capacity. Our key production processes are highly automated and can be used to produce our enoxaparin sodium injection in different strengths. Therefore, we are able to adjust our production to meet market demand and our sales target in response to market demand. As of the Latest Practicable Date, we believe our facilities and equipment are in good working condition. We own all of our production facilities and workshops. We conduct regular maintenance and repair work in compliance with applicable CGMP requirements.

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The following table sets forth the designed capacity, production volume and utilization rates of our production sites:

	For the year ended December 31,		
	2017	2018	2019
<b>Hepalink Nanshan</b>			
<i>Heparin sodium API (mega)</i>			
Designed production capacity .....	10,000,000	10,000,000	10,000,000
Production volume .....	5,501,814	6,877,959	5,049,204
Utilization rate <sup>(1)(2)</sup> .....	55.0%	68.8%	50.5%
<b>Techdow Nanshan</b>			
<i>Enoxaparin sodium API (kg)</i>			
Designed production capacity .....	9,350	9,350	9,350
Production volume .....	4,672	8,815	8,330
Utilization rate <sup>(1)(3)</sup> .....	50.0%	94.3%	89.1%
<i>Enoxaparin sodium Injection (pre-filled syringes)</i>			
Designed production capacity .....	80,000,000	80,000,000	160,000,000
Production volume .....	28,090,714	77,122,674	113,997,211
Utilization rate <sup>(1)(4)</sup> .....	35.1%	96.4%	71.2%
<b>SPL</b>			
<i>Heparin sodium API (mega)</i>			
Designed production capacity .....	3,000,000	3,000,000	3,000,000
Production volume .....	2,078,644	2,116,517	1,870,184
Utilization rate <sup>(1)(5)</sup> .....	69.3%	70.6%	62.3%

*Notes:*

- (1) Utilization rate equals actual production volume divided by designed production capacity.
- (2) The increase in the utilization rate from 2017 to 2018 was primarily attributable to a significant increase in the production volume of our finished dose pharmaceutical products driven by an increasing demand from our EU market, and the decrease in the utilization rate from 2018 to 2019 was primarily due to decreased raw material supply as a result of the outbreak of swine fever and the decrease in market demand.
- (3) The increase in the utilization rate from 2017 to 2018 was primarily attributable to a significant increase in the production volume of our finished dose pharmaceutical products driven by our increased sales in the EU market. The utilization rate remained relatively stable in 2019.
- (4) The increase in the utilization rate from 2017 to 2018 was primarily attributable to a significant increase in the production volume of our enoxaparin sodium injection products driven by our increased sales in the EU market. The decrease in the utilization rate from 2018 to 2019 was primarily attributable to a substantial increase in the production capacity as a result of our launch of a new production line.
- (5) The decrease in the utilization rate from 2018 to 2019 was primarily due to the decrease in the raw materials we acquired.

### ***Collaboration with Our OEM Partner***

16.1%, 2.4% and 3.3% of the enoxaparin sodium injections we sold in 2017, 2018 and 2019, respectively, were produced by our OEM partner, which accounted for a small portion of our revenue in the respective years. We entered into a manufacturing agreement and a quality agreement with an Independent Third Party as our OEM partner for a term of five years, subject to automatic renewal unless otherwise notified by either party. Our OEM partner is a private company that primarily engages in the development and manufacture of vaccine and biological agents. We select our OEM partner based on various factors, such as its operating history, market reputation, relevant expertise, internal quality control system, production technology, CGMP certification, production capacity and pricing. We did not experience any product quality issues in respect of the products manufactured by our OEM partner during the Track Record Period. We believe that there are other alternative OEM partners, who can meet our quality standards at comparable prices.

Under the manufacturing agreement, we are responsible for providing the required API for our OEM partner to fulfill our orders. Our OEM partner is responsible for manufacturing enoxaparin sodium injections in accordance with product specifications in the quality agreement, in compliance

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with CGMP requirements and our quality standards. We grant our OEM partner right to use our intellectual property rights for such manufacturing and packaging activities during the contract period. We are entitled to inspect and audit our OEM partner’s manufacturing process. Our OEM partner is not allowed to directly or indirectly manufacture LMWH products for any other parties in any market, during the contract period. Upon certain upscaling of our OEM partner’s production capacity, we are obligated to order a minimum amount of enoxaparin sodium injection each year and accordingly our OEM partner is bound to reserve us with a minimum amount of production capacity to fulfill our orders. As of the Latest Practicable Date, our OEM partner was still in the process of upscaling its production capacity, and thus we were not committed to any minimum order amount. Our OEM partner is also required to acquire and maintain all relevant permits and certificates. If our sales of enoxaparin sodium injection drops by more than 20% or we terminate our sales in the respective markets, we are entitled to terminate the manufacturing agreement or reduce our order amount. Our OEM partner receives processing fees according to a price schedule in the agreement, which sets per unit fees for respective production volumes, taking into account our OEM partner’s costs in the process, subject to periodic review and negotiation. Our OEM partner’s processing fees amounted to RMB18.3 thousand, RMB15.8 thousand and RMB10.4 thousand in 2017, 2018 and 2019, respectively.

### Our CDMO Manufacturing Services

Cytovance operates the manufacturing services from facilities in Oklahoma City, Oklahoma, the U.S. The facilities in total include over 3,300 sq.m of CGMP-compliant manufacturing clean room and quality control area consisting of laboratories, and additional facilities that house our process development, analytical development and administrative functions. As of the Latest Practicable Date, Cytovance had three production lines: microbial production line, mammalian cell culture production line and pDNA production line. Each of the production lines has facilities with different designed capacities.

SPL’s CDMO manufacturing services are not product line based and highly customized for each project. SPL operates from its facility at Wisconsin, U.S., with 278 sq.m. of CGMP-compliant manufacturing clean room and additional space and facilities for quality control laboratories.

The following table sets forth the manufacturing capacity and utilization rates of Cytovance production lines during the Track Record Period:

	<b>For the year ended December 31,</b>		
	<b>2017</b>	<b>2018</b>	<b>2019</b>
	(in l)		
<b>Cytovance</b>			
<i>Mammalian cell culture</i>			
Designed production capacity	14,800	14,800	22,000
Production volume	9,600	7,900	5,600
Utilization rate <sup>(1)(2)</sup>	64.9%	53.4%	25.5%
<i>Microbial fermentation</i>			
Designed production capacity	5,670	18,670	39,270
Production volume	4,620	17,490	31,890
Utilization rate <sup>(1)(3)</sup>	81.5%	93.7%	81.2%

Notes:

(1) Utilization rate equals actual production volume divided by designed production capacity.

(2) The decrease in the utilization rate from 2017 to 2018 was primarily attributable to personnel changes in our business development team resulting in a temporary slow-down in expanding our client relationships, which, together with our increased production capacity, led to the further decrease in the utilization rate in 2019.

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- (3) The utilization rate increased from 2017 to 2018, as we achieved a nearly full utilization of our increased microbial fermentation capacity in 2018, primarily because our projects at the time enabled us to put the new facilities into operation. The utilization rate decreased to a normal level in 2019, as our production capacity significantly increased from 2018 to 2019.

### **RAW MATERIALS AND SUPPLIERS**

#### **Our Suppliers**

For the years ended December 31, 2017, 2018, and 2019, purchases from our five largest suppliers in aggregate accounted for 32.7%, 22.5% and 22.4% of our total purchases (including value added tax), respectively, and purchases from our largest supplier accounted for 9.6%, 9.3% and 6.8% of our total purchases for the same years (including value added tax), respectively. During the Track Record Period, our purchases mainly include raw materials, machines and equipment and services from third parties such as syringes and porcine small intestines.

The table below sets forth the procurement of our top five suppliers. We have worked together with the majority of our top five suppliers for an average of three years. During the years ended December 31, 2018 and 2019, we sold porcine small intestines to Supplier A, and the revenue and gross profit attributable to such sales represented around 0.13% and 0.07% of our total revenue and around 0.02% and 0.02% of our gross profit, respectively. During the same years, we sold porcine small intestines to Supplier C, which contributed to around 0.05% and 0.14% of our total revenue in 2018 and 2019, respectively and generated gross loss in the respective years. During the same years, we provided examination services to Supplier D, and the revenue and gross profit attributable to such services represented around 0.04% and 0.05% of our total revenue, and around 0.09% and 0.13% of our gross profit, respectively. None of our Directors or any Shareholder who, to the knowledge of our Directors, owns more than 5% of our issued share capital immediately following completion of the [REDACTED] (but without taking into account the exercise of the [REDACTED]) nor any of their respective associates had any interest in any of our five largest suppliers during the Track Record Period.

**Five Largest Suppliers for the year ended December 31, 2017**

<b>Five Largest Suppliers for the year ended December 31, 2017</b>	<b>Company Background<sup>(1)</sup></b>	<b>Scale of Operation<sup>(1)</sup></b>	<b>Purchases</b>	<b>Purchase Amount</b>	<b>Percentage of Total Purchases</b>
				<b>RMB'000</b>	
Supplier A . . .	A supplier of crude heparin, sausage casing and other sideline products, with its principal place of business in Jiangsu, China	Operation and sales primarily in China	Crude heparin	185,301	9.6%
Supplier B . . .	A supplier of crude heparin and sausage casing, with its principal place of business in Hubei, China	Operation and sales primarily in China	Crude heparin	152,571	7.9%

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## BUSINESS

Five Largest Suppliers for the year ended December 31, 2017	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Purchases	Purchase Amount RMB'000	Percentage of Total Purchases
Supplier C . . .	A supplier of crude heparin, sausage casing and other sideline products, with its principal place of business in Jiangxi, China	Operation and sales primarily in China	Crude heparin	115,608	6.0%
Supplier D . . .	A supplier of disposal medical supplies, with its principal place of business in Shanghai, China	<ul style="list-style-type: none"> <li>• A subsidiary of an American medical technology company with global sales in over 150 countries</li> <li>• Supplier group had a total revenue of over US\$15 billion in 2019</li> </ul>	Syringes	90,355	4.7%
Supplier E . . .	A food processing company, with its principal place of business in Colorado, U.S.	<ul style="list-style-type: none"> <li>• A company with global operations that sells products in more than 80 countries</li> <li>• A subsidiary of world-leading Brazilian meat processing Company with exports to over 150 countries</li> <li>• Supplier group had a net revenue of over R\$180 billion in 2018</li> </ul>	Porcine mucosa and porcine pancreas	86,568	4.5%
<b>Total . . . . .</b>				<b><u>630,403</u></b>	<b><u>32.7%</u></b>

*Note:*

(1) Company background and scale of operation are based on public information.

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Five Largest Suppliers for the year ended December 31, 2018	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Purchases	Purchase Amount RMB'000	Percentage of Total Purchases
Supplier D . . .	A supplier of disposal medical supplies, with its principal place of business in Shanghai, China	<ul style="list-style-type: none"> <li>A subsidiary of an American medical technology company with global sales in over 150 countries</li> <li>Supplier group had a total revenue of over US\$17 billion in 2019</li> </ul>	Syringes	257,976	9.3%
Supplier E . . .	A food processing company, with its principal place of business in Colorado, U.S.	<ul style="list-style-type: none"> <li>A company with global operations that sells products in more than 80 countries</li> <li>A subsidiary of world-leading Brazilian meat processing Company with exports to over 150 countries</li> <li>Supplier group had a net revenue of over R\$180 billion in 2018</li> </ul>	Porcine mucosa and porcine pancreas	106,241	3.8%
Supplier C . . .	A supplier of crude heparin, sausage casing and other sideline products, with its principal place of business in Jiangxi, China	Operation and sales primarily in China	Crude heparin	95,623	3.5%
VWR International LLC . . . . .	A supplier of laboratory products, with its principal place of business in Pennsylvania, U.S.	<ul style="list-style-type: none"> <li>A company with global manufacturing and sales activities in more than 30 countries</li> <li>A subsidiary of a global manufacturer and distributor of products and services to life sciences industries that serves customers in over 180 countries</li> <li>Supplier group had a total revenue of over US\$6 billion in 2019</li> </ul>	Raw material for CDMO Service	83,968	3.0%
Supplier A . . .	A supplier of crude heparin, sausage casing and other sideline products, with its principal place of business in Jiangsu, China	Operation and sales primarily in China	Crude heparin	79,142	2.9%
<b>Total . . . . .</b>				<b><u>622,950</u></b>	<b><u>22.5%</u></b>

Note:

(1) Company background and scale of operation are based on public information.



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Five Largest Suppliers for the year ended December 31, 2019	Company Background <sup>(1)</sup>	Scale of Operation <sup>(1)</sup>	Purchases	Purchase Amount RMB*000	Percentage of Total Purchases
Supplier D . . . . .	A supplier of disposal medical supplies with its principal place of business in Shanghai, China	<ul style="list-style-type: none"> <li>A subsidiary of an American medical technology company with global sales in over 150 countries</li> <li>Supplier group had total revenue of over US\$17 billion in 2019</li> </ul>	Syringes	186,155	6.8%
Supplier C . . . . .	A supplier of crude heparin, sausage casing and other sideline products, with its principal place of business in Jiangxi, China	Operation and sales primarily in China	Crude heparin	103,723	3.8%
Supplier B . . . . .	A supplier of crude heparin and sausage casing, with its principal place of business in Hubei, China	Operation and sales primarily in China	Crude heparin	126,444	4.6%
Supplier G . . . . .	A supplier of crude heparin, with its principal place of business in Anhui, China	Operation and sales primarily in China	Crude heparin	103,591	3.8%
Supplier H . . . . .	A food processing company, with its principal place of business in Virginia, U.S.	<ul style="list-style-type: none"> <li>A company with global operations that sells in over 40 countries</li> <li>A subsidiary of a leading Company in the pork industry with global operations and sales</li> <li>Supplier group had total revenue of over US\$20 billion in 2019</li> </ul>	Porcine pancreas glands and heparin on resin	92,533	3.4%
<b>Total . . . . .</b>				<b><u>612,446</u></b>	<b><u>22.4%</u></b>

*Note:*

(1) Company background and scale of operation are based on public information.

### Raw Materials and Packaging Materials

We have established an integrated supply chain to support the entire manufacturing process of our products. Heparin sodium API and enoxaparin sodium API are our primary products and at the same time the principal raw materials for our respective heparin sodium injection products. The

## **BUSINESS**

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heparin sodium API also serves as the principal raw material for the production of our enoxaparin sodium API. We have stringent quality control measures in place that manage the quality of the raw materials we produce, and we have also established sufficient control on the quality management of our suppliers to ensure the quality of the raw materials we purchase from Independent Third Parties.

For the principal packaging materials and raw materials we purchase from third parties, including syringes, porcine small intestines and crude heparin, we select our product quality, reputation and business scale. The purchase price of our principal materials is primarily based on the prevailing market prices for raw materials of similar quality. We generally contract with more than one supplier for each major type of materials. As of the Latest Practicable Date, we maintained two alternative suppliers for syringes in China. We also maintained a network of 36 suppliers for crude heparin, and we maintained a network of 30 suppliers for porcine small intestines. We have not experienced significant difficulties in maintaining reliable sources of supplies and expect to be able to maintain adequate sources of quality supplies in the future.

We generally enter into supply agreement with a term of one to three year with our syringe suppliers, which lists the product specifications and quality standards our suppliers should comply with. We generally enter into supply agreements with a term of one year with our suppliers of porcine small intestines. The supply agreements set forth our requirements and specifications for the porcine small intestine to ensure its high quality. We have entered into procurement agreement for a term of two to five years with our principal suppliers for crude heparin. Our procurement agreement sets forth relevant requirements to ensure the traceability of the crude heparin. All suppliers are obligated to conduct their production in compliance with relevant requirements, such as CGMP standards, and their manufacturing facilities and process are subject to our audit from time to time.

Other than the increase in the price of porcine small intestine and crude heparin in 2019 as a result of the outbreak of swine fever, as disclosed in this document, we do not believe we have experienced any discernible trends in raw materials costs during the Track Record Period. During the Track Record Period, except as disclosed in this document, fluctuations in raw materials costs have not had a material impact on our results of operations or gross profit margin. For details, see the section entitled “Financial Information.”

## **INVENTORY**

Our inventory primarily consists of finished products, work in progress, raw materials, active pharmaceutical ingredients, excipients and packaging materials. We generally maintain an inventory level of three months of inventory for our API products and four months of inventory for our enoxaparin sodium injection and such level will vary according to the demand of our customers, sales and production plans. We generally keep one to two months’ supply of our raw materials, and specifically for our principal raw material, we keep one to two weeks’ supply of porcine small intestines, one months’ supply of crude heparin and two months’ supply of syringes. Our inventory is sufficient for our production, primarily because the procurement for our principal raw materials, such as crude heparin, usually takes at most two weeks and the production cycle of our valve products is usually approximately three to four weeks/months. Our raw material, porcine small intestines have to be fresh when used in production and crude heparin has a 24-month effective period. Our API products have a shelf life of two to five years, and our enoxaparin sodium injection products have a shelf life of two to three years.

All our products are sold on a first-in-first-out basis. To minimize the risk of building up inventory, we regularly review our inventory levels. We also carry out physical stock counts and stock

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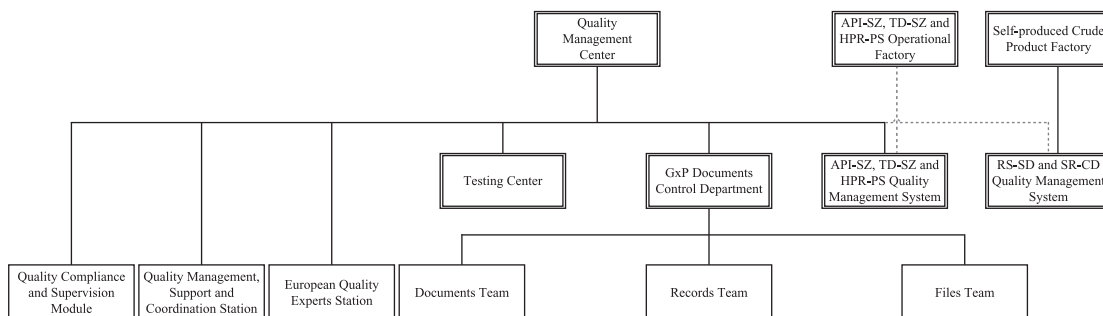
inspections from time to time to identify damaged products or obsolete or about-to-expire products, which are disposed of or for which provisions are made. In 2017 and 2018 and 2019, we incurred write-down of inventories of approximately RMB37.6 million, RMB40.6 million and RMB48.0 million respectively.

We have established an inventory management system that monitors each stage of the warehousing process. Warehousing personnel are responsible for the inspection, storage and distribution of production materials and finished products. All materials and products are stored in different areas in warehouse according to their storage condition requirement, properties, usage and batch number. Warehousing personnel regularly check to ensure consistency among the raw material or product, logbook and material card. Our production material control department, production plan control department and raw material supply chain department manages our inventory levels by monitoring in real time our production activities and sales orders and also taking into consideration any emerging trends through discussions with our quality management department and other departments. Based on this information, the production material control department and raw material supply chain department develops a production and inventory plan, which is updated on a monthly basis, and raw materials supply chain department places orders with suppliers for any inventory which is expected to decline below targeted levels.

## QUALITY CONTROL

We have established a comprehensive quality control system that manages the quality control through our entire business operation, ranging from procurement of raw materials, manufacturing process and the sales and distribution of our products. We have devoted significant attention and resources to quality control, led by our management, who is actively involved in setting quality control policies and targets. Our quality management department is responsible for the design and implementation of quality control measures and standards, with the cooperation of other departments in their respective fields.

As of the Latest Practicable Date, our quality management center consisted of 240 employees, including 66 members in our quality assurance team, 139 members in our quality control team and 35 members in our GxP document control department. The diagram below illustrates the structure of the quality management center:



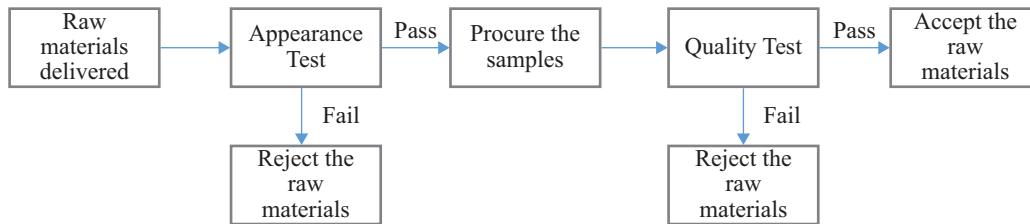
### Quality Control of Raw Materials

Prior to entering into supply agreements with our raw material suppliers, we perform background checks on the operating history, track record and market reputation of a list of potential suppliers, procure different product samples from the potential suppliers for inspection and testing by

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our quality control team, conduct site visits and examine the production facilities of the potential suppliers to ensure that the suppliers we select meet our quality requirements.

We routinely conduct on-site audits at the suppliers' premises to monitor their compliance with the quality management requirements pursuant to our agreement. Traceability of the raw material supplies is required for our principal suppliers. Upon receiving supplies, we retain the right to reject or return based on our inspection and examination results. The diagram below shows the verification process for raw materials:



### Quality Control of Manufacturing

Our quality management center is responsible for ensuring that we comply with applicable regulatory and industry standards throughout the entire manufacturing process through regular on-site inspections. In addition, each subsidiary has set up its own quality control department and quality assurance department to carry out the duties of supervision and routine inspection. After completing each step of the production process, we perform cleaning and maintenance procedures to prevent contamination or cross contamination before we proceed to the next production cycle. We also perform regular dust and microbiological testing in our production facilities in accordance with our detailed manufacturing standards.

Each batch of our products is subject to a strict inspection before sales. We conduct sample testing on certain work in progress and semi-finished products at particular stages of production. In addition, our quality assurance department inspects the documentation relating to product quality, including its batch records, laboratory control records, production process records and other information that may impact product quality. Thereafter, they conduct a final review on all documents and determine whether a specific product can be released for shipment. Products that do not meet our quality standards are destroyed or otherwise disposed of in accordance with the relevant disposal requirements.

### Quality Control of Inventory

Our inventory, including crude heparin and our finished products, are required to be stored below a certain temperature. We have designated warehouse personnel to monitor our inventory and conduct regular inspection of the facility and the inventory strictly following our protocol.

### Quality Control of Transportation

Our quality management center monitors the transportation process and administers transportation records, and our sales and marketing department provides technical support.

### After-Sale Quality Control

We are able to track our products sold to our end customers. The team continues to focus on the safety risks of post-marketing products, to protect patient safety. If we determine that an incident

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involving our product constitutes a major adverse event under relevant regulations, we will report the incident to governmental authorities, such as the NMPA, FDA, and analyze the expectedness, severity, and causality of the event.

We analyze feedback from our distributors and hospitals and handle any customer complaints with respect to the quality of our products. Quality complaints, both verbal and written, are documented and investigated pursuant to standard procedures. We have dedicated employees responsible for responding to complaint calls. If any product falls short of the relevant quality standards due to our fault, we will replace the defective product at our own costs. During the Track Record Period and up to the Latest Practicable Date, we did not experience any product returns, recalls or product liability claims, nor have we received any major customer complaints.

### **INVESTMENT IN FUNDS**

We intend to seek opportunities to expand our business through investment in funds. We hold over 20% equity interest as a limited partner in investment funds, including Shenzhen Maple Sea Capital Equity Investment Fund Partnership, TPG Biotechnology Partners IV, L.P., TPG Biotechnology Partner V, L.P., Shanghai Taiyi Venture Capital Partnership (Limited) and ORI Healthcare Fund L.P. We are the largest limited partner of TPG Biotechnology Partners V, holding 68.52% of its shares and we are the only limited partner of Shenzhen Maple Sea Capital Equity Investment Fund Partnership, holding 99.00% of its equity interest. For details of these investments, please see “History, Development and Corporate Structure—Shareholding Structure Prior to the [REDACTED].” The funds we invest in have primarily invested in companies that engage in drug discovery and development, therapeutics or health care services.

The limited partnership agreement for each fund typically describes the purpose of the partnership or its investment strategies as investing in companies in industries such as pharmaceuticals, biotechnology, health care and life science. Under the limited partnership agreement for certain funds, we are also entitled to appoint our representative in the investment or advisory committee, who participates in the decision-making process regarding the fund’s investment portfolio selection and routine management. Under the limited partnership agreement, we are not allowed to take part in the conduct of the business of the partnership or transact any business in the names of the partnership. At the same time, as a limited partner, we are not personally liable for any amounts except to the extent of our capital commitment to the partnership. Furthermore, we are entitled to the proceeds arising from the partnership’s investments or disposition of the partnership’s investments or properties, in the discretion of the general partner, typically in proportion to our capital commitment to the respective investments or to the partnership. We may transfer our interest in the partnership under certain conditions as agreed in the partnership agreement with the consent of the general partner. The initial term of the partnership ranges from seven to ten years, subject to further renewal. Other than the expiration of its term, the partnership will also dissolve in other circumstances listed in the agreement, such as consent among partners, expiration of the agreed commitment or investment period and withdraw or termination of all of the partnership’s investments, failure to appoint a substitute when the general partner ceasing to be the general partner.

In the future, we may expand our investment portfolio via funds investment by identifying and investing in the biotechnology start-ups and mature pharmaceutical companies with significant growth potential, which will help solidify our leading position in the biopharmaceutical industry.

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### INTELLECTUAL PROPERTY

We have acquired intellectual property in and outside China and may seek additional patents to protect our innovations in the future.

As of the Latest Practicable Date, we had been granted with 43 patents in total, among which 27 were in China, seven were in the U.S., four were in the EU and five patents were in other overseas region. As of the Latest Practicable Date, we had pending applications for 32 patents in total, among which five were in China, six were in the U.S., five were in the EU, 13 were in other overseas regions and three pending applications were under PCT. As of the Latest Practicable Date, we owned 145 registered trademarks and nine pending trademark applications in China. We also had exclusive in-licensing arrangements with respect to patents for the development of our innovative drug candidates. For details of our intellectual property, please refer to “Appendix VI—Statutory and General Information—Further Information About Our Business—Intellectual Property Rights” in this document.

The following table summarizes the material patents and patent applications we owned as of the Latest Practicable Date:

<u>Product/Technology</u>	<u>Coverage of Patent Protection</u>	<u>Status</u>	<u>Covered Regions</u>
DS	Method	Granted	China
HS	Method	Granted	China
Sulodexide	Method	Granted	China
Lower anticoagulant heparin	Product and usage	Granted	China
Sulphated oligosaccharide	Product and Method	Granted	China
Sulphated oligosaccharide	Product and Method	Pending	Europe
Sulphated oligosaccharide	Product and Method	Pending	Japan
Sulphated oligosaccharide	Product and Method	Pending	United States
Heparanase inhibitor	Product and Method and Usage	Pending	PCT
Heparanase inhibitor	Product and Method and Usage	Pending	Taiwan
Enoxaparin sodium injection	Method	Granted	China
Dalteparin Sodium injection	Method	Granted	China
Heparanase deficient non-human mammals	Method	Granted	China
Heparanase deficient non-human mammals	Product and Method	Granted	United States
Heparanase deficient non-human mammals	Method	Granted	Japan
Heparinase I	Method	Granted	China
Heparinase I and Heparinase III	Method	Granted	China
Heparinase II	Method	Granted	China
Heparinase from <i>Sphingobacterium daejeonense</i>	Method and product	Granted	China
Heparinase from <i>Sphingobacterium daejeonense</i>	Method	Granted	Japan
Heparinase from <i>Sphingobacterium daejeonense</i>	Method	Granted	United States
Heparinase from <i>Sphingobacterium daejeonense</i>	Method and product	Pending	Europe
Heparinase from <i>Pseudomonas stutzeri</i>	Method and product	Pending	China
Heparinase from <i>Pseudomonas stutzeri</i>	Method and product	Pending	Europe
Heparinase from <i>Sphingobacterium multivorum</i>	Method and product	Pending	China
Chondroitinase B and AC	Method	Granted	China
Immobilization of Heparinase II	Method	Granted	China
Immobilization of Heparinase III	Method	Granted	China
Electrophoresis method	Analysis method	Granted	China
Detecting of Enoxaparin by HPLC	Analysis method	Granted	China
Separating of oligosaccharides by RP-IP-HPLC	Analysis method	Granted	China



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<u>Product/Technology</u>	<u>Coverage of Patent Protection</u>	<u>Status</u>	<u>Covered Regions</u>
Detecting of Sulodexide by HPLC	Analysis method	Pending	China
Molecular weight and distribution of LMWH	Analysis method	Granted	China
Analysis of degraded fragments of dalteparin by nitrous acid	Analysis method	Pending	PCT
Chain mapping method of LMWH	Analysis method	Pending	PCT
Heparinase from <i>Pseudomonas stutzeri</i>	Method and product	Pending	Japan
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Granted	China
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Granted	Europe
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Pending	India
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Pending	Japan
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Granted	Korea
Derivatives of N-Desulfated Glucosaminoglycans	Product, usage and method	Pending	United States
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Granted	China
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Granted	Europe
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Pending	India
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Pending	Japan
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Pending	Korea
Carboxylated derivatives of glucosaminoglycans	Product, usage and method	Pending	United States

The following table summarizes patents and patent applications we licensed from other entities for the development of our innovative drug candidates as of the Latest Practicable Date:

<u>PRODUCT</u>	<u>Scope of patent protections</u>	<u>Jurisdiction</u>	<u>Patent status</u>	<u>Applicant.</u>	<u>Patent expiration</u>
Oregovomab	Tumor antigen specific antibodies and TLR3 stimulation to enhance the performance of checkpoint interference therapy of cancer	China	Pending	Oncoquest	8/7/2035
mAb-AR20.5	Tumor antigen specific antibodies and tlr3 stimulation to enhance the performance of checkpoint interference therapy of cancer	China	Pending	Oncoquest	8/7/2035
AR-301	Human monoclonal antibody againsts <i>S. aureus</i> derived alpha-toxin and its use in treating or preventing abscess formation	China	Granted	Aridis	8/10/2030

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PRODUCT	Scope of patent protections	Jurisdiction	Patent status	Applicant.	Patent expiration
AR-101	Human monoclonal antibody specific for lipopolysaccharides LPS of the <i>pseudomonas aeruginosa</i> IATSO11 serotype	China	Granted	KENTA BIOTECH AG	2/13/2026
RVX-208	Compounds for the prevention and treatment of cardiovascular diseases	China	Granted	Resverlogix	2/1/2027
		China-DIV	Granted		2/1/2027
		Hong Kong	Granted		2/1/2027
		Hong Kong	Granted		2/1/2027
	Methods of preparing quinazolinone derivatives	China	Granted		6/24/2029
		Hong Kong	Granted		6/24/2029
	Oral immediate release formulations for substituted quinazolinones	China	Granted		10/31/2032
		Hong Kong	Pending		10/31/2032
	Compositions and therapeutic methods for the treatment of complement-associated diseases	China	Pending		3/10/2036
		Hong Kong	Pending		3/10/2036
		Taiwan	Pending		3/11/2036
	Compounds useful in the synthesis of benzamide compounds	China	Granted		10/9/2033
		Hong Kong	Granted		10/9/2033
Novel anti-inflammatory agents	China	Granted		4/21/2030	
	China-DIV	Pending		4/21/2030	
	Hong Kong	Granted		4/21/2030	

We also rely on trade secrets, proprietary know-how and continuing technological innovation to develop and maintain a competitive position for our products. We generally require our employees, consultants and advisors to enter into confidentiality agreements. These agreements provide that all confidential information developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except under specific circumstances. In the case of our employees, the agreements provide that all of the technology which is conceived by the individual during the course of employment is our exclusive intellectual property. Furthermore, as a matter of company policy, all scientific and technical employees have entered into agreements that generally require disclosure and assignment to us of ideas, developments, discoveries and inventions made by them which are relating to their employment with us.

We follow procedures to ensure that we do not infringe on the intellectual property rights of others. As of the Latest Practicable Date, we had not been involved in any material intellectual property disputes or encountered major difficulties in enforcing our intellectual property rights in China.

## COMPETITION

The pharmaceutical and biopharmaceutical industries are characterized by rapidly advancing technologies, competition, and a strong emphasis on proprietary drugs. While we believe that our

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development experience and scientific knowledge are able to equip us with competitive advantages in drug development and manufacture, we face potential competition from many different sources, including a number of established pharmaceutical companies and emerging biotechnology start-ups. For our CDMO business, we compete with smaller to medium sized CDMOs, both multinational and locally based.

Our products primarily compete with products that are indicated for similar conditions as our products on the basis of efficacy, price and general market acceptance by medical professionals and hospitals. The identities of our key competitors vary by product or drug candidate, while in certain cases, our competitors may have greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do.

Additionally, for our CDMO business, we face competition from major biologics CDMO providers based on several factors, including but not limited to quality and breadth of services, ability to protect our customers’ intellectual property or other confidential information, timeliness of delivery, maintenance of CGMP compliance, depth of customer relationships, and price. Please refer to “—Our CDMO Business” above and “Industry Overview” for further details of our major competitors.

We believe our continued success will primarily depend on our capability to develop innovative products and advanced technologies, our capability to apply technologies to all production lines, our capability to develop an extensive product portfolio and pipeline, our capability to effectively commercialize and market our products, our capability to establish network and maintain customer relationships, our capability to satisfy the growing demands for biologics CDMO service, our capability to attract and retain seasoned and talented technology development personnel, our ability to maintain high quality standards, our capability to maintain a highly efficient operational model, and our ability to obtain and maintain regulatory approvals.

## **EMPLOYEES**

As of the Latest Practicable Date, we had 2,069 employees, of whom 1,418 were located in China, 598 were located in the U.S., and 53 were located in Europe.

As of the Latest Practicable Date, 861 of our employees held bachelor’s or higher degrees, and 189 held master’s or higher degrees. The following table shows a breakdown of our employees by function as of the Latest Practicable Date:

	<b>Number of Employees</b>	<b>% of total</b>
Manufacturing and service .....	1,087	52.5%
Research and development .....	335	16.2%
Sales and marketing .....	105	5.1%
Quality Control .....	258	12.5%
General administration .....	284	13.7%
<b>Total</b> .....	<b><u>2,069</u></b>	<b><u>100%</u></b>

We believe that our success will depend in part on our ability to attract, recruit and retain quality employees. To maintain the quality, knowledge and skill levels of our workforce, we provide our employees with periodic training, including introductory training for new employees, technical

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training, professional and management training and health and safety training. We provide our sales and marketing team with extensive training.

We enter into individual employment contracts with our employees to cover matters such as wages, benefits, and grounds for termination. We generally formulate our employees’ remuneration package to include salary, bonus and allowance elements. Our compensation programs are designed to remunerate our employees based on their performance, measured against specified objective criteria. We also provide our employees with welfare benefits in accordance with applicable regulations and our internal policies.

Our employees are represented by relevant labor unions. We believe that we maintain a good working relationship with our employees and we did not experience any significant labor disputes or any difficulty in recruiting staff for our operations during the Track Record Period.

In accordance with applicable regulations we participate in a pension contribution plan, a medical insurance plan, an unemployment insurance plan and a personal injury insurance plan for our employees. We have made adequate provisions in accordance with applicable regulations. Also, in accordance with PRC regulations, we make annual contributions towards a housing fund, a supplemental medical insurance fund and a maternity fund.

### **INSURANCE**

We maintain insurance policies for all of our properties, manufacturing facilities, plant and material machinery, equipment and inventories against damage caused by accidents. We maintain product liability insurance against claims or liabilities that may arise from products that we have sold and key person insurance. We believe that our insurance coverage is in line with industry practice in the PRC. We believe that our insurance coverage is in line with industry practice in relevant jurisdictions. We did not experience any material industrial accidents during the Track Record Period.

### **PROPERTIES AND FACILITIES**

As of the Latest Practicable Date, we owned seven properties in China, primarily in Shenzhen, Linyi and Chengdu, and three properties overseas, primarily in the U.S. We owned in total gross floor area of approximately 177,670 sq.m. for production facilities, including 4,458 sq.m. in Hepalink Nanshan facility, 6,848 sq.m. in Techdow Nanshan facility, 129,994 sq.m. in Pingshan Industrial Park facility, and 8,853 sq.m. in SPL. We also owned gross floor area of 4,207 sq.m. for R&D activities, 45,177 sq.m. for staff housing, 11,469 sq.m. for storage and 23,222 sq.m. for office space and other general administrative use.

The following table summarizes the major properties we owned as of the Latest Practicable Date:

<u>Entity/Facility</u>	<u>Location</u>	<u>Land Use Right or Property Ownership and Gross Floor Area</u>	<u>Use</u>
Hepalink (Hepalink Nanshan)	Nanshan District, Shenzhen, China	Land use right for a total site area of approximately 10,271 sq.m; Property ownership for building area of approximately 4,874 sq.m	Production facility for our pharmaceuticals for 4,458 sq.m; Storage area for our pharmaceuticals for 89 sq.m; Office area for 328 sq.m

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<u>Entity/Facility</u>	<u>Location</u>	<u>Land Use Right or Property Ownership and Gross Floor Area</u>	<u>Use</u>
Topknow (Techdow Nanshan)	Gaoxinzhong Road, Nanshan District, Shenzhen, China	Land use right for a total site area of approximately 18,094 sq.m; Property ownership for building area of approximately 20,892 sq.m	Production facility for our pharmaceuticals for 6,848 sq.m; Storage area for our pharmaceuticals for 6,628 sq.m; R&D area for our pharmaceuticals for 3,037 sq.m; Office area for 4,378 sq.m
Hepalink (Pingshan Industrial Park)	Jinxiu East Road And Rongtian Road, Pingshan New District, Shenzhen, China	Land use right for a total site area of approximately 50,721 sq.m	Production facility for our pharmaceuticals for 43,661 sq.m; Housing area for 31,680 sq.m <sup>(1)</sup>
Hepalink (Pingshan Industrial Park)	Jinxiu East Road And Juqing Road, Pingshan New District, Shenzhen, China	Land use right for a total site area of approximately 154,111 sq.m	Production facility for our pharmaceuticals for 86,333 sq.m <sup>(2)</sup>
Shenzhen Beidi Aoke (Technology Development Co., Ltd.)	Nanshan District, Shenzhen, China	Land use right for a total site area of approximately 4,507 sq.m; Property ownership for building area of approximately 9,997 sq.m	R&D area for our pharmaceuticals for 151 sq.m; Office area for 9,847 sq.m
Shandong Ruisheng (crude heparin production)	Volve Road, Shandong Province, China	Land use right for a total site area of approximately 74,666 sq.m; Property ownership for building area of approximately 23,474 sq.m	Production facility for our pharmaceuticals for 13,510 sq.m; Housing area for 6,031 sq.m; Office area for 3,935 sq.m
Chengdu Sunrace (crude heparin production)	Mengxingxi Road, Chengdu City, Sichuan Province, China	Land use right for a total site area of approximately 42,571 sq.m; Property ownership for building area of approximately 23,917 sq.m	Production facility for our pharmaceuticals for 14,007 sq.m; Housing area for 7,466 sq.m; Office area for 2,444 sq.m
SPL	Murray Street, Sioux City, Iowa, United States	Land ownership for a total site area of approximately 188,721 sq.m; Property ownership for building area of approximately 3,268 sq.m	Production facility for our pharmaceuticals for 1,543 sq.m; Storage area for our pharmaceuticals for 641 sq.m; Office area for 325 sq.m

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<u>Entity/Facility</u>	<u>Location</u>	<u>Land Use Right or Property Ownership and Gross Floor Area</u>	<u>Use</u>
SPL	Main Street, Waunakee, Wisconsin, United States	Land ownership for a total site area of approximately 156,007 sq.m; Property ownership for building area of approximately 10,223 sq.m	Production facility for our pharmaceuticals for 6,938 sq.m; Storage area for our pharmaceuticals for 1,230 sq.m; R&D area for our pharmaceuticals for 1,019 sq.m; Office area for 1,036 sq.m
SPL	Main Street, Waunakee, Wisconsin, United States	Land ownership for a total site area of approximately 35,612 sq.m; Property ownership for building area of approximately 4,182 sq.m	Production facility for our pharmaceuticals for 372 sq.m; Storage area for our pharmaceuticals for 2,881 sq.m; Office area for 929 sq.m

*Notes:*

- (1) Total production facility for our pharmaceuticals for 56,500 sq.m, total housing area for 58,900 sq.m and total office area for 29,500 sq.m are planned for construction.
- (2) Total production facility for our pharmaceuticals for 270,200 sq.m is planned for construction.

As of the Latest Practicable Date, we leased 13 properties from third parties, primarily in Shenzhen, China and Oklahoma, U.S. We leased gross floor area of 23,999 sq.m., including 3,972 sq.m. for production facilities, 1,335 sq.m. for R&D activities, 13,446 sq.m. for storage and other general use and 5,246 sq.m. for office space and other general administrative use.

As of December 31, 2019, none of the properties held or leased by us had a carrying amount of 15% or more of our consolidated total assets. Therefore, according to Chapter 5 of the Listing Rules and section 6(2) of the Companies (Exemption of Companies and Prospectuses from Compliance with Provisions) Notice (Chapter 32L), this document is exempted from compliance with the requirements of section 342(1)(b) of the Companies (Winding Up and Miscellaneous Provisions) Ordinance in relation to paragraph 34(2) of the Third Schedule to the Companies (Winding Up and Miscellaneous Provisions) Ordinance which require a valuation report with respect to all our Group’s interests in land or buildings.

With respect to the manufacturing facilities we leased in China with a gross floor area of 665.7 sq.m., the title owner of such property is Office of the Leading Group of Shenzhen Hi-Tech Industrial Park (深圳高新技術產業園區領導小組辦公室), who had obtained the planned construction permit although it has not yet obtained the title certificate to the property. Shenzhen Software Park Management Center (深圳市科技評審管理中心) has been authorized to lease such property to us. Since Office of the Leading Group of Shenzhen Hi-Tech Industrial Park has not yet obtained the certificate of ownership for such property, Shenzhen Software Park Management Center could not provide us with the certificate of ownership. In accordance with the relevant PRC laws and regulations, if the lessor fails to obtain the certificate of ownership for the leased property, the lease may become invalid. Nevertheless, since Office of the Leading Group of Shenzhen Hi-Tech Industrial Park has obtained the permit for the planned construction project and has granted an authorization to lease the property to us, our PRC legal adviser is of the view that the likelihood of our lease being invalid is relatively low.



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### **ENVIRONMENTAL AND SOCIAL MATTERS**

#### **Environmental Protection**

We are subject to national and local environmental laws and regulations of the PRC. During our manufacturing processes, we must comply with PRC laws and regulations concerning the discharge of air, water and solid waste as well as noise control. In addition, manufacturers engaging in any new construction project must prepare an environmental impact study report setting forth the impact the proposed construction project may have on the environment and the measures to prevent or mitigate the impact for approval by the government authority prior to commencement of construction of the relevant project. Please refer to the section headed “Regulatory Environment — Laws and Regulations Related to Our Business in the PRC — Environmental Regulations” in this document for details on PRC environmental laws and regulations we are subject to.

We have established detailed internal rules regarding environmental protection. We test effluent water to ensure compliance with national emission standards. Solid waste is sorted for proper disposal. Hazardous waste is sent to qualified third parties for treatment. When a new construction project is proposed, we conduct comprehensive analysis and testing on the environmental issues involved in the manufacturing processes. Our production team and in-house legal department are primarily responsible for ensuring our compliance with applicable environmental rules and regulations. During the Track Record Period, we did not incur any additional costs specifically attributable to environmental compliance. Going forward, we expect that our annual cost of compliance will be consistent with our scale of operations. All our property, plant and equipment meet the standards required for compliance with applicable environmental rules and regulations, and we believe we have maintained good relationship with the communities surrounding our production facilities.

Our PRC legal adviser has confirmed that, during the Track Record Period and up to the Latest Practicable Date, we had complied with all applicable laws and regulations relating to production safety and environmental requirements in all material respects.

#### **Occupational Health and Safety**

We strive to provide a safe working environment for our employees. We have implemented work safety guidelines setting out safety practices, accident prevention and accident reporting. We require new employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. In particular, we invite experts on fire control safety to conduct training sessions and regularly perform emergency evacuation drills to reduce risks associated with potential fire accidents. Also, we have policies in place and have adopted relevant measures to ensure the hygiene of our work environment and the health of our employees. We have endeavored to provide a safe work environment in light of the recent outbreak of COVID-19, including conducting regular sterilization of the facility, maintenance of ventilation system, daily routine check of each employee’s temperature and sufficient supply of face masks.

We are subject to various PRC laws and regulations in respect of occupational health and safety. We are committed to complying with PRC regulatory requirements, preventing and reducing hazards and risks associated with our operation, and ensuring the health and safety of our employees and surrounding communities. We have adopted and maintained a series of rules, standard operating procedures and measures to maintain a healthy and safe environment for our employees, including those required under the CGMP certification. For example, we construct and maintain all of our

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production facilities in accordance with the CGMP certification. We also engage qualified inspectors each year to carry out on-site monitoring of our waste water, noise and boiler emission control, the results of which show that we have complied with relevant PRC laws and regulations in material respects. We require new employees to participate in safety training to familiarize themselves with the relevant safety rules and procedures. In particular, we invite experts on fire control safety to conduct training sessions and regularly perform emergency evacuation drills to reduce risks associated with potential fire accidents.

Additionally, we appoint qualified consulting firms to conduct on-site safety assessment and hazard identification, which help us enhance our overall health and safety management effectiveness. As of the Latest Practicable Date, we had not experienced any material accidents in the course of our operation and our Directors were not aware of any claims for personal or property damages in connection with health and occupational safety.

## **RISK MANAGEMENT AND INTERNAL CONTROL**

We are dedicated to establishing and maintaining a robust internal control system. We have adopted and implemented risk management policies in various aspects of our business operations to address various potential risks in relation to our strategic plan, research and development, infrastructure, procurement, manufacturing, marketing and distribution. Our risk management system also covers general finance management, human resources, information technology, projects, logistics, subsidiaries and policy matters. The Audit Committee reviews and supervises our risk management and internal control system.

In addition, as part of our risk management measures, we have implemented specific measures against corruption and bribery and to ensure we are compliant with International Sanctions laws. We require our employees, especially those involved in procurement, distribution and sales, and other business functions which are highly susceptible to bribery and corruptions, and exposed to risks relating to International Sanctions, to abide by our compliance requirements, and make necessary representations and warranties to the Company. We generally communicate our anti-bribery, anti-corruption and compliance with International Sanctions requirements and principles to all relevant stakeholders, including customers and suppliers. We have established a system of supervision that allows complaints and reports to be submitted to management regarding non-compliant behavior of our internal employees, external customers and suppliers. We conduct strict customer identification procedures, and create necessary records, analysis, verification and reports in relation to large-sum or suspicious transactions, for purpose of avoiding anti-money laundering and identifying potential risks in dealing with such counterparty. Our internal control and audit department specifically supervises compliance matters in relation to procurement, construction, distribution and retails, and conducts special audit with respect to the implementation of anti-bribery and anti-corruption on a regular or irregular basis.

We refer to the section headed “Risk Factors—A small amount of our revenue was derived from countries that are targets of sanctions imposed by the United States, the European Union, Australia and other government entities during the Track Record Period”. We have discontinued our sales and/or deliveries to the Relevant Countries commencing from December 2019 and we are not subject to any claims for compensation as a result of the discontinuation of such sales and/or deliveries. Further, we will not knowingly and intentionally conduct any future business with persons, entities or organizations on the SDN Lists, or any business connected to any comprehensively sanctioned

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countries and we will not use the [REDACTED] from the [REDACTED] to finance or facilitate, directly or indirectly, activities or business with, or for the benefit of, the countries subject to International Sanctions or persons designated on the SDN List. Hogan Lovells, our International Sanctions legal adviser, is of the view that our business activities during the Track Record Period do not appear to implicate restrictions under International Sanctions and thus would not result in material sanctions risks, based on the following:

- all sales and/or deliveries to the Iranian customers were settled exclusively in Renminbi and had no other U.S. nexus; similarly for the remittances of payments related to our sales involving the banks on the SDN Lists, there was no involvement of U.S. dollars or other U.S. nexus; as such, the activities involving Iranian parties (the "Iranian Transactions") did not violate or implicate any violations of the relevant U.S. sanctions laws; in addition, the Iranian Transactions did not implicate any sanctions laws administered by the European Union, the United Nations or Australia;
- other than with respect the Iranian Transactions, which are covered in (i), none of the counterparties in the Relevant Countries have been designated on the SDN Lists or other restricted parties lists maintained by the United States, the United Nations, the European Union, or Australia during the Track Record Period;
- we had not undertaken, either directly or indirectly, a contract or any other activity with a counterparty, nor have otherwise provided goods or services to any person, in Cuba, North Korea, Sudan, Syria or the Crimea region of Ukraine/Russia (these countries or territories, together with Iran, were subject to comprehensive U.S. sanctions); and
- the export control laws of the United States, the European Union and Australia do not appear to have been implicated given our sales and/or deliveries to the Relevant Countries were limited to our pharmaceutical products.

We have undertaken to the Stock Exchange that, after the [REDACTED], (i) we will not use the [REDACTED] from the [REDACTED] to finance or facilitate, directly or indirectly, activities or business with, or for the benefit of, the countries subject to International Sanctions or persons designated on the SDN List; (ii) we will not enter into any transaction that would cause our Group, the Stock Exchange, HKSCC, HKSCC Nominees or our Shareholders to violate or become a target of International Sanctions; and (iii) we will make timely disclosures on the Stock Exchange's website and on our own website if we should believe that any of our business transactions would put our Group or our Shareholders at risk of being sanctioned and in our annual reports or interim reports our efforts on monitoring our business exposure to sanctions risks and our business intentions relating to the countries subject to International Sanctions.

We have adopted enhanced internal control and risk management measures to help us continuously monitor and evaluate our business and take measures to protect the interest of our Group and our Shareholders from economic sanctions risks. The following measures have been implemented as at the Latest Practicable Date:

- we will set up before [REDACTED] and maintain a separate bank account, which is designated for the sole purpose of the deposit and deployment of the [REDACTED] from the [REDACTED] or any other funds raised through the Stock Exchange; our Directors will continuously monitor the use of [REDACTED] from the [REDACTED], as well as any other funds raised through the Stock Exchange, to ensure that such funds will not be used to finance or

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facilitate, directly or indirectly, activities or business with, or for the benefit of, countries subject to International Sanctions or Sanctioned Persons;

- we will evaluate the sanctions risks prior to determining whether we should embark on any business opportunities in countries subject to International Sanctions and with Sanctioned Persons. According to our internal control procedures, the internal control and audit department will review and approve all relevant business transaction documentation, including identity and nature of business as well as its ownership, from customers or potential customers from countries subject to International Sanctions and with Sanctioned Persons. If any potential sanctions risk is identified, we will seek advice from reputable external international legal counsel with necessary expertise and experience in International Sanctions matters;
- the Audit Committee will monitor our exposure to sanction risks and our implementation of the related internal control procedures, and periodically review our internal control policies and procedures with respect to sanctions matters. As and when the Audit Committee considers necessary, we will retain external international legal counsel with necessary expertise and experience in sanctions matters for recommendations and advice; and
- Hogan Lovells, our International Sanctions legal adviser, has provided trainings to our Executive Directors, senior management and other relevant personnel regarding risks and compliance with respect to International Sanctions. If necessary, external international legal counsel will provide additional training programs relating to the sanctions to our Directors, our senior management and other relevant personnel to assist them in evaluating the potential sanctions risks in our daily operations. Our external international legal counsel will provide current list of countries subject to International Sanctions and Sanctioned Persons to our Directors, senior management and other relevant personnel, who will in turn disseminate such information throughout our domestic operations and overseas offices and branches.

Hogan Lovells has reviewed and evaluated these internal control measures and are of the view that these measures are adequate and effective for the Company to comply with our undertakings to the Stock Exchange.

Having taken the above advice of Hogan Lovells into account, our Directors are of the view that our measures provide a reasonably adequate and effective internal control framework to assist us in identifying and monitoring any material risk relating to sanctions laws so as to protect the interests of our Shareholders and us. Having regard to the above and subject to the full implementation and enforcement of such measures, the Joint Sponsors are of the view that these measures will provide a reasonably adequate and effective internal control framework to assist the Company in identifying and monitoring any material risk relating to International Sanctions.

## **LEGAL PROCEEDINGS AND COMPLIANCE**

We may from time to time be involved in contractual disputes or legal proceedings arising out of the ordinary course of business. During the Track Record Period and up to the Latest Practicable Date, none of us or any of our subsidiaries was subject to any material claims, damages or losses. As of the Latest Practicable Date, no material litigation, arbitration or administrative proceedings had been threatened against us or any of our subsidiaries.

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During the Track Record Period and up to the Latest Practicable Date, save as otherwise disclosed, we did not have any non-compliance incidents which our Directors believe would, individually or in aggregate, have a material operational or financial impact on our Group as a whole.

The following sets forth certain incidents which our Company considers to be immaterial and do not constitute material or systemic non-compliances.

### **Social Insurance and Housing Provident Funds**

During the Track Record Period, we, specifically our Company and two of its subsidiaries, failed to make full contribution to the social insurance and housing provident funds for our employees as required under the applicable PRC law. Such insufficient contribution was primarily because we calculated the contribution based on employees' salaries, without taking into account of the bonuses and welfare they received. Our subsidiary Chengdu Sunrace did not make any contribution to the housing provident funds for its employees during the Track Record Period, since most of its employees were not local residents and thus were less inclined to the deduction from their salaries for the housing provident funds, when they had access to proper housing, including the staff housing we provided and the government housing we applied for our employees, with a low rental fee. As of December 31, 2019, the total payable amount of social insurance premium and housing provident fund was approximately RMB38.6 million for which we had made provision in the financial statement for the year ended December 31, 2019. According to the relevant PRC laws and regulations, in respect of overdue social insurance contributions, (a) the relevant PRC authorities may demand us to pay the outstanding social insurance contributions within a stipulated deadline and we may be liable to a late payment fee equal to 0.05% of the outstanding amount for each day of delay; if we fail to make such payments, we may be liable to a fine of one to three times the amount of the outstanding contributions; and (b) in respect of outstanding housing provident fund contributions, we may be ordered to pay the outstanding housing provident fund contributions within a prescribed time period. We have obtained written confirmations from the relevant local social insurance and housing provident fund authorities confirming no administrative penalty has been imposed to Hepalink and Techdow. Based on the consultation with the local social insurance and housing provident fund authorities, it is confirmed that relevant authorities will not take the initiative to request Hepalink, Shenzhen Techdow and Chengdu Sunrace to make full payments, or impose fines or other administrative penalties. Accordingly, our PRC legal adviser is of the view that the likelihood that we will be required to make full payment, or imposed fine or other administrative penalties initiated by the relevant authorities is relatively low. We have adjusted our calculations to ensure that our Company and the two subsidiaries can make adequate contribution to social insurance for all of their eligible employees in compliance with relevant laws and regulations starting from March 2020. We will adjust our calculations to ensure that our Company and the two subsidiaries can make adequate contribution to housing provident funds for all of their eligible employees starting from July 2020, being the earliest applicable date pursuant to relevant laws and regulations for us to make the adjustment.

### **Construction of Pingshan Industrial Park**

On January 8, 2013, we entered into Shenzhen land use right grant agreements with the Pingshan Administrative Bureau of Shenzhen Planning and Land Resource Committee (“**Pingshan Administrative Bureau**,” currently known as Pingshan Administrative Bureau of Shenzhen Planning and Natural Resources), pursuant to which Pingshan Administrative Bureau agreed to grant us two parcels of land with a total site area of 204,832.69 sq.m., which are related to our Pingshan Industrial



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Park for a total premium of RMB107.55 million. We further entered into supplemental agreements (the “**Supplemental Agreements**”) with Pingshan Administrative Bureau, pursuant to which we are required to complete the construction of Pingshan Industrial Park by January 4, 2019. As of the Latest Practicable Date, we have not completed the construction of certain buildings by the completion date as required under the Supplemental Agreements, primarily because the surrounding public infrastructure, including the sewage system, water supply system and roads, is still under construction, and the governmental agencies of two adjacent cities were disputing over the determination of border with respect to a parcel of land in the Pingshan Industrial Park, both of which had postponed or delayed our construction. According to the relevant PRC laws and regulations, in respect of failure to complete construction in time other than due to the reasons of the government authorities, the relevant PRC authorities may impose liquidated damages on the company since the required completion date set forth under the relevant land use right grant agreement. If the delay is within two years since the required completion date, the company may be imposed a liquidated damages of up to 1.5% of the land premium every three months since the required completion date. If a company fails to complete construction for more than two years since the required completion date, the company may be imposed a liquidated damages of up to 20% of the land premium and the land may be subject to forfeiture to the PRC government. As of the Latest Practicable Date, we paid liquidated damages of RMB2.42 million in total with respect to the delay in construction of Pingshan Industrial Park occurred before January 4, 2019. Pingshan Administrative Bureau has confirmed that the land with respect to the Pingshan Industrial Park is not regarded as idle land and the delay is not due to our reason, therefore such land and the construction built on it are not subject to forfeiture. As advised by our PRC legal advisor, the likelihood of forfeiture and imposition of penalties for the delay in construction due to reasons other than the Company is relatively low.

### Caution Letter Issued by Shenzhen Bureau of CSRC

On December 19, 2019, the Shenzhen Securities Regulatory Bureau (the “**Shenzhen Bureau**”) of the China Securities Regulatory Commission (the “**CSRC**”) issued a letter of caution (“**Caution Letter**”) to the Company which identified three issues of concern, being (i) irregular accounting treatment of our equity investment in Resverlogix from July 20, 2015 to November 30, 2017; (ii) internal approval process discrepancies with respect to certain related party transactions, including the approval and basis of pricing adjustment and proper documentation of certain agreements, and other related pricing policy disclosure discrepancies, including the disclosure of the pricing basis of certain related party transactions and; and (iii) inadequate registration of insider information during the process of preparing for certain transactions and disclosures (the “**Concerned Matters**”). On the same day, the Shenzhen Bureau of the CSRC also issued invitations to three of our Directors, being Mr. Li Li, Mr. Shan Yu and Mr. Bu Haihua and our financial controller, Mr. Zhang Bin (together with the Company, the “**Relevant Parties**”), to attend regulatory interviews in respect of all or certain of the Concerned Matters (the “**Regulatory Interviews**”). The Regulatory Interviews have been completed. The Caution Letter was issued by the Shenzhen Bureau of the CSRC based on the results of its on-site inspection, which was an annual routine spot inspection of listed companies pursuant to the Measures for the Spot Inspection of Listed Companies and relevant implementation regulations issued by the CSRC, in order to evaluate listed companies’ information disclosure, corporate governance and other compliance matters. The Company, for the first time since its listing on the Shenzhen Stock Exchange in 2010, was one of the fifteen companies listed on the Shenzhen Stock Exchange randomly selected for the inspection in 2019.



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Since we received the Caution Letter and completed the Regulatory Interviews, there has not been any further correspondence with the Shenzhen Bureau of the CSRC and we have not been required to adopt any rectification measures, nor have the Relevant Parties been imposed any penalties by the Shenzhen Bureau of the CSRC relating to the Concerned Matters. Our PRC legal adviser is of the view that Shenzhen Bureau of the CSRC has concluded the Concerned Matters relating to the Caution Letter and the Regulatory Interviews, and the Caution Letter and the Regulatory Interviews are administrative regulatory measures that do not constitute administrative penalties, because (i) caution letters and regulatory interviews are deemed as administrative regulatory measures, under the Administrative Measures for the Disclosure of Information of Listed Companies and the Provisions for Establishing a Registration and Administration System for Persons with Inside Information published by the CSRC, (ii) administrative regulatory measures differ from administrative penalties, as according to the Notice on Further Improving the Administrative Penalty System of the China Securities Regulatory Commission published by the CSRC, for certain reported activities that do not constitute legal noncompliance, or any legal noncompliance that does not result in administrative penalties pursuant to relevant rules and regulations, CSRC shall take administrative regulatory measures, and (iii) the Relevant Parties have not received any form of decision issued by the Shenzhen Bureau of CSRC, which is mandatory for regulatory authorities to impose any administrative penalties according to the Administrative Penalty Law of the PRC. According to our PRC legal adviser, the Concerned Matters may give rise to certain breaches of the Administrative Measures for the Disclosure of Information of Listed Companies and the Provisions for Establishing a Registration and Administration System for Persons with Inside Information published by the CSRC. Nevertheless, based on the aforementioned, our PRC legal adviser is of the view that the risk of such Concerned Matters resulting in any penalties imposed by any other regulatory authority on the Relevant Parties is low. As such, they do not constitute material non-compliance incidents under the PRC law nor do they represent disciplinary sanctions (紀律處分) taken by the Shenzhen Stock Exchange on the Relevant Parties.

Even though rectification measures were not requested by regulatory authorities, we have taken steps to ensure our compliance with relevant rules and regulations. We have organized trainings for our directors, supervisors, management and staffs regarding the Concerned Matters, including increasing their knowledge of related party transactions, insider information and disclosure requirements for listed companies, as well as enhancing their awareness of our internal control requirements and review and approval procedures to ensure our compliance with relevant rules and policies. We have also improved our personnel training system, through approving an internal training mandate of directors, supervisors and senior management, which will be implemented upon the [REDACTED]. The mandate specifically requires that our directors, supervisors and senior management will be subject to trainings on disclosure requirements, administration of related party transactions, other key legal requirements and principles and policies on internal control. Our independent Directors and financial controller are also subject to trainings on the latest development in accounting polices.

We have conducted and will maintain periodic review and update of internal control policies. We have engaged independent accountant to conduct yearly audit on internal control since 2012. Our Board has also approved a full-spectrum internal control and risk management policy to be implemented upon the [REDACTED]. Additionally, we have updated relevant policies on related party transactions and registration of insiders with material inside information as described below.

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Specifically, we have adopted measures to address each of the Concerned Matters, and our Directors are of the view that such rectification measures will properly address the Concerned Matters and significantly enhance our internal control to avoid occurrence of similar incidents in the future.

- Accounting treatment of equity investment in Resverlogix

During the period from July 20, 2015 to November 30, 2017, we treated our equity investment in Resverlogix as “available for sale financial asset,” since we did not regard our Company as having significant influence over Resverlogix, when holding less than 20% equity interest during the same period. Since December 2017 when we increased our equity interest in Resverlogix to over 40%, we changed to equity method to account for such investment. Our independent accountant, Ruihua Certified Public Accountants (special general partnership), had not questioned such accounting treatment or raised different views when preparing for the financial statements for respective years nor had they issued a qualified opinion in the accounting reports. On the contrary, the Shenzhen Bureau of the CSRC considered that despite our insignificant shareholding from July 20, 2015 to November 30, 2017, we still had significant influence over Resverlogix, because we were the second largest shareholder and appointed one board representative, and thus, the Shenzhen Bureau of the CSRC held the view that we should regard our equity investment in Resverlogix as “investments in associates” and adopt accounting treatment under equity method, during the same period.

In response to the Caution Letter, we changed the accounting treatment of our equity investment in Resverlogix from “available for sale financial asset” to “investments in associates” under the equity method during the period from July 20, 2015 to November 30, 2017. In preparing for our consolidated financial statements set forth in Appendix I to this document, we accounted for our investment in Resverlogix prior to December 1, 2017 as “investment in associates” under the equity method and therefore, current accounting treatment of our investment in Resverlogix prior to December 1, 2017 was appropriate and complied with all applicable accounting standards. Such adjustment will also be reflected in our 2019 annual report to be published on Shenzhen Stock Exchange, specifically resulting in certain adjustment of our 2018 financial.

- Internal control on related party transactions

- (a) The Shenzhen Bureau of the CSRC found that in the end of 2018, we adjusted the pricing of certain transactions between our Company and Shenzhen Techdow that took place in January and February of 2018, without seeking approval from the secretary to the Board and the Chairman of the Board in accordance with our approval process for related party transactions.

We made the adjustment so that the annual average price of our Company’s sales of heparin sodium API to Shenzhen Techdow would be similar to the sales price of the same kind of product to independent third parties, which complied with our pricing policy for related party transactions. At the time of the pricing adjustment in the end of 2018, Shenzhen Techdow was already our subsidiary as a result of our acquisition of Topknow in May 2018, based on which we did not treat the transactions between our Company and Shenzhen Techdow as related party transactions. Whereas, during

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our communication, the Shenzhen Bureau of the CSRC was of the view that as the transactions between our Company and Shenzhen Techdow happened in January and February of 2018, when Shenzhen Techdow was still a related party by definition under relevant CSRC regulations, we should have applied internal procedures for related party transactions when making the pricing adjustment, even though the adjustment itself was made at a time when Shenzhen Techdow was not a related party.

We have not conducted any related party transactions since our acquisition of Topknow. For any potential future related party transactions, we will strictly follow our existing decision-making policy and implementation procedure for the pricing of related party transactions, to obtain approval from the secretary to the Board and the Chairman of the Board for any pricing adjustment of related party transactions.

- (b) The Shenzhen Bureau of the CSRC identified an inaccurate disclosure of our pricing method for related party transaction, as our pricing policy was disclosed as “open, fair and just market principles and based on the sales price and method of settlement between our Company and customers of similar products,” while we have in practice changed the pricing method to cost-plus basis since September 2017. Our pricing was still consistent with open, fair and just market principle, and generally subject to adjustments based on the pricing of our transactions with third-parties. However, as the price of crude heparin fluctuated since the second half of 2017 and purchase of heparin sodium API from Shenzhen Techdow increased significantly, which became substantially more than the purchase of the same kind of product from nearly all of our Company’s other customers, using the price of transactions with third parties as the primary benchmark was no longer applicable or reasonable, and thus we have also adopted the cost-plus basis for pricing related party transactions to ensure our pricing is fair and justifiable.

In response to the Caution Letter, we have revised our implementation procedure for the pricing of related party transactions, which requires reporting to the Board office who will further arrange public disclosure, if required by relevant regulations and policies, for the adjustment of pricing principle or method of related party transactions.

- (c) The Shenzhen Bureau of the CSRC also found that the supply agreements between our Company and Shenzhen Techdow provided that the agreement shall take effect from the date of execution, however, some of the agreements did not specify the execution date.

The abovementioned agreements have expired, and to ensure proper documentation of any potential related party transactions, we have strengthened our legal department’s responsibility of review and recordkeeping of all the legal documents for related party transactions.

- Registration of insiders with material inside information

The Shenzhen Bureau of the CSRC found that we did not conduct registration of insiders with inside information regarding certain matters, including planning employee share

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option schemes, preparation of annual and interim business preview announcement, Board approval and announcements related to our acquisition of Topknow.

In response, we have revised our insider information registration and management policy, in accordance with the requirements of the CSRC and the HKSE, which includes certain specific matters listed in the Caution Letter, such as our preview of business and financial information, and will be implemented upon the [REDACTED].

### Outbound Investments in Overseas Subsidiaries

We did not obtain the approvals from NDRC with respect to our outbound investments in certain overseas subsidiaries, including incorporation of Hepalink (Hong Kong) in 2010 and increase in the share capital of Hepalink (Hong Kong) in 2014, in Techdow (Hong Kong) in 2016 and in OncoVent in 2016. In accordance with the Administrative Measures for Approval and Record-filing of Overseas Investment Projects (the “**NDRC Order No.9**”), the NDRC is authorized to suspend the unapproved outbound investment activities, and may impose legal and administrative measures upon the responsible party. The Measures for the Administration of Overseas Investment (the “**NDRC Order No. 11**”) took effect in March 2018 and replaced NDRC Order No. 9. Based on our consultation with the NDRC Shenzhen Branch, we have obtained the confirmation that since the aforementioned investments took place before the NDRC Order No. 11 became effective, such lack of approval will not adversely affect our future outbound investment and we are not required to reapply the NDRC approvals for the above outbound investments. As advised by our PRC legal adviser, the likelihood of us being penalized is relatively low based on the consultation with the competent official of the NDRC Shenzhen Branch.

### LICENSES AND PERMITS

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 required for our operation in the PRC and overseas:

<u>License/Permit</u>	<u>Holder</u>	<u>Grant Date</u>	<u>Expiration Date</u>
Registration Approval (enoxaparin sodium injection for five strengths, including 0.2ml:20mg, 0.4ml:40mg, 0.6ml:60mg, 0.8ml:80mg, 1.0ml:100mg) (China)	Shenzhen Techdow	December 5, 2019	December 4, 2024
Registration Approval (enoxaparin sodium API) (China)	Shenzhen Techdow	June 28, 2015	June 27, 2020
GMP Certificate (enoxaparin sodium API) (China)	Shenzhen Techdow	October 12, 2015	October 11, 2020
Drug Manufacturing Certificate	Hepalink	January 1, 2016	December 31, 2020
Drug Manufacturing Certificate	Shenzhen Techdow	January 1, 2016	December 31, 2020
Registration Approval (Inhixa for five strengths, including 0.2ml:20mg, 0.4ml:40mg, 0.6ml:60mg, 0.8ml:80mg, 1.0ml:100mg) (EU)	Techdow Pharma Netherland B.V.	September 15, 2016 <sup>(1)</sup>	September 14, 2021
Registration Approval (Inhixa for four strengths, including 120mg/0.8ml, 150mg/1.0ml, 300mg/3.0ml, 500mg/5.0ml) (EU)	Techdow Pharma Netherland B.V.	September 17, 2018 <sup>(2)</sup>	September 14, 2021

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<u>License/Permit</u>	<u>Holder</u>	<u>Grant Date</u>	<u>Expiration Date</u>
Registration Approval (Inhixa for 1000mg/10.0ml) (EU)	Techdow Pharma Netherland B.V.	July 25, 2019 <sup>(3)</sup>	September 14, 2021
GMP Certificate (enoxaparin sodium injection) (China)	Shenzhen Techdow	September 29, 2016	September 28, 2021
FDA 6th Inspection Approval Letter (heparin sodium API)	Hepalink	January 13, 2017	N/A
GMP Certificate (heparin sodium API) (Germany)	Hepalink	January 13, 2020	January 12, 2022
DUNS Registered Certificate	Hepalink	March 2020	March 2022
GMP Certificate (Brazil) (enoxaparin sodium API)	Shenzhen Techdow	March 14, 2019	March 17, 2021
GMP Certificate (Brazil) (enoxaparin sodium API)	Shenzhen Techdow	April 20, 2020	April 20, 2022
GMP Certificate (packaging materials for enoxaparin sodium injection) (Poland)	Shenzhen Techdow	April 26, 2018	January 22, 2021
DUNS Registered Certificate	Shenzhen Techdow	April 2020	April 2022
GMP Certificate (heparin sodium API) (Brazil)	Hepalink	May 6, 2019	May 5, 2021
GMP Certificate (enoxaparin sodium API) (Poland)	Shenzhen Techdow	May 10, 2018	January 22, 2021
FDA GMP Inspection Approval Letter (enoxaparin sodium API and enoxaparin sodium injection)	Shenzhen Techdow	May 29, 2018	N/A
GMP Certificate (enoxaparin sodium API) (Poland)	Shenzhen Techdow	November 18, 2019	July 21, 2022
GMP Certificate (enoxaparin sodium injection) (Poland)	Shenzhen Techdow	May 14, 2018	January 22, 2021
GMP Certificate (enoxaparin sodium injection) (Poland)	Shenzhen Techdow	June 13, 2019	March 18, 2022
EDQM-CEP Certificate (heparin sodium API)	Hepalink	April 21, 2020	N/A
API Export Certificate (heparin sodium API) (EU)	Hepalink	July 31, 2019	July 30, 2022
API Export Certificate (enoxaparin sodium API) (EU)	Shenzhen Techdow	October 16, 2019	October 15, 2022
FDA GMP Inspection Approval Letter (enoxaparin sodium API and enoxaparin sodium injection)	Shenzhen Techdow	October 28, 2019	N/A
GMP Certificate (heparin sodium API) (Germany)	Hepalink	January 17, 2020	June 30, 2021
GMP Certificate (non-sterile drugs) (Japan)	Hepalink	May 31, 2020	May 30, 2025

*Notes:*

- (1) The approval was granted to Techdow Europe AB on September 15, 2016, and transferred to Techdow Pharma Netherland B.V. on February 10, 2020.
- (2) The approval was granted to Techdow Europe AB on September 17, 2018, and transferred to Techdow Pharma Netherland B.V. on February 10, 2020.
- (3) The approval was granted to Techdow Europe AB on July 25, 2019, and transferred to Techdow Pharma Netherland B.V. on February 10, 2020.

We do not expect any material legal impediment in renewing these licenses, approvals, permits and certificates as long as we are in compliance with applicable rules, laws and regulations.

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### AWARDS AND RECOGNITION

The table below set forth a summary of the major awards, and projects for which we received government grants as of the Latest Practicable Date:

Award/Project	Grant Year	Grant Authority	Grant Amount
2017 Foreign Investment and Economic Development Special Fund—Shenzhen Foreign Investment Cooperation Project (2017年外經貿發展專項資金深圳市對外投資合作項目)	2017	Shenzhen Commission of Economy and Information Technology	RMB22,558,000
Enterprise R&D funding (企業研發資助)	2017	Shenzhen Commission of Science and Technology Innovation	RMB2,609,000
Enterprise R&D funding (企業研發資助) (Shenzhen Techdow)	2017	Shenzhen Commission of Science and Technology Innovation	RMB1,070,000
2016 International Marketing Network (2016國際營銷網絡)	2017	Shenzhen Commission of Economy and Information Technology	RMB600,000
“Honoring Contracts and Standing Reputation” Enterprise (守合同重信用企業)	2018	Shenzhen Bureau of Market Supervision	N/A
Enterprise R&D Funding (企業研發資助)	2019	Shenzhen Commission of Science and Technology Innovation	RMB2,030,000
Enterprise R&D Funding (企業研發資助) (Shenzhen Techdow)	2019	Shenzhen Commission of Science and Technology Innovation	RMB1,199,000
2018 Technology Transformation Investment Subsidy Project (2018年技術改造投資補貼項目)	2018	Shenzhen Commission of Economy and Information Technology	RMB1,010,000
Nanshan District Industrial Value Added Project (Shenzhen Techdow) (南山區工業增加值項目)	2018	Nanshan Bureau of Economic Promotion	RMB1,000,000
Large-scale Industrial Enterprises Innovation Ability Cultivation and Improvement Plan (大型工業企業創新能力培育提升支持計劃項目)	2019	Nanshan Bureau of Science and Technology Innovation	RMB319,100
International Marketing Network Fund (Nanshan District) (國際營銷網絡資助項目(南山區))	2018	Nanshan Bureau of Economic Promotion	RMB300,000
Key Export Enterprise Exhibition Project (重點出口企業參展資助項目)	2018	Nanshan Bureau of Economic Promotion	RMB161,200
Shenzhen Famous Brand (深圳市知名品牌)	2018	Shenzhen Confederation of Industry	N/A
2018 Annual Enterprise Technology Transformation Multiplier Support and Funding Plan (Key Project Awards and Subsidies) (2018年度企業技術改造倍增專項資助計劃(重大項目獎補))	2019	Shenzhen Bureau of Industry and Information Technology	RMB17,350,000



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<u>Award/Project</u>	<u>Grant Year</u>	<u>Grant Authority</u>	<u>Grant Amount</u>
2019 Enterprise Expansion and Efficiency Increase Support Plan (Shenzhen Techdow) (2019年企業擴產增效扶持計劃)	2019	Shenzhen Bureau of Industry and Information Technology	RMB1,000,000
Nanshan District National High-tech Enterprise Multiplier Support Program (南山區國家高新技術企業倍增支持計劃)	2019	Nanshan Bureau of Science and Technology Innovation	RMB100,000
Shenzhen Top 20 Leading Life Science Enterprise (深圳領先生物科技企業20強)	2019	Shenzhen National High Technology Industry Innovation Centre	N/A
High-tech Enterprise Certification (高新技術企業證書)	2018-2021	Shenzhen Commission of Science and Technology Innovation	N/A
2020-2022 Demonstration Enterprise of Manufacturing Industry Single Championship (製造業單項冠軍示範企業)	2019	Ministry of Industry and Information Technology	N/A