
SUMMARY

This summary aims to give you an overview of the information contained in this document. As this is a summary, it does not contain all the information that may be important to you. You should read the entire document before you decide to [REDACTED] in the [REDACTED]. In particular, we are a biotechnology company seeking to [REDACTED] on the Main Board of the Stock Exchange under Chapter 18A of the Listing Rules on the basis that we are unable to meet the requirements under Rule 8.05 (1), (2) or (3) of the Listing Rules. There are unique challenges, risks and uncertainties associated with [REDACTED] in companies such as ours. In addition, we have incurred significant operating losses since our inception, and we expect to remain loss making in the near term. We had negative net cash flow from operating activities during the Track Record Period. We did not declare or pay any dividends during the Track Record Period and do not intend to pay any dividends in the near future. Your [REDACTED] decision should be made in light of these considerations.

There are risks associated with any [REDACTED]. Some of the particular risks in [REDACTED] in the [REDACTED] are set out in the section headed “Risk Factors” in this document. You should read that section carefully before you decide to [REDACTED] in the [REDACTED].

BUSINESS OVERVIEW

We are a leading China-based, global rare disease-focused biopharmaceutical company committed to the research, development and commercialization of transformative therapies. As of the Latest Practicable Date, we had developed a comprehensive and differentiated pipeline of 13 drug assets with significant market potential targeting some of the most prevalent rare diseases as well as rare oncology indications, including three marketed products, three drug candidates at clinical stage, two at IND-enabling stage, two at preclinical stage and another three gene therapy programs at lead identification stage.

We are led by a seasoned management team with significant industry experience in rare diseases, spanning R&D, clinical development, regulatory affairs, business development and commercialization, supported by a pool of talent of 151 employees where 22 had a Ph.D. and/or M.D. degree and more than 80% of our employees had experience working at multinational biopharmaceutical companies as of the Latest Practicable Date. Our management team collectively has a track record of successfully commercializing rare disease therapies across the key markets including China, the United States, Europe, Latin America, and Southeast Asia. Leveraging our management’s expertise, we play an active role in advancing the rare disease industry and shaping the rare disease ecosystem in China. For example, our founder Dr. Xue is currently serving as the Deputy Director General of China’s Alliance for Rare Disease (CHARD).

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Since our inception in 2012, we have built a comprehensive portfolio targeting diseases with validated mechanisms of action with significant market potential, consisting of biologics, small molecules and gene therapy solutions. We have built our pipeline through, and will continue to enrich it via, business partnerships and collaborations with academic institutions together with in-house research and development.

- In the rare disease area, we have seven biologics and small molecules products and product candidates for the treatment of Hunter Syndrome (MPS II) and other lysosomal storage disorders (LSDs), complement mediated disorders, hemophilia A, metabolic disorders, and rare cholestatic liver diseases including Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA). Among these, we obtained the marketing approval for Hunterase® (CAN101) for MPS II in mainland China in September 2020. We are conducting a Phase 1 clinical trial in healthy volunteers for CAN106 in Singapore, and received an IND acceptance notice from the NMPA for CAN106 in April 2021 for a Phase 1 study.
- In the rare oncology area, we are developing CAN008 for the treatment of glioblastoma multiforme (GBM). In 2018, we completed a Phase 1 clinical trial for CAN008 in Taiwan, which has successfully bridged CAN008 to Asian patients with newly diagnosed GBM on the back of clinical data previously obtained in overseas trials. We plan to dose the first patient in a Phase 2 clinical trial of CAN008 for the first-line treatment of GBM patients in mainland China in the second half of 2021. We also obtained marketing approval for two other oncology products, Caphosol™ (CAN002) in mainland China and Nerlynx® (CAN030) in Greater China.

In addition to biologics and small molecules, we are investing in next-generation technology for gene therapies. Gene therapies provide a potentially one-time, durable treatment for various underserved rare genetic diseases. As of the Latest Practicable Date, we are using AAV sL65 capsid vector licensed in from LogicBio Therapeutics to develop two gene therapy products for the treatment of Fabry disease and Pompe disease, with options to develop two additional indications using the same vector and a clinical-stage gene editing program for the treatment of methylmalonic acidemia (MMA) pursuant to our collaboration agreements with LogicBio Therapeutics. We are also working with our research partner UMass on sponsored research programs to develop gene therapy solutions for neuromuscular disorders, with the exclusive option to license-in the assets for development. In addition, we are internally developing an adeno-associated virus (AAV) delivery platform targeting different tissues such as the central nervous system (CNS) and muscle.

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The following chart summarizes our portfolio and the development status of each drug asset as of the Latest Practicable Date:

Product	Modality	Mechanism	Indication	Discovery/ Pre-clinical	IND-enabling	Ph I	Ph II/III	NDA	Marketed	Partner	Commercial Rights ⁽¹⁾
CAN008 ★ (Asunerecept)	Biologic	CD95-Fc fusion protein	Glioblastoma Multiforme ⁽²⁾	Taiwan Phase 1 trial completed China Phase 2 - Ind approval						apogenix	Greater China
Hunterase® (Idursulfase beta)	Biologic	ERT iduronate-2-sulfatase (IDS)	Hunter syndrome (Mucopolysaccharidosis type II) ⁽³⁾							GC Pharma	Greater China
CAN 108 (maralixibat)	Small molecule	ASBT-inhibitor	Alagille Syndrome ⁽⁴⁾ Progressive Familial Intrahepatic Cholestasis ⁽⁶⁾	China Pre-NDA				NDA accepted by FDA MMA filed with EMA		mirum	Greater China Greater China Greater China
CAN 106	Biologic	Anti-C5 mAb	Biliary Atresia ⁽⁵⁾ Paroxysmal nocturnal hemoglobinuria (PNH) and other Complement Disorders ⁽⁶⁾					Global U.S., Europe and China Phase 2 initiated			Greater China/ Global ⁽⁷⁾
CAN 103	Biologic	ERT GBA	Gaucher Disease ⁽⁸⁾	Singapore Phase 1 trial initiated China Phase 1 trial IND accepted by NMPA						WuXi Biologics / Privus	Greater China/ Global ⁽⁷⁾
CAN 107	Biologic	Anti-FGF23 mAb	X-linked hypophosphatemia							WuXi Biologics / Privus	Greater China/ Global ⁽⁷⁾
CAN 104	Biologic	ERT GLA	Fabry Disease							WuXi Biologics	Global
CAN 105	Biologic	Anti-Factor IXa/ X bssAb	Hemophilia A							WuXi Biologics	Greater China
Undisclosed	Gene Therapy	AAV	Neuromuscular Disorders ⁽⁹⁾							University of Liverpool UMMS Medical School	Global
CAN 201	Gene Therapy	AAV sL65 GLA	Fabry Disease ⁽⁹⁾							LogicBio	Global
CAN 202	Gene Therapy	AAV sL65 GAA	Pompe Disease ⁽⁹⁾							LogicBio	Global
Caphosol™	Small molecule ⁽¹⁰⁾	Calcium phosphate rinse	Oral Mucositis							USA Pharma	China
Nerlynx® (Neratinib)	Small molecule	Tyrosine kinase inhibitor	HER2+ Breast Cancer HER2+ Metastatic Breast Cancer							Pierre Fabre	Hong Kong, Taiwan Macau ⁽¹¹⁾

★ Core Product █ Clinical trials performed by license partner ◻ Next Milestone

Notes:

- Greater China includes mainland China, Hong Kong, Taiwan and Macau.
- We have completed Phase 1 trial in Taiwan and obtained IND approval for the first line GBM Phase 2 clinical trial in China.
- We obtained a clinical trial waiver and the NDA approval for Hunterase® (CAN101) for MPS II from the NMPA.
- We expect to file NDA in Greater China by the end of 2021 based on data obtained by our license partner in global studies.
- For BA, we are supporting the patient recruitment and clinical site management in China for a global Phase 2 clinical trial initiated by our license partner in the U.S. and Europe. IND approval was obtained from the NMPA in May 2021 and we plan to begin patient enrollment in China as part of the global Phase 2 trial.
- We are conducting a Phase 1 clinical trial for CAN106 in Singapore and worldwide excluding Greater China right granted from Privus.
- Greater China right granted from WuXi Biologics and worldwide excluding Greater China right granted from Privus.
- We expect to submit the IND application to the NMPA for CAN103 in 2H2021.
- Gene therapy programs at lead identification stage, including two programs (CAN201 and CAN202) licensed from LogicBio and one undisclosed program with exclusive option to enter into a licensing agreement with UMass.
- Caphosol™ is an oral electrolyte solution and designated as a prescription medical device.
- We have entered into a distribution agreement with Pierre Fabre pursuant to which Pierre Fabre appointed us as its distributor with exclusive rights to sell Nerlynx® (CAN030) for Pierre Fabre in Hong Kong, Macau, and Taiwan.

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OUR BUSINESS MODEL

We strategically combine global collaborations and internal research to build and diversify our drug portfolio. As the Chinese rare disease market rapidly expands, many international biopharmaceutical companies are interested in accessing this growing and untapped market but lack the local expertise. Leveraging our global collaborations and R&D capabilities, we believe we can serve as a gateway to China and a preferred partner for international biopharmaceutical companies. As of the Latest Practicable Date, our global partners include but not limited to Apogenix, GC Pharma, Mirum, Wuxi Biologics, Privus, University of Massachusetts Medical School (UMass) and LogicBio. In 2019, we in-licensed Hunterase® (CAN101) from an international biopharmaceutical company, GC Pharma, which is our first commercialized rare disease product to address significant unmet needs in China, supported by clinical validation and marketing authorization in over 10 countries worldwide by GC Pharma. We are working with our research partner UMass on sponsored research programs to develop gene therapy solutions for neuromuscular disorders, with the exclusive option to license-in the assets for development. We also seek to replicate the model by working with China-based academic institutions. In addition, our experienced research team continues our efforts in identifying and developing drug candidates to further expand our portfolio. For example, our internal research team is developing gene therapy solutions for neuromuscular disorders. We leverage our commercialization capabilities to maximize the market potential of our drug candidates. We established key operation hubs in Beijing and Shanghai and offices in other locations in Greater China, and plan to expand to each of the key target provinces with local offices in mainland China. We are currently expanding our targeted, in-house commercialization team, which is expected to expand into over 300 members in the next five years.

Leveraging a world-class management team, a robust product portfolio and an integrated platform with access to industry leading rare disease technologies, we believe we are well positioned to capture the vast and underserved rare disease market in China and globally.

OUR DRUG CANDIDATES

Late Stage Drug Products and Candidates

CAN008 CD95-Fc fusion protein for GBM

CAN008, our Core Product, is a glycosylated CD95-Fc fusion protein being developed for the treatment of GBM. We commenced a Phase 1 trial of CAN008 in combination with radiation therapy (RT) and temozolomide (TMZ) in patients with newly diagnosed GBM in September 2016 in Taiwan under the authorization of the Taiwan Food and Drug Administration ("TFDA"). A Phase 2 trial of CAN008 was completed by Apogenix AG (Apogenix) in recurrent GBM in Europe in September 2014. We completed the Phase 1 trial in Taiwan in September 2018 after 24 months of clinical research and development and results show CAN008 was generally well tolerated in patients with GBM. No dose-limiting toxicity was observed and no treatment-related serious adverse events were reported. We, on the back of the data obtained from the Phase 1 trial in Taiwan and results from the Phase 2 trials completed overseas by Apogenix, received the IND approval for CAN008 from the NMPA in March 2018 for a second-line Phase 2 trial and subsequently amended our IND application and

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received the approval for a first-line Phase 2 trial in China on patients with GBM in April 2021. We plan to dose the first patient in the Phase 2 trial of CAN008 as a first-line treatment for GBM patients in China in the second half of 2021. It is designed to be multi-center, randomized, double-blind and placebo-controlled to investigate the efficacy and explore the correlation of different biomarkers with treatment outcome.

There are currently three targeted drugs for GBM marketed in China and seven being developed in China and worldwide. For details, see “Industry Overview – Glioblastoma Multiforme (GBM)”.

Hunterase® (CAN101) targeting MPS II/Hunter syndrome

Hunterase® (CAN101) is an enzyme replacement therapy being developed for the treatment of mucopolysaccharidosis type II (“MPS II”). We in-licensed Hunterase® (CAN101) from GC Pharma (or “GC”) in January 2019. Multiple clinical trials have been conducted to date by GC to evaluate the safety and efficacy of Hunterase® (CAN101), including the pivotal Phase 1/2 trial for the approval from MFDS (formerly known as the Korea Food & Drug Administration or KFDA) and certain post-approval studies. The pivotal study indicated significant subject benefit, a significant decrease in uGAG level from baseline, and an improvement in the primary endpoints. Hunterase® (CAN101) is currently marketed in over 10 countries worldwide by GC Pharma. It received marketing authorization as an orphan drug from the MFDS in January 2012. As of the Latest Practicable Date, Hunterase® (CAN101) has received marketing authorization from authorities in Algeria, Belarus, Kazakhstan and Russia and has been available for prescription in Brazil, Egypt, India, Malaysia, Oman, Turkey and Venezuela, for treatment of MPS II. We obtained a clinical trial waiver and the NDA approval for Hunterase® (CAN101) for MPS II from the NMPA in September 2020.

We plan to conduct a post-approval study in China as required by the NMPA.

Hunterase® (CAN101) is currently the only targeted therapy to MPS II available in China. There are eight targeted drugs for MPS II in clinical stage in China and worldwide. For details, see “Industry Overview – Mucopolysaccharidosis Type II (MPS II or Hunter syndrome)”.

CAN108 (maralixibat)

CAN108 (maralixibat) is a novel, oral, minimally-absorbed agent designed to selectively inhibit apical sodium-dependent bile acid transporter (ASBT) and treat rare cholestatic liver diseases, including Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA). In April 2021, we obtained an exclusive license from Mirum to develop, manufacture and commercialize CAN108 (maralixibat) in Greater China for ALS, PFIC and BA. ASBT is primarily responsible for recycling bile acids from the intestine back to the liver. ASBT inhibition results in more bile acids being excreted in the feces, leading to lower levels of bile acids systemically, thereby reducing bile acid mediated effects and liver damage. By targeting bile acids in these settings, maralixibat has the potential to improve long-term outcomes and symptoms in our targeted settings and provide an alternative treatment to liver transplant. Maralixibat possesses an extensive safety dataset, having been evaluated in more than 1,600 human subjects. Maralixibat has been studied in a number of completed and ongoing clinical trials in ALGS and PFIC with over 120 children treated and some on study for over seven years.

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We have started preparation of NDA for ALGS and PFIC for CAN108 and expect to file the initial NDA by the end of 2021 in mainland China and Taiwan based on data obtained by our collaboration partner in global studies. For BA, we are supporting the patient recruitment and clinical site management in China for a Phase 2 clinical trial initiated in the first half of 2021 by our collaboration partner.

There is currently no approved product in China or worldwide for ALGS, PFIC or BA. There are two targeted drugs for ALGS, two for PFIC and four for BA being developed in China and worldwide respectively. For details, see "Industry Overview – Rare Cholestatic Liver Diseases".

CAN106 long-acting anti-C5 antibody for complement disorders

CAN106 is an innovative humanized monoclonal antibody against complement C5 being developed for the treatment of complement-mediated diseases including paroxysmal nocturnal hemoglobinuria (PNH), and various other complement-mediated diseases that are targeted by approved anti-C5 antibodies and other new potential indications. We have global rights to develop and commercialize this drug candidate. Based on preclinical data, CAN106 has demonstrated a favorable PK/PD profile and tolerability, indicating that CAN106 has the potential to effectively inhibit C5 in patients with PNH and potentially with reduced dosing frequency. We submitted the first IND application for a Phase 1 clinical trial of CAN106 in Singapore in October 2020 and received IND approval from Health Sciences Authority (HSA) in December 2020. We are conducting a Phase 1 clinical trial for CAN106 in Singapore. This first-in-human study is designed to be a randomized, double-blind, placebo-controlled and single ascending dose study in 31 healthy volunteers to evaluate the safety, pharmacokinetics, pharmacodynamics and development of anti-drug antibodies of CAN106. A Phase 1 study is planned in China. We received an IND acceptance notice from the NMPA for the Phase 1 study in April 2021.

SOLIRIS is currently the only approved product in China targeting PNH. There are eight C5 inhibitors targeting PNH being developed in China and worldwide. For details, see "Industry Overview – Complement Mediated Diseases".

Our Preclinical Candidates

CAN103

CAN103 is an ERT for Gaucher disease (GD) being locally developed in China and the first rare disease asset we acquired in 2018 from WuXi Biologics, which we have global proprietary rights to develop and commercialize. It is produced in an engineered cell line that produces recombinant beta-glucocerebrosidase (GCase) with highly exposed mannose for efficient uptake by macrophage and Kupfer cells in Gaucher patients to break down glucocerebrosides (GL1), the lipids that accumulate in the body of patients with GD. GD is a lysosomal storage disorder due to mutations in the GBA gene. It is one of the best known and prototypical rare diseases in China with approximately 3,000 patients in 2020.

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We expect to submit the IND application to the NMPA for CAN103 in the second half of 2021. Subject to regulatory approval, we plan to conduct a Phase 1/2 trial in adult and adolescent GD patients.

There are currently six targeted drugs for GD marketed in the U.S. and seven being developed in China and worldwide. For details, see "Industry Overview – Gaucher Disease (GD)".

CAN107

CAN107 is recombinant humanized anti-FGF23 mAb for X-linked hypophosphatemia (XLH) being developed in China currently at CMC stage in preparation to initiate IND-enabling studies. XLH is an inherited disease of phosphate metabolism where mutations inactivating the Phosphate Regulating Endopeptidase Homolog, X-Linked (PHEX) gene lead to inactivation of the PHEX protein. The lack of PHEX protein/activity prevents it from correctly regulating fibroblast growth factor 23 (FGF23), resulting in overactivity of FGF-23 that reduces vitamin D1 α -hydroxylation and phosphate reabsorption by the kidneys, leading to hypophosphatemia and the related features of hereditary hypophosphatemic rickets, local and systemic effects including impaired growth, rickets, bone abnormalities and muscular dysfunction. The prevalence of the disease is estimated at 1 in 20,000 people, according to Frost & Sullivan.

CAN105

CAN105 is being developed for the treatment of Hemophilia A with massive market potential. It is a recombinant, humanized, bispecific antibody that bridges activated factor IX and factor X to restore the function of the missing activated factor VIII, which is not expected to be affected by existing factor VIII inhibitors or induce new development of such inhibitors. There were over 120,000 Hemophilia A patients in China in 2020 with an expected growth at a CAGR of 0.5% from 2020 to 2025 and 0.1% from 2025 to 2030. CAN105 is expected to enter preclinical research phase in the second half of 2021.

Gene Therapy – CAN201 and CAN202

sL65 is a next generation liver-tropic AAV capsid platform for use in gene editing and gene therapy. At the American Society of Gene & Cell Therapy ("ASGCT") conference in May 2020, data was presented showing that the capsids delivered highly efficient functional transduction of human hepatocytes in a humanized mouse model and non-human primates. The data also showed the capsids exhibited improved manufacturability and more resistance to pre-existing neutralizing antibodies in human serum samples. We are devising preclinical strategies on CAN201 as we and our collaboration partner conduct preclinical evaluations of this drug candidate. Our development plan on CAN202 is subject to the development status of CAN201 to de-risk the process.

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Core Product Candidate Development Process

Since in-licensing CAN008 from Apogenix in June 2015, we have engaged in substantial R&D work for more than 12 months on CAN008, primarily including:

- (a) From July 2015 to January 2016, we completed a biomarker study for expression of CD95L, the first of its kind in China, in over 60 Chinese patients with GBM. The biomarker study confirmed the existence of CD95L in Chinese GBM patients and demonstrated a high degree of consistency of CD95L expression between geographically diverse Chinese and Western GBM patients;
- (b) From April 2016 to July 2016, we consulted a reputable CRO on managing clinical trials in Taiwan and their experience with going through TFDA consultation, researched and compared contract research organizations and engaged another reputable CRO to prepare for the Phase 1 trial of CAN008 in Taiwan. We conducted further specialized research, improved our trial design and prepared pre-IND materials for communications with the TFDA. We submitted the Taiwan IND application in March 2016 and received approval from the TFDA in July 2016;
- (c) From September 2016 to September 2018, we completed a Phase 1 trial of CAN008 in combination with RT and TMZ in 10 patients with newly diagnosed GBM in three hospitals in Taiwan under the authorization of the TFDA: Chang Gung Memorial Hospital, Linkou, National Taiwan University Hospital and Tri-Service General Hospital. On the back of the Phase 1 trial, we filed an IND application with the NMPA in June 2017, which was accepted in July 2017;
- (d) Since April 2016, in parallel with the Phase 1 trial of CAN008 in Taiwan, we have invested significant development efforts into the CMC tech transfer of CAN008 to manufacture it in China. For example, it underwent antibody effector function testing. A 30-month stability test was also included to extend batch stability monitoring of CAN008.
- (e) Since we received IND approval from the NMPA for CAN008's Phase 2 trial in March 2018, we have continued to dedicate extensive R&D efforts into the preparation of the trial, including:
 - (i) engaging experts from over 15 hospitals in China and Europe, to evaluate and refine the clinical trial protocol design;

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- (ii) assessing 9 trial clinical sites for potential participation in the trial based on their patient flow, medical capabilities and doctors' experience; and
- (iii) holding site-initiation visits at Beijing Tiantan Hospital, Tianjin Medical University General Hospital, Huashan Hospital Fudan University, Peking Union Medical College Hospital, Tongji Medical College of Huazhong University of Science & Technology and Harbin Medical University Cancer Hospital and discussed with principal investigators on study design, safety monitoring and mitigation plan, efficacy endpoints, as well as patient screening and enrollment.

While the Phase 2 trial previously approved by the NMPA was for a second-line trial, we submitted updated Phase 2 first-line clinical trial application for CAN008 in December 2020 and have received CDE clearance in April 2021. We plan to dose the first patient in the Phase 2 clinical trial of CAN008 for the first-line treatment of GBM patients in China in the second half of 2021. It is designed to be multi-center, randomized, double-blind and placebo-controlled to investigate the efficacy and explore the correlation of different biomarkers with treatment outcome.

OUR COMPETITIVE STRENGTHS

We believe the following strengths differentiate us from our competitors:

- A leading rare disease focused biopharmaceutical company dedicated to addressing vast and unmet medical needs
- A robust and comprehensive portfolio of rare disease focused therapies with significant revenue potential
- Extensive strategic partnerships to source innovative therapies globally
- A fully integrated rare disease platform positioned to drive rapid and comprehensive product development and market access in China and globally
- Management team with deep industry experience and a track record of commercializing rare disease therapies globally

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OUR STRATEGIES

We aspire to become a global biopharmaceutical leader that delivers transformative and affordable therapies for rare disease patients in China and worldwide. We plan to implement the following strategies to achieve our vision:

- Further solidify our leadership in the China's rare disease ecosystem and build a global rare diseases franchise
- Drive commercialization of our late-stage assets in Greater China
- Rapidly advance and expand our portfolio
- Maximize value creation through partnership and collaboration
- Build fully integrated capabilities with in-house drug research, development and manufacturing infrastructure in global and Greater China markets

RESEARCH AND DEVELOPMENT

We believe that R&D is key to driving our therapeutics strategy and maintaining our competitiveness in the biopharmaceutical industry. We are dedicated to enhancing our rare disease drugs portfolio by leveraging our world-class in-house R&D capabilities, which span from preclinical research to clinical development.

Our R&D team members have extensive preclinical and clinical development experience, including a proven track record in the development of drugs for the treatment of different types of rare diseases. As of the Latest Practicable Date, we had a total of 151 employees, among whom 22 have a Ph.D. and/or M.D. degree, and more than 80% of our employees had experience working at multinational biopharmaceutical companies. Our R&D team members have an average of approximately 10 years of relevant industry experience.

Our R&D team is led by our founder, Chairman and CEO, Dr. Xue (Ph.D., M.B.A.), a veteran entrepreneur with over 22 years of experience in medical and pharmaceutical companies. Serving as the founding general manager of Genzyme China, he had successfully managed the launch of several life-saving drugs for the treatment of hematologic cancer and rare metabolic diseases in China, including but not limited to Thymoglobulin and Cerezyme. He is also the Deputy Director General at CHARD, Vice Chair of R&D Committee of China Pharmaceutical Innovation and Research Development Association (PhIRDA) and a member of Leadership Council of Joint Institute of Peking University Health Science Center and University of Michigan Medical School.

For the years ended December 31, 2019 and 2020 and the three months ended March 31, 2021, our R&D expenses were RMB55.4 million, RMB109.6 million and RMB67.0 million respectively.

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INTELLECTUAL PROPERTY RIGHTS

Intellectual property rights are important to the success of our business. Our success depends, in part, on our ability to obtain and maintain patent and other intellectual property and proprietary protections for commercially important technologies, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating or otherwise violating the valid, enforceable intellectual property rights of third parties.

As of the Latest Practicable Date, we own or otherwise have exclusive rights to 19 granted patents and 38 pending patent applications worldwide. We believe there is no material legal impediment for us to obtain the approvals for these pending patents and trademarks.

The following table includes the information on our key patent rights for our Core Product:

Product	Scope of Patent Protection	Patent Applicant/Holder	Jurisdiction	Status	Patent Expiration*
CAN008	CD95-Fc Variants	Apogenix	China, Hong Kong	Granted	2033
	Reagents and methods of detecting cancer	Apogenix	China	Granted	2033
	CD95-Fc isoforms	Apogenix	China, Hong Kong	Pending	N/A

Our Directors confirm that, as of the Latest Practicable Date, we were not a party to any material legal or administrative proceedings in connection with intellectual property rights or otherwise, and we are not aware of any instances of infringement of any third parties’ intellectual property rights by us which could materially and adversely affect our business.

For details on the portfolio of patent applications material to our business operations, see “Business – Intellectual Property”.

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 development experience and scientific knowledge provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biopharmaceutical companies, academic institutions and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing drugs and new drugs that may become available in the future.

For the competitive landscape of our specific drug candidates, please refer to “Business – Our Portfolio.”

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COLLABORATION AND LICENSING ARRANGEMENTS

Development and License Agreement with Apogenix

On June 26, 2015, we entered into a development and license agreement with Apogenix AG (previously known as Apogenix GmbH) (“Apogenix”) as amended in December 2015 and in May 2021 (the “Apogenix Agreement”) concerning our exclusive right to develop, manufacture and commercialize the compound known as APG101 (CAN008) and pharmaceutical products containing APG101 (“Apogenix Licensed Products”) in mainland China, Hong Kong, Macau and Taiwan (the “Greater China”).

Pursuant to the Apogenix Agreement, Apogenix granted us an exclusive, royalty-bearing, license under specified Apogenix patent rights, materials and know-how to develop (not including any modification to the compound), manufacture and commercialize, including to market, promote, label, package, distribute, import, export, offer to sell and sell the Apogenix Licensed Products in Greater China for the treatment of patients with glioblastoma disease (the “GBM”). Any sublicense to a third party by us (excluding to affiliates of us and Apogenix) requires the prior written consent of Apogenix. Pursuant to the Apogenix Agreement, should we, our affiliates or sublicensees outside the scope of the agreement commence clinical trials or commercialize any CD95 ligand inhibitor for the treatment of GBM within Greater China, then Apogenix may terminate and convert our exclusive license into a non-exclusive license and may independently exploit the Apogenix Licensed Products in Greater China, and we must grant to Apogenix a non-exclusive license to our development data.

Under the Apogenix Agreement, we are responsible for the development, manufacturing and commercialization of APG101 for the treatment of GBM in Greater China. We must use commercially reasonable efforts to develop, obtain regulatory approval for and commercialize the Apogenix Licensed Products in Greater China, and we are responsible for all costs and expenses incurred by us, or by Apogenix under the development plan and technology transfer as specified in the Apogenix Agreement associated with such activities.

Exclusive License Agreement with GC Pharma

On January 3, 2019, we entered into a license agreement (the “GC Pharma Agreement”) with Green Cross Corporation (“GC Pharma”) concerning the exclusive right to develop and commercialize any biopharmaceutical products containing the compound Idursulfase- β developed by GC Pharma as an active pharmaceutical ingredient that is formulated for intravenous administration in the treatment of Mucopolysaccharidosis Type II (also known as Hunter Syndrome) (the “GC Pharma Licensed Products”) in all indications except for the indication specifically for CNS symptoms (the “GC Pharma Licensed Field”). The GC Pharma Licensed Products include the product currently marketed by or on behalf of GC Pharma outside Greater China under the product name Hunterase®.

Pursuant to the GC Pharma Agreement, GC Pharma granted to us an exclusive, sublicensable (subject to certain conditions), royalty-bearing right and license under certain patent rights, know-how and product names and trademarks relating to the GC Pharma

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Licensed Products to develop and commercialize (excluding manufacturing activities) the GC Pharma Licensed Products in the GC Pharma Licensed Field in Greater China. We elected under the GC Pharma Agreement not to commercialize in the following provinces: Shanxi, Guizhou, Gansu, Qinghai, Xizang, Jilin and Yunnan, and are required, upon written request of GC Pharma, to enter into a sublicense agreement licensing our commercialization rights under the GC Pharma Agreement to a designated GC Pharma affiliate in one or more of such provinces. GC Pharma has granted to us a right of first negotiation with respect to collaborations in the licensed territory regarding development and commercialization of the GC Pharma Licensed Products for treatment of Mucopolysaccharidosis Type II in the CNS indication. GC Pharma has also granted to us a right of first refusal with respect to GC Pharma granting to, or obtaining an offer from, a third party to develop or commercialize the GC Pharma Licensed Products in the licensed territory for treatment of Mucopolysaccharidosis Type II in the CNS indication.

Under the GC Pharma Agreement, we are responsible, and must use commercially reasonable efforts, to develop, obtain regulatory approval for and commercialize the GC Pharma Licensed Products, and we are responsible for all costs and expenses incurred by us or on behalf of us associated with such activities. Unless separately agreed, we agree to purchase and GC Pharma agrees to supply to us GC Pharma Licensed Products at a fixed price as set forth in the GC Pharma Agreement and supply samples to us for regulatory approval at no charge. We also agreed not to directly or indirectly develop, manufacture or commercialize any product indicated for the treatment of Mucopolysaccharidosis Type II in China, other than the GC Pharma Licensed Products.

Exclusive License Agreement with WuXi Biologics

On January 7, 2019, we entered into a license agreement (the "WuXi Biologics Agreement") with WuXi Biologics Ireland Limited ("WuXi Biologics"), wherein WuXi Biologics granted to us (i) an exclusive, transferable (subject to certain conditions), royalty-bearing license under (a) all patents and patent applications controlled by WuXi Biologics or its affiliates during the term of agreement in Greater China that claim any aspect of the anti-C5 antibody that binds specifically to the C5 protein or a pharmaceutical composition containing the anti-C5 antibody (the "WuXi Biologics Licensed Product") and (b) know-how solely pertaining to the WuXi Biologics Licensed Product, and (ii) a non-exclusive, royalty-bearing license under certain know-how that relates to both the WuXi Biologics Licensed Product and other products, in each case of (i) and (ii), with the right to sublicense through multiple tiers (subject to certain conditions), and to make, have made, use, register, sell, offer to sell, have sold, import, export, exploit, research, improve, develop and commercialize the WuXi Biologics Licensed Product (including all improvements and/or modifications) in Greater China for all indications related to the anti-C5 antibody. We granted back to WuXi Biologics a co-exclusive, irrevocable, fully paid, royalty-free license under all patent rights and know-how controlled by us, our affiliates or sublicensees at any time during the term of the agreement that is solely related to the WuXi Biologics Licensed Product or anti-C5 antibody or the research, development, manufacture, commercialization, sale or use

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thereof. WuXi Biologics has granted to us a right of first negotiation with respect to a global license for the WuXi Biologics Licensed Product and a right of first refusal with respect to a third party granting to or receiving from WuXi Biologics a global license, in each case outside of Greater China.

Under the WuXi Biologics Agreement, we will be responsible for the development and commercialization of the WuXi Biologics Licensed Product. We must use commercially reasonable efforts to develop, obtain regulatory approval and commercialize the WuXi Biologics Licensed Product, and we are responsible for all costs and expenses incurred by us or on behalf of us associated with such activities. Unless separately agreed, WuXi Biologics is our exclusive clinical supplier and primary commercial supplier for the WuXi Biologics Licensed Product.

Exclusive License Agreement with Privus

On May 9, 2020, we entered into a license agreement (the "Privus Agreement") with Privus Biologics, LLC ("Privus"), wherein Privus granted to us (i) an exclusive, transferable (subject to certain conditions), royalty-bearing license under (a) all patents and patent applications controlled by Privus or its affiliates during the term of agreement in worldwide except for Greater China with regard to a terminal complement inhibitor of the C5a and C5b proteins, and all other terminal complement inhibitors of the C5a and C5b proteins controlled by Privus (the "Privus Licensed Product") and (b) know-how solely pertaining to the Privus Licensed Product, and the right to sublicense through multiple tiers in worldwide except for Greater China for all Privus Licensed Product.

Under the Privus Agreement, we will have sole control over and responsibility and decision-making authority for, at our sole cost and expenses, all development and commercialization of the Privus Licensed Product. We must use commercially reasonable efforts to develop, seek regulatory approval and commercialize the Privus Licensed Product, and we are responsible for all costs and expenses incurred by us or on behalf of us associated with such activities.

Collaboration with UMass

On June 1, 2020, we entered into a sponsored research agreement with The University of Massachusetts as represented by and solely on behalf of its medical school ("UMass"), pursuant to which we were granted an exclusive option to obtain a worldwide, royalty-bearing, exclusive license (with the right to sublicense through multiple tiers) under certain of UMass' patent rights and future patent rights related thereto, to use and practice such rights for the prevention, treatment, cure or control of conditions relating to certain neuromuscular disorders. Our exercise of the exclusive option obligates us and UMass to negotiate in good faith a license agreement containing reasonable terms. In consideration of the performance of research projects and the rights granted, we are obligated to provide financial support to UMass in periodic advance biannual payments as set forth in the sponsored research agreement. Pursuant to the sponsored research agreement, UMass granted to us a royalty-free, fully paid-up,

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perpetual, non-exclusive, worldwide license, without the right to grant sublicenses, under all of UMass' patent rights arising from the sponsored research project to make, have made, use, lease, sell, have sold, offer for sale and import products and otherwise practice such patent rights, provided that we agree to (a) demonstrate reasonable efforts to commercialize such products in the public interest and (b) pay a pro rata portion (in equal portions with each other non-exclusive licensee) of patent prosecution and maintenance costs in all countries, including the United States, in which we are granted a non-exclusive license right. Unless terminated earlier, the sponsored research agreement remains in effect until the later of two years from June 1, 2020 or completion of the research project. We may terminate the sponsored research agreement upon 30 days' prior notice if (i) a principal investigator leave UMass and no acceptable substitute is identified within 60 days or otherwise terminated his or her involvement in the research project, or (ii) parties are unable to reach agreement on the update of the research project pursuant to relevant provisions of the sponsored research agreement. Either party may terminate the sponsored research agreement upon the material uncured breach of the agreement by the other party.

On September 1, 2020, we entered into another sponsored research agreement with UMass, as represented by and solely on behalf of its medical school, for a research project on engineering AAV capsids with lower sensitivity to antibody neutralization and enhanced CNS and muscle tropism, pursuant to which we were granted an exclusive option to obtain a worldwide, royalty-bearing, exclusive license (with the right to sublicense through multiple tiers) under certain of UMass' patent rights and future patent rights related to the sponsored research project, to use and practice such rights for the prevention, treatment, cure or control of human indications, disease, disorder or conditions. Our exercise of the exclusive option obligates us and UMass to negotiate in good faith a license agreement containing reasonable terms. In consideration of the performance of research projects and the rights granted, we are obligated to provide financial support (including, material, reagents, consumables, supply and personnel costs) to UMass in periodic advance biannual payments as set forth in the sponsored research agreement. In turn, we and UMass have joint, undivided ownership of all patent rights which is conceived or reduced to practice jointly by us and UMass. Unless terminated earlier, the sponsored research agreement remains in effect until the later of two years from June 1, 2020 or completion of the research project. We may terminate the sponsored research agreement upon 30 days' prior notice if (i) a principal investigator leave UMass without acceptable substitute is identified within 60 days or otherwise terminated his or her involvement in the research project, or (ii) parties are unable to reach agreement on the update of the research project pursuant to relevant provisions of the sponsored research agreement. Either party may terminate the sponsored research agreement upon the material uncured breach of the agreement by the other party.

Collaboration with LogicBio

On April 26, 2021, we entered into a strategic collaboration and licensing agreement with LogicBio Therapeutics, Inc. ("LogicBio"), wherein LogicBio granted to us (i) a worldwide, royalty-bearing, sublicensable through multiple tiers (subject to certain conditions), exclusive license to certain LogicBio patents and know-how to develop, manufacture and commercialize

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gene therapy candidates for two targets for the treatment of Fabry and Pompe diseases, such as LogicBio patents and know-how being inclusive of LogicBio's adeno-associated virus (AAV) sL65, a capsid produced from the LogicBio sAAVy™ platform; (ii) options for the development of AAV sL65-based treatments for two additional targets; and (iii) an option to obtain an exclusive, royalty-bearing, sublicensable through multiple tiers (subject to certain conditions) license to LogicBio patents and know-how to LB-001, an investigational in-vivo gene editing technology based on GeneRide™ platform for the potential treatment of methylmalonic acidemia (MMA), in Greater China (collectively, the "LogicBio Licensed Products"). Pursuant to the agreement, we granted to LogicBio a royalty-free, non-exclusive, sublicensable, license for LogicBio to perform its obligations under the agreement.

We are required to use commercially reasonable efforts to develop and seek regulatory approval for LogicBio Licensed Product directed against each target corresponding to each licensed indication in certain countries, and upon approval of the applicable biologics license application in such country, we are obligated to use commercially reasonable efforts to obtain regulatory approval and commercialize such product in such country. Similarly, if we exercise the LB-001 option, we are required to use commercially reasonable efforts in Greater China to develop, seek regulatory approval and commercialize LogicBio Licensed Product for LB-001. Except as otherwise provided in the agreement, we are solely responsible for, and will have sole control over, preparing, filing, and maintaining regulatory submissions and communicating with regulatory authorities in Greater China with respect to LogicBio Licensed Products.

Subject to the terms of the agreement, LogicBio will have an option, on a target-by-target basis with respect to certain targets, to enter into a separate worldwide, co-exclusive (with us) co-development and co-commercialization agreement with us with regard to products that are directed to the applicable target in certain time period. We and LogicBio will have sole responsibility for the conduct of the activities allocated to us or LogicBio, respectively.

Subject to the terms of the agreement, on a product-by-product basis for products other than LB-001, during an initial LogicBio manufacturing period, LogicBio has sole responsibility for all manufacturing activities. Following the initial LogicBio manufacturing period, we will have sole responsibility for and sole decision-making authority with respect to all manufacturing activities.

Collaboration with Mirum

On April 28, 2021, we entered into a license agreement with Mirum Pharmaceuticals, Inc. ("Mirum"), wherein Mirum granted to us an exclusive, royalty-bearing, sublicensable (subject to certain conditions) license to certain Mirum licensed know-how and patents to develop, manufacture and commercialize maralixibat, an investigational, orally administered medication, and pharmaceutical products containing maralixibat ("Mirum Licensed Products"), which is being evaluated in several indications including Alagille syndrome (ALGS), progressive familial intrahepatic cholestasis (PFIC), and biliary atresia (BA), within the

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licensed territory of Greater China for ALGS, PFIC, and BA. The licenses granted to us constitute sublicenses of upstream license agreements to Mirum which Mirum may not amend or terminate without our prior written consent.

In collaboration with Mirum, we have agreed to oversee Mirum’s clinical study sites in China, with the goal of accelerating enrollment of the global Phase 2b EMBARK study, which was recently initiated for patients with BA. We also have the right to manufacture maralixibat in Greater China under certain conditions. We are required to use commercially reasonable efforts, at our sole cost and expense, to develop and commercialize the Mirum Licensed Products in Greater China and are responsible for obtaining regulatory approval for Mirum Licensed Products in the licensed territory.

For more details, see “Business – Collaboration and Licensing Arrangements”.

SALES AND MARKETING

As of the Latest Practicable Date, we had commercialized three products, Caphosol™ (CAN002) in mainland China, Nerlynx® (CAN030) in Greater China, and Hunterase® (CAN101) in mainland China. We use a combination of our in-house sales and marketing team and a network of independent distributors to sell our products in Greater China. Our management team has a track record of successfully commercializing rare disease therapies across various key markets including China, Southeast Asia, the United States, Latin America and Europe. Led by them, we have assembled an experienced commercial team to ensure the successful commercialization of our drug candidates upon approval. As of the Latest Practicable Date, we had established a commercial team jointly led by Mr. Yijun Lu, our China General Manager and Mr. Marcelo Cheresky, our Chief Business Officer, consisting of 73 members.

CUSTOMERS

For the years ended December 31, 2019 and 2020 and the three months ended March 31, 2021, the aggregate sales to our five largest customers were RMB1.5 million, RMB9.4 million and RMB4.6 million, representing 100.0%, 77.7% and 70.5% of our revenue, respectively. Sales to our largest customer for the same periods were RMB1.1 million, RMB5.3 million and RMB2.2 million, representing 72.2%, 44.2% and 33.1% of our revenue, respectively.

RAW MATERIALS AND SUPPLIERS

During the Track Record Period, our suppliers primarily consisted of (i) licensors from which we obtained intellectual property rights in respect of our in-licensed drug candidates and (ii) CROs and CDMOs, who provide third-party contracting services for research and development. We select our suppliers by considering their product quality, industry reputation and compliance with relevant regulations and industry standards.

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For the years ended December 31, 2019 and 2020 and the three months ended March 31, 2021, purchases from our five largest suppliers in aggregate accounted for 63.1%, 83.7% and 83.1% of our total purchases (including value added tax), respectively, and purchases from our largest supplier accounted for 42.8%, 55.6% and 59.6% of our total purchases for the same periods (including value added tax), respectively. During the Track Record Period, our purchases mainly include rights under license agreement and R&D services.

During the Track Record Period, we have not procured raw materials or equipment for commercial manufacturing.

OUR SINGLE LARGEST SHAREHOLDER

The Company had no controlling shareholder as defined under the Listing Rules as at the Latest Practicable Date. As of the Latest Practicable Date, Dr. Xue, our founder, Chairman of the Board, executive Director and CEO, is entitled to ultimately control an aggregate of 18.84% of the voting rights of the Company, being more voting rights than any other Shareholder of the Company, through (i) Dr. Xue (holding beneficially under his own name), (ii) CTX Pharma (an investment holding entity wholly-owned by Dr. Xue); and (iii) the Voting Rights Proxy Agreement. The Voting Rights Proxy Agreement shall terminate upon [REDACTED]. Immediately following the completion of the Share Subdivision and the [REDACTED] (assuming that the [REDACTED] is not exercised and without taking into account any additional Shares to be issued upon the exercise of the Share Options granted under the [REDACTED] Equity Incentive Plan), Dr. Xue is expected to ultimately control an aggregate of [REDACTED] of the voting rights of the Company, which continues to be more than any other Shareholders, through (i) himself beneficially and (ii) CTX Pharma. See sections headed “History, Reorganization and Corporate Structure – Our Structure Immediately Prior to the Share Subdivision, Conversion and [REDACTED]”, “History, Reorganization and Corporate Structure – Our Structure Immediately Following the [REDACTED]” and “Substantial Shareholders” for further details.

OUR [REDACTED] INVESTORS

Since 2015, we have secured [REDACTED] investments of an aggregate amount of approximately US\$269 million pursuant to the respective investment agreements. Our [REDACTED] Investors includes certain Sophisticated Investors, such as WuXi PharmaTech Healthcare Fund I L.P., WuXi AppTec (HongKong) Limited, RA Capital Health Fund, L.P., RA Capital Nexus Fund L.P., Blackwell Partners LLC – Series A, Qiming Venture Partners IV, L.P. and Qiming Managing Directors Fund IV, L.P. Please refer to the section headed “History, Reorganization and Corporate Structure – [REDACTED] Investments” in this document.

SUMMARY OF KEY FINANCIAL POSITIONS

This summary historical data of financial information set forth below have been derived from, and should be read in conjunction with, our consolidated financial statements, including the accompanying notes, set forth in the Accountants’ Report set out in Appendix I to this document, as well as the information set forth in “Financial Information” of this document. Our financial information was prepared in accordance with IFRSs.

SUMMARY

Summary Data from Consolidated Statements of Profit or Loss

The table below sets forth our consolidated statements of profit or loss for the periods indicated derived from our consolidated statements of profit or loss set out in the Accountants’ Report included in Appendix I to this Document:

	For the year ended		For the three months	
	December 31,		ended March 31,	
	2019	2020	2020	2021
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
			<i>(unaudited)</i>	
Revenue	1,469	12,032	742	6,555
Cost of sales	(504)	(5,154)	(287)	(2,891)
Gross profit	965	6,878	455	3,664
Other income and gains	580	1,359	387	10,956
Selling and distribution expenses	(28,881)	(51,008)	(6,616)	(20,568)
Administrative expenses	(53,719)	(77,716)	(14,249)	(20,202)
Research and development expenses	(55,383)	(109,642)	(8,414)	(67,001)
Fair value changes of convertible redeemable preferred shares	(73,694)	(591,385)	(99,114)	(24,386)
Fair value changes of convertible loans	(1,584)	1,689	1,689	–
Fair value changes of derivative financial instruments	(17)	(20,746)	(2,755)	7,101
Other expenses	(3,667)	(1,599)	(478)	(1,083)
Finance costs	(2,275)	(3,873)	(1,433)	(844)
Loss before tax	(217,675)	(846,043)	(130,528)	(112,363)
Income tax expense	–	–	–	–
Loss for the year/period	(217,675)	(846,043)	(130,528)	(112,363)
Attributable to:				
Owners of the parent	(217,675)	(846,043)	(130,528)	(112,363)

For more details, see “Financial Information – Description of Selected Components of Statements of Profit or Loss” in this Document.

SUMMARY

Summary Data from Consolidated Statements of Financial Position

The table below sets forth selected information from our consolidated statements of financial position as of the dates indicated, which have been extracted from the Accountants’ Report set out in Appendix I to this Document:

	As of December 31,		As of
	2019	2020	March 31,
	<i>RMB’000</i>	<i>RMB’000</i>	<i>RMB’000</i>
Total non-current assets ⁽¹⁾	50,645	195,313	72,321
Total current assets	37,905	391,045	427,191
Total assets	88,550	586,358	499,512
Total current liabilities	43,749	108,103	118,155
Total non-current liabilities	1,035,447	2,224,111	2,251,595
Total liabilities	1,079,196	2,332,214	2,369,750
Net current (liabilities)/assets	(5,844)	282,942	309,036
Net liabilities	(990,646)	(1,745,856)	(1,870,238)
Share capital	5	5	5
Reserves	(990,651)	(1,745,861)	(1,870,243)
Total equity	(990,646)	(1,745,856)	(1,870,238)

We recorded net current liabilities of RMB5.8 million and net current assets of RMB282.9 million as of December 31, 2019 and December 31, 2020, respectively. As of March 31, 2021, we had net current assets of RMB309.0 million. As of April 30, 2021, being the latest practicable date for the purpose of liquidity disclosure in this document, we had net current assets of RMB280.1 million.

For more details, see “Financial Information – Discussion of Certain Selected Items from the Consolidated Statements of Financial Position” in this Document.

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Summary Data from Consolidated Cash Flow Statements

The following table sets forth summary data from our consolidated statements of cash flows for the periods indicated:

	As of December 31,		As of March 31,	
	2019	2020	2020	2021
	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>	<i>RMB'000</i>
Cash flows from operating activities before movements in working capital	(116,440)	(197,647)	(23,091)	(95,595)
Net cash flows used in operating activities	(126,175)	(151,648)	(24,857)	(69,556)
Net cash flows from/(used in) investing activities	(42,420)	(153,483)	(1,243)	130,169
Net cash flows from/(used in) financing activities	96,967	679,263	402,824	(12,794)
Net increase/(decrease) in cash and cash equivalents	(71,628)	347,132	376,720	47,819
Cash and cash equivalents at beginning of year	85,240	13,873	13,873	360,804
Effect of foreign exchange rate changes, net	261	(27,201)	3,371	(22)
Cash and cash equivalents at end of year	13,873	360,804	393,968	408,601

During the Track Record Period, we incurred negative net cash flows from operations, substantially due to our research and development expenses. Our operating cash flow will continue to be affected by our research and development and selling and distribution expenses. During the Track Record Period and up to the Latest Practicable Date, we primarily funded our working capital requirements through proceeds from private equity financing. Our management closely monitors uses of cash and cash balances and has maintained a healthy liquidity for our operations and as our business develops and expands, we expect to generate more cash flow from our operating activities, through launching and commercializing our products upon approval and enhancing our operating efficiency.

Our cash burn rate refers to the average monthly (i) net cash used in operating activities, which includes research and development expenses, and (ii) capital expenditures. We had bank balance and cash of RMB408.6 million as of March 31, 2021. We estimate that we will receive net [REDACTED] of approximately HK\$[REDACTED] million after deducting the [REDACTED] fees and expenses payable by us in the [REDACTED], assuming no [REDACTED] is exercised and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED] in this Document. Assuming an average cash burn rate going forward of two times the level in 2020, we estimate that our cash and cash equivalents

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as of March 31, 2021 will be able to maintain our financial viability for 15 months or, together with the proceeds of approximately RMB237.5 million under our Series D-1 (tranche 2) financing and approximately RMB98.0 million under our Series E (tranche 2) financing, if we also take into account the estimated net [REDACTED] from the [REDACTED], 43 months. We will continue to monitor our working capital, cash flows, and our business development progress.

Key Financial Ratios

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

	For the year ended December 31,		For the three months ended March 31,
	2019	2020	2021
Gross margin ⁽¹⁾	65.7%	57.2%	55.9%
	As of December 31,		As of March 31,
	2019	2020	2021
Current ratio ⁽²⁾	86.6%	361.7%	361.6%

Notes:

- (1) Gross margin equals gross profit divided by revenue as of the end the year/period.
- (2) Current ratio equals current assets divided by current liabilities as of the end of the year/period.

[REDACTED]

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DIVIDEND

No dividend has been paid or declared by us during the Track Record Period. You should note that historical dividend distributions are not indicative of our future dividend distribution policy.

We are a holding company incorporated in the Cayman Islands. We may need dividends and other distributions on equity from our PRC subsidiary to satisfy our liquidity requirements. Current PRC regulations permit our PRC subsidiary to pay dividends to us only out of their accumulated after-tax profits, if any, determined in accordance with PRC accounting standards and regulations. In addition, our PRC subsidiary is required to set aside at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain reserve funds until the total amount set aside reaches 50% of their respective registered capital. Our PRC subsidiary may also allocate a portion of its after-tax profits based on PRC accounting standards to employee welfare and bonus funds at their discretion. These reserves are not distributable as cash dividends. Furthermore, if our PRC subsidiary incurs debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us.

We currently expect to retain all future earnings for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Any declaration and payment as well as the amount of dividends will be subject to our constitutional documents and the Cayman Companies Act. The declaration and payment of any dividends in the future will be determined by our Board, in its discretion, and will depend on a number of factors, including our earnings, capital requirements, overall financial condition and contractual restrictions. Our Shareholders in a general meeting may approve any declaration of dividends, which must not exceed the amount recommended by our Board. As advised by our Cayman Islands legal adviser, under the Cayman Companies Act, a Cayman Islands company may pay a dividend out of either profits or share premium account, provided that in no circumstances may a dividend be paid if this would result in our Company being unable to pay its debts as they fall due in the ordinary course of business. In light of our accumulated losses as disclosed in this Document, it is unlikely that we will be eligible to pay a dividend out of our profits in the foreseeable future. We may, however, pay a dividend out of our share premium account unless the payment of such a dividend would result in our Company being unable to pay our debts as they fall due in the ordinary course of business. There is no assurance that dividends of any amount will be declared to be distributed in any year.

USE OF [REDACTED]

We estimate that we will receive net [REDACTED] from the [REDACTED] of approximately HK\$[REDACTED] million, after deducting [REDACTED] commissions, fees and estimated expenses payable by us in connection with the [REDACTED], assuming no [REDACTED] is exercised and assuming an [REDACTED] of HK\$[REDACTED] per [REDACTED], being the mid-point of the indicative [REDACTED] stated in this document.

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We intend to use the net [REDACTED] for the following purposes, subject to changes in light of our evolving business needs and changing market conditions:

- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund the ongoing and future R&D (including planned clinical trials, preparation of registration filings and milestone fees), and manufacturing of our Core Product candidate CAN008;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund our major products and product candidates in our pipeline;
 - i. Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing commercialization, post-approval study and milestone fees of Hunterase® (CAN101);
 - ii. Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials in Singapore and China, preparation of registration filings and milestone fees) of CAN106;
 - iii. Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) of CAN103;
 - iv. Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) and future commercial launches (including sales and marketing) of CAN108;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to fund ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) of other non-gene therapy products and product candidates in our pipeline;
- Approximately [REDACTED]%, or HK\$[REDACTED], is expected to fund the ongoing and future R&D (including ongoing and planned clinical trials, preparation of registration filings and milestone fees) of CAN201, CAN202 and our other gene therapy programs;

The remaining [REDACTED]% of the net [REDACTED], or HK\$[REDACTED] million, will be allocated to fund the R&D and other general business purposes as follows:

- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to develop our R&D and manufacturing facilities in both China and the U.S., and potential office and site expansion and upgrade in China and the U.S.;

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- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated to our other R&D activities including employment costs in both China and the U.S.;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be allocated for potential strategic acquisitions, investments, in-licensing or collaborations;
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used for our commercialization activities, including expanding our sales and marketing team; and
- Approximately [REDACTED]%, or HK\$[REDACTED], will be used for our working capital and general corporate purposes.

For further details, see “Future Plans and Use of [REDACTED]”.

RISK FACTORS

We believe that there are certain risks involved in our operations, many of which are beyond our control. These risks are set out in the section headed “Risk Factors” in this document. Some of the major risks we face include:

- We have incurred significant net losses and net operating cash outflows since our inception, and expect to continue to incur net losses and net operating cash outflows for the foreseeable future and may not be able to generate sufficient revenue to achieve or maintain profitability. Potential [REDACTED] are at risk of losing substantially all of their [REDACTED] in our Shares.
- Our business and financial prospects depend substantially on the success of our clinical stage and pre-clinical stage drug candidates. If we are unable to successfully complete their clinical development, obtain relevant regulatory approvals or achieve their commercialization, or if we experience significant delays in any of the foregoing, our business and profitability may be adversely affected.
- We face substantial competition and our competitors may discover, develop or commercialize competing drugs earlier or more successfully than we do.
- We may not be able to identify, discover or in-license new drug candidates, and may allocate our limited resources to pursue a particular candidate or indication and fail to capitalize drug candidates or indications that may later prove to be more profitable, or for which there is a greater likelihood of success. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials and non-head-to-head analyses may not be predictive of future trial results. As such, we may not be able to successfully expand our drug portfolio, which could materially and adversely affect our future growth and prospects.

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- All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated and the approval process is usually lengthy, costly and inherently unpredictable. Any failure to comply with existing or future regulations and industry standards or any adverse actions by the drug-approval authorities against us could negatively impact our reputation and our business, financial condition, results of operations and prospects.
- We have limited experience in manufacturing pharmaceutical products on a large commercial scale, which is a highly exacting and complex process, and our business could be materially and adversely affected if we encounter problems in manufacturing our future drug products.
- If we and our licensing partners are unable to obtain and maintain adequate patent and other intellectual property protection for our drug candidates throughout the world, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully develop and commercialize any of our drug candidates or technologies would be materially adversely affected.
- We have entered into collaborations and may form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, we may not realize the benefits of such alliances or licensing arrangements, and disputes may arise between us and our Collaboration Partners which could harm our business.
- Our results of operations, financial condition and prospects may be adversely affected by fair value changes in our convertible redeemable preferred shares, convertible loan and derivative financial instruments at fair value through profit or loss.
- We rely on third parties to conduct a certain number of our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates, or experience delay in doing any of the foregoing, and our business could be substantially harmed.
- We rely on third parties to manufacture or import our clinical drug supplies and expect to rely on third parties to supply raw materials for manufacturing and/or manufacture our drugs when approved, and our business could be harmed if those third parties fail to provide us with sufficient quantities of the raw materials or the drug product or fail to do so at acceptable quality levels or prices.

SUMMARY

[REDACTED] EXPENSES

The total [REDACTED] expenses (including [REDACTED] commissions) payable by our Company are estimated to be approximately HK\$[REDACTED] (or approximately US\$[REDACTED]) assuming the [REDACTED] is not exercised and based on an [REDACTED] of HK\$[REDACTED] (being the mid-point of our [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]). These [REDACTED] expenses mainly comprise legal and other professional fees paid and payable to the professional parties, commissions payable to the [REDACTED], and printing and other expenses for their services rendered in relation to the [REDACTED] and the [REDACTED].

In 2019, 2020 and for the three months ended March 31, [REDACTED], [REDACTED] charged to our consolidated statements of profit or loss were [REDACTED], [REDACTED], and [REDACTED], respectively. After March 31, 2021, we estimate that approximately HK\$[REDACTED] (including [REDACTED] commissions, assuming the [REDACTED] is not exercised and based on the mid-point of our [REDACTED] of HK\$[REDACTED] to HK\$[REDACTED] per [REDACTED]) is expected to be charged to our consolidated statements. The [REDACTED] expenses above are the latest practicable estimate for reference only, and the actual amount may differ from this estimate.

RECENT DEVELOPMENTS

Newly-commercialized Product in May 2021

We obtained the marketing approval for Hunterase® (CAN101) for MPS II in mainland China in September 2020. We delivered the first commercial prescription of Hunterase® (CAN101) in China in May 2021 and the China treatment consensus that includes Hunterase® (CAN101) as the standard of care ERT was published in June 2021. We expect to gradually commence nationwide sales of Hunterase® (CAN101) in Greater China.

Impact of the COVID-19 Outbreak

Since the end of December 2019, the outbreak of COVID-19 has materially and adversely affected the global economy. In response, local governments has imposed widespread lockdowns, closure of work places and restrictions on mobility and travel to contain the spread of the virus. As of the Latest Practicable Date, substantially all of the Chinese cities had eased or lifted domestic travel restrictions and resumed normal social activities, work and production.

The government lockdown and other restrictive measures had resulted in significantly reduced mobility of our employees, causing most of the employees to work remotely during early phases of COVID-19 outbreak. As a result, we had implemented various precautionary measures and adjusted our employee's work arrangements according to the relevant regulations and policies, which had allowed us to maintain a sufficient number of personnel on-site who managed to work under flexible schedule to continue our research and development activities.

SUMMARY

There has not been any material disruption of our ongoing clinical trials. We have not experienced and currently do not expect any material delays in regulatory affairs with respect to our clinical trials or any long-term impact on our operation or deviation from our overall development plans due to the COVID-19 pandemic.

To some extent, reduced transportations and disruption to manufacturing and logistics networks in China due to the COVID-19 outbreak affected our suppliers' abilities to manufacture and transport consumables, equipment and other supplies necessary for our operations. Nevertheless, as of the Latest Practicable Date, most of our suppliers had resumed normal operations and we had not experienced any material disruption or shortage of supplies during the COVID-19 outbreak since the outbreak of COVID-19.

As of the Latest Practicable Date, we had no suspected or confirmed active COVID-19 cases on our premises or among our employees. To prevent any spread of COVID-19 in our offices and production facilities, we have implemented preventive measures such as regularly sterilizing and ventilating our offices and production facilities, checking the body temperature of our employees daily, keeping track of the travel history and health conditions of employees, and providing face masks and disinfectant to employees attending our offices and facilities. We will continue to implement our remedial measures and may implement additional measures as necessary to ease the impact of the COVID-19 outbreak on our operations. However, we cannot guarantee you that the COVID-19 pandemic will not further escalate or have a material adverse effect on our results of operations, financial position or prospects.

U.S.-China Relationship

In light of the current situations and the particular nature of the biopharmaceutical industry, we are of the view that the U.S.-China tension has not had any material impact on our business or operations, our clinical trial designs and execution, patient enrollment, data transfer, related regulatory approval processes, ability to find alternative suppliers to source, develop and manufacture our pipeline products, and prospects. We cannot guarantee, however, that the U.S.-China tension will not escalate which may have a material adverse effect on our results of operations.

No Material Adverse Change

Save as otherwise disclosed above, our Directors confirm that, as of the date of this Document, there has been no material adverse change in our financial or trading position, indebtedness, mortgage, contingent liabilities, guarantees or prospects since March 31, 2021, the end of the period reported on in the Accountants' Report set out in Appendix I to this document. As we continue to advance the development of our pipeline and expand our clinical development programs, we expect to incur increasing research and development expenses and administrative expenses. Therefore, based on the assumptions made by and information currently available to our management, we expect to incur an increased amount of losses in 2021 compared to 2020.