OUR VISION

Our vision is to be a global biopharmaceutical company delivering life-changing therapies built upon a foundation in China.

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 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, 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).

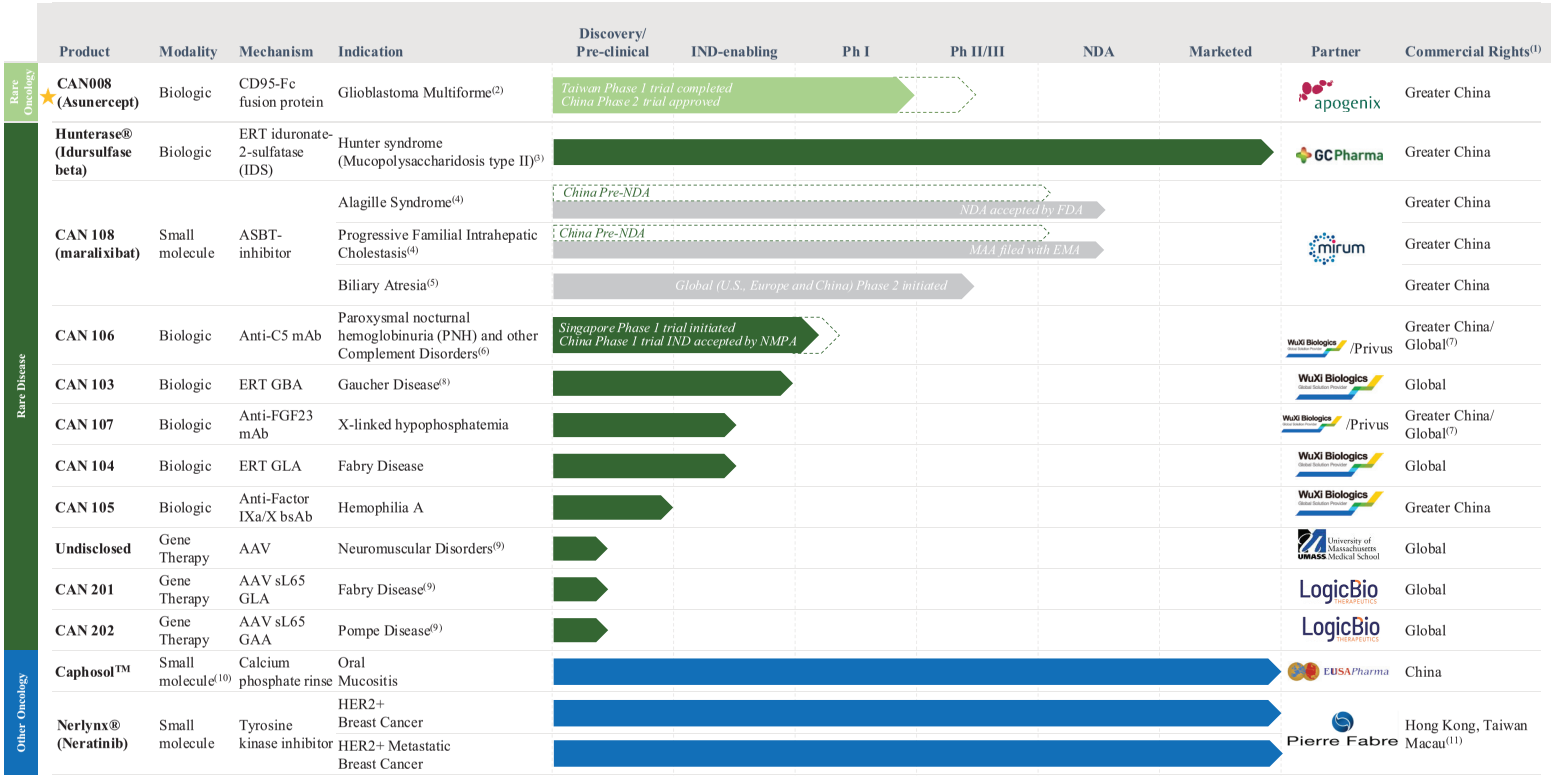
Since our inception in 2012, we have built a comprehensive portfolio targeting diseases with validated mechanisms of action with significant market potential, consisting of biologics, small molecules, and gene therapy solutions. We have built our pipeline through, and will continue to enrich it via business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

- 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 for the treatment of Fabry disease and Pompe disease licensed in from LogicBio Therapeutics to develop two gene therapy products, 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.

The following chart summarizes our portfolio and the development status of each product or product candidate as of the Latest Practicable Date:



Notes:

1. Greater China includes mainland China, Hong Kong, Taiwan and Macau.
2. We have completed Phase 1 trial in Taiwan and obtained IND approval for the first line GBM Phase 2 clinical trial in China.
3. We obtained a clinical trial waiver and the NDA approval for Hunterase® (CAN101) for MPS II from the NMPA.
4. We expect to file NDA in Greater China by the end of 2021 based on data obtained by our license partner in global studies.
5. 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 enrolment in China as part of the global Phase 2 trial.
6. We are conducting a Phase 1 clinical trial for CAN106 in Singapore and received an IND acceptance notice from the NMPA for a Phase 1 study in China.
7. Greater China right granted from Wuxi Biologics and worldwide excluding Greater China right granted from Privus.
8. We expect to submit the IND application to the NMPA for CAN103 in 2H2021.
9. 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.
10. Caphosol™ is an oral electrolyte solution and designated as a prescription medical device.
11. 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.

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 lacks 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 Apogenix, GC Pharma, Mirum, Wuxi Biologics, Privus, 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.

Market opportunities in the rare disease industry

The global rare disease industry is a sector of biopharmaceutical market focusing on the discovery and commercialization of medicines for the treatment of diseases which affect a small number of people, as compared with other more prevalent diseases in the general population. Driven by its unique features, the rare disease industry is considered to be a highly efficient business model. According to Frost & Sullivan, most rare diseases are caused by genetic mutations with well-defined pathology, which leads to higher probability of technical and regulatory success ("PTRS") in the research & development ("R&D") of rare disease drugs. Certain rare disease patients are treated at a limited number of specialized hospitals and therefore sales efforts for rare disease drugs can be much more targeted. The unique nature of rare diseases has also led to a favorable regulatory environment in various countries, such as the Orphan Drug Act in the United States, which helps accelerate the development and commercialization process of rare disease drugs.

The global rare disease drug market has grown rapidly since 1983, when the Orphan Drug Act was first promulgated by the US FDA, which set standards for regulatory pathways that have been followed by other jurisdictions. The size of global rare disease drug market grew from US$109.0 billion in 2016 to US$135.1 billion in 2020, representing a CAGR of 5.5%. It is estimated to further grow to US$383.3 billion in 2030 at a CAGR of 11.0% from 2020 to 2030. Growing awareness of rare disease has augmented the demand for special treatments, together with rising healthcare expenditure, positively impacting the rare disease treatment market growth. The U.S. and Europe remain the largest rare diseases markets globally.

The rare disease markets in developing countries are relatively underserved and underpenetrated due to limited access to diagnosis and treatments of rare diseases. The market size of rare disease drugs in China was only approximately US$1.3 billion in 2020, far below that in the U.S or Europe. Applying the definition of rare disease used by the FDA in the U.S., the prevalence of rare diseases in China in 2019 indicates a patient pool potentially over four times larger than the U.S. according to Frost & Sullivan. The discrepancy between patient population and market size suggests significant room for rare disease drug growth in China. According to Frost & Sullivan, the rare disease drug market in China is expected to grow dramatically from US$1.3 billion in 2020 to US$25.9 billion in 2030 at a CAGR of 34.5%, as compared to the market growth in the U.S. and the rest of the world in the same period at a CAGR of 10.5% and 10.0%, respectively. The China rare disease drug market accounted for 0.4% and 1.0% of the global rare disease market in 2016 and 2020, respectively, and is expected to account for 6.8% in 2030, indicating favorable rare disease market outlook. With a concentrated population of untreated patients larger than that of the U.S. and Europe, China offers great opportunities for rare disease pharmaceutical companies to capture a massive market at potentially lower costs than other disease areas. In response to such significant market opportunity, many leading pharmaceutical companies such as Sanofi have launched products in China and other developing countries. We believe that companies like CANbridge is uniquely positioned to bridge the gap and provide sustainable solutions to meet the medical needs of global patients in an efficient manner.

In addition, the rare disease industry in China is expected to benefit from various regulatory initiatives. In recognition of the urgency for the development of effective rare disease treatment and the unique clinical challenges associated with such development, authorities in the U.S. and Europe have provided regulatory incentives and adopted special regulatory frameworks to encourage development and commercialization of drugs to treat rare diseases and to support companies with a focus on rare disease treatment. In 2018, China published the first edition of the Rare Disease List that includes 121 rare diseases, hallmarking the transformational debut of the Chinese rare disease market. Similar to the U.S. and Europe, a high degree of regulatory flexibility has been introduced to rare disease drug approval process in China, including simplified application process, flexibility in clinical trial design, higher likelihood of clinical trial waiver on the basis of overseas clinical data and post-approval clinical trials. China has also moved towards a more favorable reimbursement environment for rare diseases. After years of efforts in providing insurance mechanism of rare diseases at local level, an aggregate of 29 provinces have implemented insurance policies for rare disease with various reimbursement models. For more details, see "Industry Overview –

Significant Unmet Medical Needs and Market Opportunities". In 2021, the initiation of formulation of the second edition of the Rare Disease List was announced by the National Health Commission of the PRC and more rare disease drugs are expected to be included, according to Frost & Sullivan.

Enabled by new technologies, gene therapies have become an emerging solution for rare diseases. Approximate 80% of rare diseases result from genetic disorders, according to Frost & Sullivan. Gene therapies serve as a promising solution for a broad spectrum of rare diseases by fundamentally addressing the underlying cause of the diseases. Recent advances in genetic engineering and recombinant viral vector development have ignited interest in the field, with several gene therapy products gaining approvals. The success of several pioneering clinical trials in gene therapy validated its efficacy and safety, such as SPINRAZA developed by Biogen, and Zolgensma developed by Novartis and AveXis, making targeted treatments available for spinal muscular atrophy (SMA), and thus marking the potential of gene therapies to provide solutions to rare diseases that currently have no specific therapeutic options.

OUR STRENGTHS

A leading rare disease focused biopharmaceutical company dedicated to addressing vast and unmet medical needs

Our Company is a leading China-based, global rare disease-focused biopharmaceutical company devoted to providing transformative and sustainable therapies for rare disease patients in China and worldwide. As a pioneer in developing rare disease therapies in China, we contributed to developing the rare disease ecosystem in China by working closely with key stakeholders including regulatory authorities, key opinion leaders (KOLs), doctors, patients through patient registry and advocacy groups, center of excellence, as well as reimbursement and insurance institutions. At the same time, we have built a robust product portfolio, an integrated platform and access to global rare disease markets, which we believe will position us to capture the vast and untapped rare disease market in China and globally.

Our Portfolio. We have built a comprehensive portfolio targeting diseases with validated mechanisms of action, consisting of biologics and small molecules solutions, addressing significant unmet medical needs in rare diseases and rare oncology indications. As of the Latest Practicable Date, our portfolio is comprised of three marketed products, three product candidates at the clinical stage, two at IND-enabling stage, two at preclinical stage and another three gene therapy programs at lead identification stage, featuring both innovative and validated targets with improved characteristics to maximize PTRS and commercialization opportunities. We are also one of the few R&D-driven Chinese pharmaceutical companies investing in innovative and early-stage candidates. We are actively exploring next-generation technology in gene therapy through a combination of external collaborations and in-house research. As of the Latest Practicable Date, we are using adeno-associated virus (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.

Our Platform. We have built a fully integrated in-house biopharmaceutical platform, spanning preclinical research, clinical development and commercialization. We are also developing proprietary technologies through global collaborations with leading biopharmaceutical companies such as GC Pharma and Apogenix, whose previous overseas clinical data helped us obtain a clinical trial waiver for Hunterase® (CAN101) and a clinical trial approval for CAN008 in China, respectively. We established a strategic partnership with WuXi Biologics to develop biologics for treating LSDs, other genetic metabolic diseases, and complement mediated diseases. We are also committed to bringing some of the most innovative therapies, such as gene therapies, to China, through collaborations with top medical companies and institutions including LogicBio Therapeutics and UMass. We are building gene therapy CMC operations with AAV research process development laboratory and pilot plants enabling translational studies in the Greater Boston area. We are also internally establishing an AAV delivery platform targeting different tissues such as central nervous system (CNS) and muscles. We believe our full-fledged platform and collaboration partnerships also afford us with opportunities to pursue drug development in underserved rare diseases and quickly generate clinical proof-of-concept and data for global development. As we grow and scale up our infrastructure, we expect to enjoy a cost advantage which will enable us to optimize our pricing and bring our rare disease therapies to as many overseas markets as possible.

A robust and comprehensive portfolio of rare disease focused therapies with significant revenue potential

Our Company was founded on the commitment in developing innovative therapies that address significant unmet medical needs in rare diseases. To that end, we strategically combine global collaborations and internal research and have built a portfolio of therapies targeting some of the most prevalent rare diseases in China with limited treatment options available, including, among others, GBM and mucopolysaccharidosis type II (MPS II or Hunter Syndrome). We acquired our first rare disease asset CAN103 for LSD, in 2018, and in-licensed Hunterase® (CAN101) for Hunter syndrome in 2019 as our first commercialized rare disease product to address significant unmet needs in China. We are further expanding our partnership in developing multiple additional product candidates and potential novel programs both in China and globally, such as the collaborative program with UMass on gene therapies.

As of the Latest Practicable Date, we had a comprehensive and differentiated portfolio of 13 drug assets with both late-stage and early-stage drug candidates, among which three are at commercial stage, three are at clinical stage, two are at IND-enabling stage, two are at preclinical stage and another three gene therapy programs are at lead identification stage.

Selected late-stage assets

CAN008 is an artificially engineered antibody-like fully human fusion protein for the treatment of GBM. It binds to CD95L and blocks its interaction with the CD95 receptor. As our Core Product, CAN008 has demonstrated robust efficacy and favorable safety profiles in both the completed and ongoing clinical trials, presenting a potentially effective option in the treatment of GBM. A Phase 2 pivotal trial conducted by Apogenix has shown statistically significant improvements by over 50% in 4-month to 6-month progression-free survival and quality of life as well as a positive trend in overall survival in patients with relapsed GBM. We completed the Phase 1 trial in Taiwan 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 have also obtained the IND approval for a Phase 2 clinical trial for the first-line treatment of GBM patients in mainland China, which is expected to start dosing the first patient in the second half of 2021.

Hunterase® (CAN101) is the first ERT approved for the treatment of Hunter Syndrome (MPS II) in China. Given that ERT is the standard of care for Hunter Syndrome and there is currently no other drug treatment available in China, we believe there is a significant market opportunity for Hunterase® (CAN101). We successfully received the marketing approval from China's NMPA for Hunterase® (CAN101) in September 2020. Hunterase® (CAN101) is currently marketed in over 10 countries worldwide by GC Pharma. In a head-to-head Phase 1 study, Hunterase® (CAN101) demonstrated favorable efficacy as compared to Elaprase®, a drug commonly used to treat Hunter Syndrome globally. We commercially launched Hunterase® (CAN101) in China in May 2021. We are currently expanding a dedicated, in-house commercialization team and expect to assemble a full-fledged commercialization team following the launch of Hunterase® (CAN101) in China with over 300 members in the next five years.

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). 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. In ICONIC, a Phase 2b placebo-controlled randomized clinical trial conducted for ALGS by our collaboration partner in the U.S., patients receiving maralixibat experienced significant reductions in bile acids and pruritus compared to placebo, improvements in quality of life and xanthomas and accelerated long-term growth. In INDIGO, a Phase 2 study conducted for PFIC by our collaboration partner in the U.S., patients who responded to maralixibat were shown to have significant improvement in transplant-free survival and experienced improvements across multiple parameters including normalization of liver enzyme and bilirubin levels, decreased pruritus, and improvements in growth.

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.

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 obtained global rights to develop and commercialize this drug candidate from WuXi Biologics and Privus in 2019 and 2020 respectively. 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 are conducting a Phase 1 clinical trial for CAN106 in Singapore and received an IND acceptance notice from the NMPA for CAN106 in April 2021 for a Phase 1 study in China.

Selected preclinical stage assets

CAN105 is a treatment being developed for the treatment of Hemophilia A with significant market potential. It is a recombinant, humanized, bispecific monoclonal 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. CAN105 is expected to enter preclinical research phase in the second half of 2021.

AAV Delivery Platform

In addition to our biologics and small molecules portfolio, we are also building a gene therapy platform focusing on adeno-associated virus (AAV) as our next research engine. AAV is widely recognized as a safe gene delivery vehicle with the potential as one-time durable therapy for many genetic diseases. Our first gene therapy candidate will focus on a neuromuscular disorder, with high unmet medical need and significant commercial potential. All genetic muscular dystrophies, currently have no curative treatment options, according to Frost & Sullivan. We are internally developing an AAV delivery platform targeting different tissues such as the central nervous system (CNS) and muscle, and also exploring a next generation AAV gene therapy for neuromuscular disorders through collaboration with UMass. In addition, we are also collaborating with LogicBio, a U.S. based biopharmaceutical company to develop AAV gene therapies for LSDs, including Fabry disease (CAN201) and Pompe disease (CAN202), and have obtained an option for two additional indications. We also have an option to acquire a clinical-stage gene editing program for the treatment of MMA pursuant to our collaboration agreements with LogicBio.

For more details and our other assets, please see "– Our Portfolio."

Extensive strategic partnerships to source innovative therapies globally

We believe we are the ideal gateway partner for global rare disease biopharmaceutical companies trying to access the Chinese market. As the growth of the Chinese rare disease market accelerates, many global biopharmaceutical companies are interested in accessing this vast and untapped market but lack local expertise and resources. We offer unique "best of both worlds" value propositions with our management's global and domestic drug development know-how, our deep rare disease expertise, robust and comprehensive drug portfolio, and the manufacturing and commercial capabilities we are developing.

Our management and clinical development teams have vast experience working at leading multinational and domestic biopharmaceutical companies. They possess extensive experience in the Chinese and international regulatory frameworks and unique insights to the rare disease industry in China to help accelerate clinical trials, drug registration and commercialization. Furthermore, given the large pool of treatment-naive rare disease patients in China, we are well positioned to generate high quality clinical data from local trials as a valuable addition to facilitate global registration, and maintain operational efficiency given the relatively low cost of clinical trials in China. We believe our experience in sales and marketing and the reimbursement pathway will also contribute to the successful commercialization of our future drug candidates.

We have a proven track record of in-licensing innovative and validated therapies from global innovators and quickly progress through clinical development to commercialization, including but not limited to Apogenix, GC Pharma, Mirum, Wuxi Biologics, Privus, UMass and LogicBio. Since we obtained exclusive license rights in Hunterase® (CAN101) from GC Pharama in January 2019, our own R&D efforts led to a clinical trial waiver and NDA submission to the NMPA in July 2019. In addition, we have conducted a Phase 1 clinical trial for our late-stage drug candidate CAN008 in Taiwan, which has successfully bridged the drug candidate to Asian patients with newly diagnosed GBM on the back of the clinical data previously obtained in European trials by our partner, Apogenix. We plan to dose the first patient in a first line Phase 2 clinical trial for CAN008 on GBM patients in mainland China in the second half of 2021. Given the deep patient pool in China, we contributed to generating high quality clinical data from local trials as a valuable addition to facilitate potential global registration.

Our collaborations with top international partners have also enabled us to draw on the strengths from the global science frontier. For example, we initiated two research programs in 2020 with the Horae Gene Therapy Center at the UMass for gene therapy research for rare genetic diseases, with a focus on neuromuscular conditions. We are potentially among the first China based companies to commence global-level collaboration in AAV gene therapy. In 2021, we obtained an exclusive worldwide license from LogicBio Therapeutics for a next generation

capsid platform for use in gene editing and gene therapy, which further fueled our potential to extend our rare disease portfolio by integrating next-generation technology as we advance as a global leader in the treatment of rare diseases in the future.

A fully integrated rare disease platform positioned to drive rapid and comprehensive product development and market access in China and globally

We have built a fully integrated platform that covers the entire spectrum of drug development functionalities, including preclinical research, clinical development, manufacturing and commercialization.

Preclinical Research. Leveraging our integrated platform and industry leading CRO/CMO partners, our world-class teams of rare disease experts and our U.S. based research team strive to bring promising therapies to China and worldwide and accelerate the drug development. Our insights on the drug ability, clinical trials and commercialization also feed into early research to cultivate promising targets with clinical and commercial potential. We plan to conduct early R&D on gene therapy in the U.S. and have opened our R&D center in Greater Boston opened in March 2021 for our in-house development of AAV platform. We are also in the process of building our AAV research and process development lab in Greater Boston area, which is expected to be opened in 2022. In addition, we plan to set up China research site in Suzhou for preclinical research, CMC, and early research, and expand further as programs enter late-stage development.

Clinical Development. Apart from our preclinical research capabilities, we have also streamlined our clinical development process to accelerate registration. We have completed the Phase 1 trial on CAN008 in Taiwan in September 2018 and plan to dose the first patient in a Phase 2 clinical trial for the first-line treatment of GBM patients in China in the second half of 2021. We are also conducting a Phase 1 clinical trial for CAN106 in Singapore and received an IND acceptance notice from the NMPA for a Phase 1 study in April 2021. Apart from our in-house R&D capabilities, we also leverage strong relationships with governmental authorities and KOLs to enhance the efficiency and effectiveness of our drug development process. For example, opinions delivered by KOLs during the advisory board meetings we organized formed a key part of our trial waiver application for Hunterase® (CAN101). Similarly, we worked closely with the Center for Drug Evaluation (CDE) and secured regulatory approval for Nerlynx® (CAN030) (neratinib) in China in 2020. In addition, we also benefit from collaborations with global rare diseases players with a track record of drug development and regulatory success. For example, we leveraged data of pivotal trials of Hunterase® (CAN101) from GC Pharma and successfully obtained approval from the NMPA to directly submit NDA and have obtained waiver for clinical trials. We also leveraged overseas data from Phase 2 studies completed by Apogenix for CAN008 to obtain NMPA approval in a Phase 2 clinical trial in China and expect to dose the first patient in the second half of 2021.

Manufacturing. We have secured manufacturing capacity for selected in-licensed programs, including from third party collaboration partners such as WuXi Biologics, GC Pharma and LogicBio Therapeutics. We are also entitled to the transfer of all relevant manufacturing technologies with respect to the product for development by our third party partners, including but not limited to an upstream process and a downstream affinity purification process. We aim to balance cost-efficiency and control over quality of our drug products and will establish our in-house process development and manufacturing infrastructures. In an effort to scale up our gene therapy development, we are in the process of building our AAV process development lab in Greater Boston, which is expected to be opened in 2022. In addition, we are also establishing our manufacturing facilities in Suzhou, which is designed to comply with cGMP with several production lines.

Commercialization. With our late-stage drug candidates entering into the commercialization stage, we have established our key operation hubs in both Beijing and Shanghai with 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 have already set up a commercialization team dedicated to our late-stage drug candidates that can be quickly expanded in line with our business growth to over 300 members to cover the China market for rare diseases in the next five years, comprising three major functions including marketing and sales, medical affairs and patient advocacy and assistance, with the mission to execute medical engagement plan for KOL development, promote community awareness and explore industry insights for better drug development and marketing strategy.

Management team with deep industry experience and a track record of commercializing rare disease therapies globally

We are led by a global management team of seasoned members with significant industry experience in rare diseases, spanning R&D, clinical development, regulatory, business development and commercialization, together with a track record of successfully commercializing rare disease therapies across various key markets including China, Southeast Asia, the United States, Latin America and Europe.

Our visionary founder, Chairman and CEO, Dr. Xue (Ph.D., M.B.A.), is a veteran entrepreneur 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.

Besides Dr. Xue, other key management members are also leaders in their respective fields globally or in China, heading clinical, medical, business development, commercial or corporate functions in globally renowned biopharmaceutical companies or multi-national corporations before joining us:

Dr. Gerald Cox (M.D., Ph.D), our Chief Development Strategist and interim CMO, has 21 years of biotechnology executive management experience and served as the former CMO at Editas Medicine and VP at Genzyme. He oversaw multiple global rare disease clinical development programs, including Cerdelga, olipudase alfa, Hectorol, Cerezyme, Myozyme, Aldurazyme and Elaprase at Genzyme. Having made major contributions to 4 INDs and 3 orphan drug marketing authorizations for serious and life-threatening diseases that have generated a total of over $3.0 billion revenue for Genzyme, Dr. Cox is also the author of over 100 publications at local, regional, national and international venues for academic, patient foundation, and industry-sponsored conferences.

Mr. Glenn Hassan, our Chief Financial Officer, has more than 15 years of extensive banking, investment, and strategy consulting experience in the healthcare sector around the globe. Before joining our Company, Mr. Hassan was a director in the healthcare investment banking division at China Renaissance, where he advised prominent life science companies across Greater China and the United States on their cross-border transactions and corporate financing efforts. Mr. Hassan was also a veteran public market healthcare investor with experience at major investments firms, such as Citadel LLC and Fidelity Management & Research Company.

Dr. Yunxiang Zhu (Ph.D), our Vice President and Head of Global Research, has nearly 20 years of R&D leadership experience in the biotechnology industry. Before joining us, Dr. Zhu served as Senior Vice President at Shenogen Pharma Group, where he was responsible for company strategy in drug discovery and development, and designed more than five first-in-class bispecific and trifunctional antibody lead candidates. Before then, Dr. Zhu had over 17 years' extensive experience at Sanofi Genzyme, progressing through various positions such as principal scientist and senior director in charge of muscle disease research, during which period his research led to the invention of the second-generation enzyme replacement therapy.

Mr. Yijun Lu, our China General Manager, is a seasoned business executive with extensive experience and outstanding performance in oncology and rare disease areas. He used to serve as oncologist at Shanghai No. 1 People's Hospital and as a senior leader with diverse roles in top pharmaceutical companies. Before joining us, Mr. Lu served as head of hemophilia and rare disease at Takeda China, where he led the launch and development of certain products related to rare diseases, such as Replagal, Vpriv, Takhzyro and Firazyr.

Mr. Marcelo Cheresky, our Chief Business Officer, has nearly 20 years of business leadership experience in the biotechnology industry. Mr. Cheresky has in-depth industry knowledge and extensive execution capabilities through his previous employments at reputable biopharmaceutical companies such as Bioverativ, Ultragenyx, Synageva Biopharma and Genzyme.

We have a growing pool of talent to support our seasoned management team in achieving our mission to treat patients beyond borders with innovative and differentiated therapies. 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 efforts are also supported by a scientific advisory board with reputable key opinion leaders in the pharmaceutical industry, covering rare disease and gene therapy. Dr. Guangping Gao joined us as the advisory board member for gene therapy initiative collaboration with UMass in June 2020. Dr. Gao is an internationally recognized gene therapy researcher who has played a key role in the discovery and characterization of new AAV serotypes. He currently serves as President of the American Society of Gene and Cell Therapy, Director of Horae Gene Therapy Center and Viral Vector Core, Co-director of Li Weibo Institute for Rare Diseases Research and Penelope Booth Rockwell Professor at UMass. Dr. Gao has authored over 250 research papers, six book chapters, four edited books and holds 131 patents and 221 pending applications. Dr. Gao was ranked 4th of Top 20 Translational Researchers from 2013 to 2017 by Nature Biotechnology. He is also the co-founder of Voyager Therapeutics and Aspa Therapeutics.

Since our Company's establishment, we have received investments from industry-leading investors, including strategic investors Wuxi AppTec, Tigermed and WuXi Biologics and financial investors such as Qiming, Hudson Bay, LYFE Capital, Casdin Capital, RA Capital and General Atlantic. This blue-chip investor profile is a testament to our clinical development capability, and provided us with necessary funding and resources to support our growth.

OUR STRATEGIES

Further solidify our leadership in the China's rare disease ecosystem and build a global rare diseases franchise

At the forefront of driving research and clinical development of innovative rare diseases drugs and bringing established life-changing therapies from overseas markets to China, we endeavor to continue to shape the practice of diagnosis, orphan drug definition and treatment guidelines of rare diseases in China by leveraging:

***Regulatory Initiative and Market Awareness*:** Our management team consists of industry leaders who play an active role in advancing the rare disease industry and shaping the rare disease ecosystem in China. Our founder, Dr. Xue, is the sole industry representative serving as Deputy Director General of CHARD. Dr. Xue is currently also on the editorial board of the textbook *Textbook on Rare Disease*, which is part of the textbook series for postgraduate medical students in China published under the supervision of the National Health Commission of the People's Republic of China. Led by Dr. Xue, we have obtained the marketing authorization of our first rare disease drug Hunterase® (CAN101) in China and commercially launched it in China in May 2021. In addition, we expect to submit the IND application to the NMPA for CAN103 in the second half of 2021. We will also continue to connect the full range of stakeholders in the rare disease value chain to promote social awareness and to improve access to diagnosis and treatments. We support patient advocacy for rare disease funding by helping patient organization build advocacy capabilities. In addition, we have partnered with a commercial insurance service company to alleviate payment burden on eligible patients.

***Our Platform*:** We will continue to leverage our strong capabilities across R&D, regulatory, commercial and market access to improve our platform with a specialist focus and national network in China. We will provide high quality clinical data from local trials to facilitate global registration, and maintain operational efficiency by leveraging the abundant clinical trial resources in China. As we own global rights to most of our assets, we plan to realize the value of our therapies beyond China. We will continue to leverage the cost-efficient and rapid clinical development capabilities of our fully integrated platform to produce drug candidates beyond the proof-of-concept stage and bring transformative and cost-efficient rare disease therapies to global markets.

***Our Portfolio*:** Since acquiring our first asset in 2014, we continue to harness strategic partnerships in China, the U.S. and the EU to expand our portfolio. We will continue to adopt a strategic approach combining in-licensing late-stage drugs for China, developing promising drugs and building a next generation global portfolio.

Drive commercialization of our late-stage assets in Greater China

We successfully received the marketing approval from China's NMPA for Hunterase® (CAN101) in September 2020. Hunterase® (CAN101) is the first approved treatment in our rare disease portfolio and the first enzyme replacement therapy (ERT) for Hunter Syndrome in China.

As of the Latest Practicable Date, our commercialization team consisted of 73 members, which is expected to be further expanded into a team of over 300 members to cover the China market for rare diseases in the next five years. We're building value proposition of our assets by enhancing promotion effectiveness, and expect to improve diagnosis, standard of care and patient access in collaboration with healthcare professionals. Our commercialization team comprises three major functions including marketing and sales, medical affairs and patient advocacy and assistance, with the mission to execute medical engagement plan for KOL development, promote entire community awareness and explore industry insights for better drug development strategy. Internally, our marketing team helps align the research and business sides by formulating patient-centric development strategies, and providing compliance guidance. Externally, our marketing team plans to further build up and execute medical engagement plan for KOL development, increasing community awareness and collects industry insights for better drug development strategy.

Our marketing approach is initially focused on providing education and promoting awareness of the entire rare disease community, including physicians, KOLs and patients, as means to increase the rate of diagnosis and treatment, patient advocacy and market access.

Our regional coverage to commercialize Hunterase® (CAN101) includes the Greater China. We are establishing the nationwide management system to facilitate the implementation of Hunter Syndrome treatment guidelines, product supply network, and develop market access and reimbursement initiatives.

In mainland China, we plan to adopt a tiered provincial market-entry approach with the goal of achieving nationwide coverage in the medium term. Our priority over the next 12 months is to initially focus on top tier provinces that have favorable reimbursement coverage and high patient volume capture. Our Beijing and Shanghai offices serve as our key operation hubs. We plan to build commercial offices in each of the key target provinces in China in the next five years.

As we expand into tier 2 and other lower tier provinces, we plan to continue to invest in building our on-the-ground presence and coverage. We seek to strengthen our relationship with key stakeholders in each province to drive diagnosis and treatment, and also to support reimbursement negotiation into provincial formulary. For example, we are working closely with the Children's Hospital of Zhejiang University and thought KOLs in the pediatric society, to promote, train and standardize the practice for the diagnosis and treatment for Hunter Syndrome and other rare diseases we're targeting.

Rapidly advance and expand our portfolio

Leveraging our global R&D capabilities, we are developing a comprehensive portfolio of innovative drug candidates for rare diseases and rare oncology indications, with programs spanning preclinical, IND-enabling and clinical stages.

With the addition of Dr. Yunxiang Zhu, our Vice President and Head of Global Research and the former Head of neuromuscular diseases at Genzyme, we are intensifying our R&D efforts to rapidly advance our programs into clinical development and proof-of-concept.

We anticipate that most of our R&D activities for biologics and small molecules pipeline will be carried out in Asia in the near term, leveraging the cost effectiveness and access to a large pool of target patients with unmet needs in China. We plan to set up China research site in Suzhou with a dedicated team for preclinical research, CMC analytical operation, and early research, and expand further as programs enter late-stage development. We are also in the process of building our R&D and manufacturing facilities in Suzhou, which is designed to comply with cGMP with several production lines.

We plan to focus our R&D in gene therapy in the U.S. and have opened our R&D center in Greater Boston area in March 2021 for our in-house development of AAV platform, as well as to engage with external academic and biotech companies for potential collaborations and partnerships. We are also in the process of establishing our dedicated research facilities to host our AAV and other programs, as well as CMC plant in the Greater Boston hub, which is expected to be opened in 2022.

In rare diseases, we expect to file at least two INDs in 2021. For CAN106, an anti-C5 antibody for the treatment of multiple complement-medicated diseases, we are conducting a Phase 1 clinical trial in Singapore and received an IND acceptance notice from the NMPA for a Phase 1 study in April 2021. For CAN103, an ERT for Gaucher disease, we plan to file the IND in China in the second half of 2021. We are also accelerating the preclinical development of other candidates, for CAN104, an ERT for the treatment of Fabry disease, CAN105, a bispecific antibody for Hemophilia A and CAN107, a monoclonal antibody for the treatment of XLH.

In rare oncology, we seek to allocate appropriate resources and optimize the value for our retained oncology products including CAN008. CAN008 is currently in umbrella Phase 1/2 a clinical stage of molecularly matched targeted therapies plus radiotherapy in patients with newly diagnosed GBM without MGMT (O6-methylguanine-DNA methyltransferase) promoter methylation in Europe led by our partner Apogenix. We plan to dose the first patient in a first line Phase 2 clinical trial for CAN008 on GBM patients in China in the second half of 2021.

Maximize value creation through partnership and collaboration

Collaboration is a key part of our growth strategy as we continue to build and diversify our rare disease portfolio. We have established multiple strategic partnerships to date and plan to continue seek complementary assets globally.

Our partnership approaches correlate with our product selection strategy to in-license late-stage drugs to address huge unmet medical needs in China, develop innovative drugs in attractive markets with reasonable cost to patients and develop next generation gene therapies in the longer term. We retain exclusive global rights to seven of our drug assets and may strategically enter into strategic collaborations or other partnerships with leading biopharmaceutical companies to accelerate our development timelines and maximize the commercial value of our product candidates in designated markets.

We continue to invest in our next-generation technology development and expand our in-house R&D activity to generate promising leads for treatment of rare diseases. In particular, we dedicate efforts in developing gene therapies, which we believe are the next innovation for the treatment of multiple rare diseases. We are a pioneer in gene therapy in China and our technology has the potential for global application. In addition to our UMass research collaborations and exclusive license obtained from LogicBio, our immediate goal and initial strategy for gene therapy are to in-license mid- to late-stage assets that can address significant unmet medical need in China. We aim to leverage the deep patient pool in China and our strength in clinical development to bring these products to market in the near future. In addition to our efforts to secure promising drug candidates with exclusive global rights, we are also diligently establishing our own gene therapy platform. Led by Dr. Yunxiang Zhu, our innovation center/research site in Greater Boston is designed to and has been developing the proprietary AAV engineering strategies that aims to greatly improve muscle and central nervous system (CNS) tropisms of AAV and drug candidates with global rights, with a focus in neuromuscular disease area.

Build fully integrated capabilities with in-house drug research, development and manufacturing infrastructure in global and Greater China markets

We are progressively building our in-house R&D platform and enhancing our in-house drug research, clinical development, business development, regulatory and marketing capabilities for rare diseases with the goal to become a fully integrated company in the long term, spanning preclinical research, clinical development and manufacturing with global market coverage.

While we continue to collaborate with our partners globally, we anticipate that most of our R&D activities will be carried out in Asia in the near term with the exception of preclinical research and pilot gene therapy CMC programs in the U.S., with the goal to localize manufacturing in China in the mid-term, as supplemented by a reliable supply chain from our manufacturing partner WuXi Biologics, LogicBio Therapeutics and alternative CDMOs. In particular, we plan to invest in our own gene therapy manufacturing and technology capabilities, including building our internal cGMP facilities to ensure quality and retain control over vector production. We are also entitled to the transfer of all relevant manufacturing technologies with respect to the product for development by LogicBio Therapeutics, including but not limited to upstream process and a downstream affinity purification processes, which we will leverage to optimize our own gene therapy manufacturing capabilities.

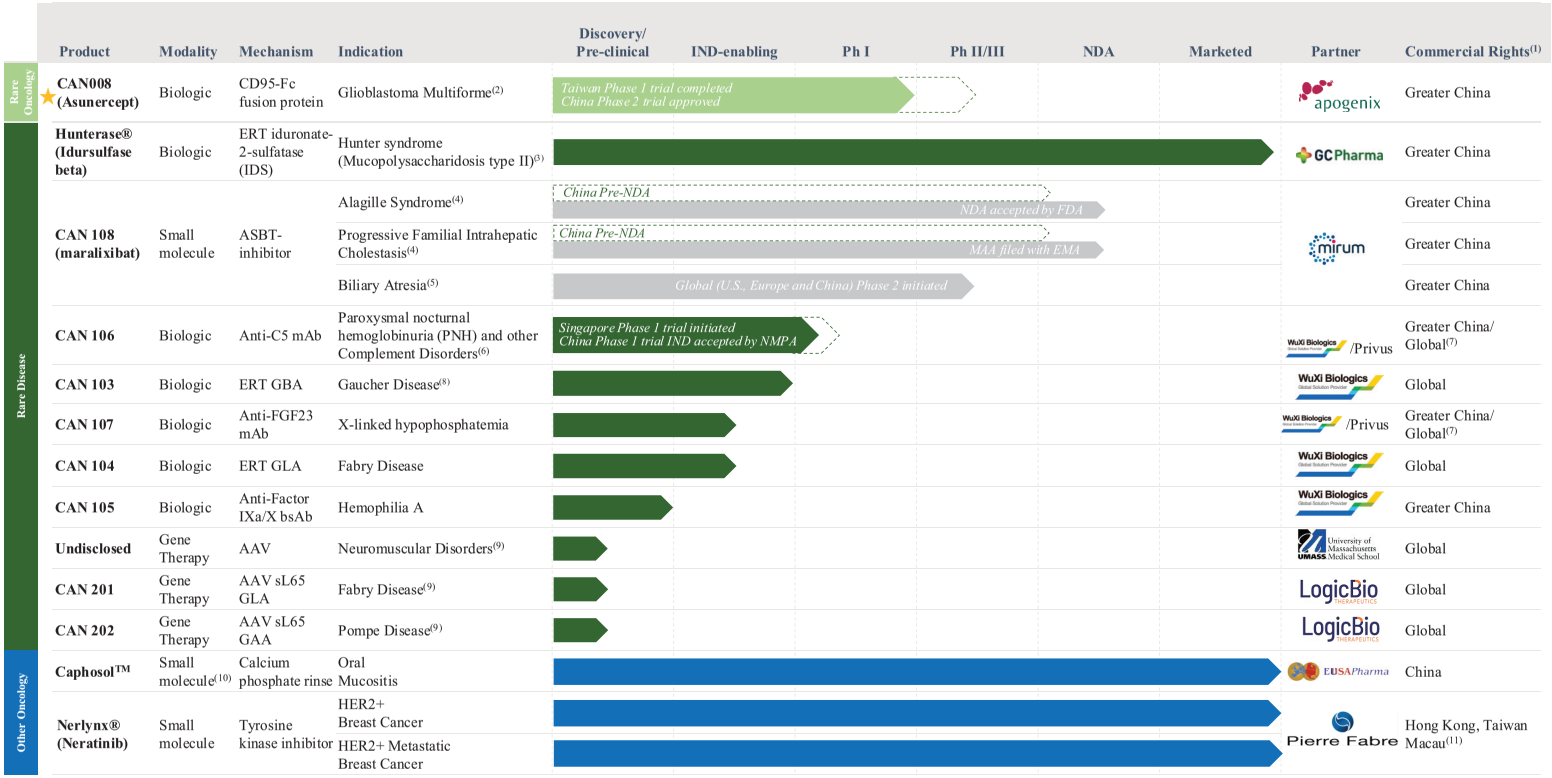
With established infrastructure in China, we target to expand our footprints globally. We have an experienced global management team and are building a global rare disease specialty coverage as we continue to innovate and enrich portfolio by leveraging our proprietary technologies, including small molecule, enzyme replacement, monoclonal antibody and gene therapy. Leaning towards the focus on proprietary rights in addition to in-licensing, we are actively generating in-house IP and conducting R&D to expand the development and application of our candidates to address unmet medical needs globally.

We are currently building a world-class CMC and process development capabilities centering recombinant enzymes, antibodies and AAV gene therapy. We will seek continuous improvements and more cost-efficient options in manufacturing and quality control process with a combination of internal investment and outsourcing. For products of critical financial impact and with no replacements, we will develop and implement parallel manufacturing sites and inventory management to ensure patient safety and to mitigate any systemic risks. In gene therapy, we plan to build fully integrated gene therapy CMC operations with research laboratories and pilot plants enabling translational studies in Greater Boston area. We will continue to leverage external expertise and capacity such as those from Wuxi Biologics to build over time a robust global manufacturing and supply network to allow access of our products by patients globally.

OUR PORTFOLIO

We have built a broad portfolio of therapies targeting prevalent rare diseases, including rare oncology diseases in China with limited treatment options available. As of the Latest Practicable Date, we had built a comprehensive and differentiated pipeline of 13 products and product candidates with significant market potential, consisting of 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.

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



Notes:

1. Greater China includes mainland China, Hong Kong, Taiwan and Macau.
2. We have completed Phase 1 trial in Taiwan and obtained IND approval for the first line GBM Phase 2 clinical trial in China.
3. We obtained a clinical trial waiver and the NDA approval for Hunterase® (CAN101) for MPS II from the NMPA.
4. We expect to file NDA in Greater China by the end of 2021 based on data obtained by our license partner in global studies.
5. 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 enrolment in China as part of the global Phase 2 trial.
6. We are conducting a Phase 1 clinical trial for CAN106 in Singapore and received an IND acceptance notice from the NMPA for a Phase 1 study in China.
7. Greater China right granted from Wuxi Biologics and worldwide excluding Greater China right granted from Privus.
8. We expect to submit the IND application to the NMPA for CAN103 in 2H2021.
9. 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.
10. Caphosol™ is an oral electrolyte solution and designated as a prescription medical device.
11. 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.

Our drug candidates are subject to NDA approval by the relevant authorities, such as the NMPA, before commercialization in the relevant jurisdictions. As of the Latest Practicable Date, we had not received any material concerns, objections or negative statements raised by the NMPA or other relevant authorities that we are not able to address in a timely manner. We believe we are on track to advance the development of our clinical-stage drug candidates as described in "– Our Portfolio."

Late Stage Drug Products and Candidates

CAN008 CD95-Fc fusion protein for GBM

Overview

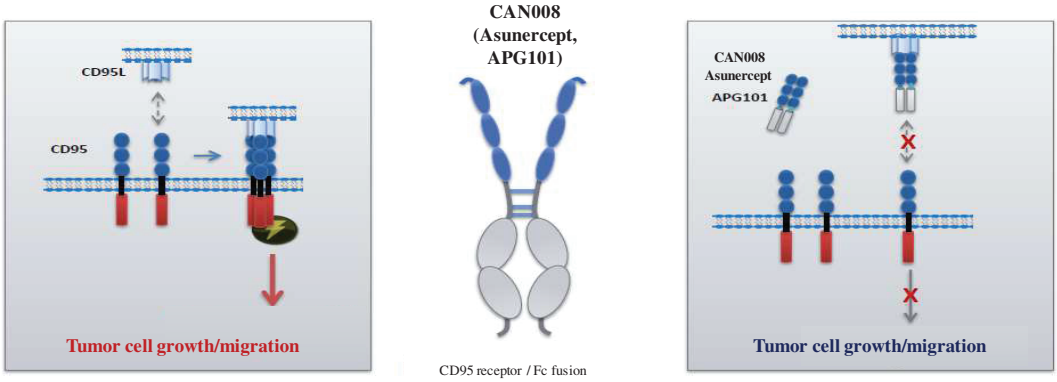
CAN008, our Core Product, is a glycosylated CD95-Fc fusion protein being developed for the treatment of GBM. We commenced a Phase 1 trial of CAN008 in combination with radiation therapy (RT) and temozolomide (TMZ) in patients with newly diagnosed GBM since September 2016 in Taiwan under the authorization 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 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 a first line Phase 2 clinical trial for CAN008 on GBM patients in China in the second half of 2021.

Mechanism of Action

CD95 (Fas/APO-1), a death receptor family member, has been linked to tumorigenicity in multiple cancers, including GBM. Binding of CD95 ligand (CD95L) to the CD95 receptor on the cell surface induces multimerization of CD95, which triggers an intracellular signaling cascade, resulting in stimulation of tumor cell growth and migration.

CAN008 is an engineered fully human CD95-Fc fusion protein that binds to CD95L, thus blocks its interaction with the cognate CD95 receptor. As such, signal transduction triggered by CD95- multimerization is inhibited, thereby reducing the invasive growth and migration of tumor cells. In addition, CAN008 also blocks the apoptosis of T cells by inhibiting CD95/CD95L engagement on T cells to restore immune function.

The diagram below illustrates the mechanism of action of CAN008:



CD95L and the receptor CD95 on the cell surface can induce the oligomerization of CD95, which subsequently triggers intracellular signal cascade and stimulates tumor cell growth and migration.

CD95 receptor / Fc fusion protein Asunercept can block CD95 signaling pathway by specifically binding to CD95L

As the oligomerization of CD95 is blocked and the signal transduction is inhibited, and the growth and migration of tumor cells are suppressed

Source: Company data

Market Opportunity and Competition

GBM is a fast-growing glioma that develops from glial cells (astrocytes and oligodendrocytes) or their precursors that support the health of the nerve cells within the brain. It is the most common and malignant type of glioma in adults. About 45% of gliomas are glioblastoma multiforme, which is classified as Grade IV (most serious) astrocytoma, is the most common and aggressive brain cancer where a large portion of tumor cells are reproducing and dividing at any given time, with an estimated 5-year survival of 5.5% globally and below 5% in China. The tumor is predominantly made up of abnormal astrocytic cells, but also contain a mix of different cell types (including blood vessels) and areas of dead cells (necrosis). GBM is infiltrative and is the most invasive type of glial tumors, rapidly growing and commonly spreading into nearby brain tissue. It can also sometimes spread to the opposite side of the brain through connection fibers (corpus callosum). GBM is characterized as a disease with one of the highest unmet needs in oncology, with patients having a median overall survival between one and two years.

Although GBM is a rare oncology with lower incidence as compared to the other cancer types, the high level of unmet need in this market creates ample opportunities for players with effective therapies. GBM is the most common malignant tumor of the central nervous system and is the most common and aggressive brain cancer. The incidence of GBM represents 46.6% of the total brain cancer incidence in China and has reached 54.7 thousand in 2020 with a CAGR of 2.0% from 2016 to 2020. With factors including increasing aging population, ionizing radiation and air pollution, the incidence of GBM in China is expected to grow to 59.8 thousand in 2025 and 64.4 thousand in 2030.

The standard of care for GBM consists of surgical resection, adjuvant chemotherapy with temozolomide (TMZ). However, radiation and chemotherapy always come with adverse events that greatly undermine the life quality of patients. In addition, tumor cells may develop some resistance to TMZ. Current GBM therapies have limited improvement in progression-free survival (PFS) with an estimated 5-year survival of 5.5% globally and below 5% in China. The current therapy treatment options for GBM in China include surgery and radiotherapy combined with TMZ concurrent chemotherapy.

The fusion protein developed in CAN008 has competitive advantages in the treatment of GBM over other treatment options, including a validated novel mechanism of action, improved efficacy and potential for combination therapy. For details on the competitive landscape of targeted therapies for GBM, see "Industry Overview – Glioblastoma Multiforme (GBM)".

Summary of Clinical Trial Data

Phase 1 Clinical Trial in Taiwan Conducted by CANbridge

Overview: The Phase 1 trial was an open-label, single-arm, dose escalation study that enrolled 10 patients with newly diagnosed and surgically accessible GBM with the goal to investigate the safety, pharmacokinetics, tolerability, preliminary efficacy and seek recommended dosage for the Phase 2 trial of CAN008 in combination with RT and TMZ. Study results demonstrated that CAN008 was generally well tolerated in patients with GBM. No dose-limiting toxicity was observed and no treatment-related serious adverse events were reported. The results of this study provide supportive information and implications for the future approach to study the add-on treatment of CAN008 for newly diagnosed GBM in the Asian populations.

Trial Design: All 10 patients were Asian, 8 were male and 2 were female, age ranged from 34 to 73 years. The primary objective of the Phase 1 trial is to evaluate the safety and tolerability of CAN008 when administered in combination with RT and TMZ. The secondary objectives of the Phase 1 trial include to evaluate the pharmacokinetics and preliminary efficacy of CAN008 when administered in combination with RT and TMZ and to evaluate the recommended dosage for the Phase 2 trial. As a part of standard care for GBM treatment, patients received 60 Gy radiation therapy, with 2 Gy/day from Monday to Friday, 10 Gy/week, for a total of 30 radiation treatments (about 6 weeks). The study consisted of three phases: a screening phase of approximately 4 weeks, the first treatment phase of CAN008 in combination with RT and TMZ for 7 weeks with weekly visits, followed by the second treatment phase of CAN008 with concomitant TMZ every four weeks until disease progression. Patients were assigned to two treatment cohorts: 200mg weekly for the first cohort and 400mg weekly for the second cohort. The study included a dose escalation scheme to identify dose limiting toxicity and adverse events.

Trial Status: The study was initiated in September 2016 and completed in September 2018.

Safety Data: No specific safety issue was observed by CAN008 treatment in combination with RT and TMZ and no anti-drug antibodies were detected. There were two patients in Cohort 2 who reported serious adverse events (SAEs) – one with hemorrhoids and the other with seizure, which were considered not related to any study treatment and both patients recovered. There was no case of discontinuation due to treatment-emergent adverse events and no patients in the Phase 1 trial experienced dose-limiting toxicity. No patients in the study experienced DLT. Taken together with the efficacy results, the maximum administered dose of CAN008 at 400 mg weekly was recommended as the RP2D by the safety monitoring committee (SMC).

Efficacy Data: The efficacy of CAN008 concurrent treatment with chemo-radio therapy for newly diagnosed GBM was evaluated by progression-free survival ("PFS"). In Cohort 1, the PFS rates were both 33.33% at 3 and 6 months after the dose, and all patients in Cohort 1 experienced disease progression within 9 months. In Cohort 2, the PFS rate at 3 months was 71.42%, whereas PFS rates at 6, 9, and 12 months were all at 57.14%. The median PFS was 2.37 months for Cohort 1 patients. Median PFS was not evaluable for Cohort 2 since 4 patients had ongoing treatment without disease progression at the time of data cutoff on September 28, 2018. Whereas methylation of the O6-methylguanine-DNA methyltransferase (MGMT) gene did not correlate with the efficacy of CAN008, low methylation of CpG2 in the CD95L gene promoter and higher CD95L protein expression correlated with the efficacy of CAN008, suggesting that they could be used as predictive biomarkers to screen patients who will benefit more from CAN008 treatment.

Phase 2 Clinical Trial in Europe Conducted by Apogenix

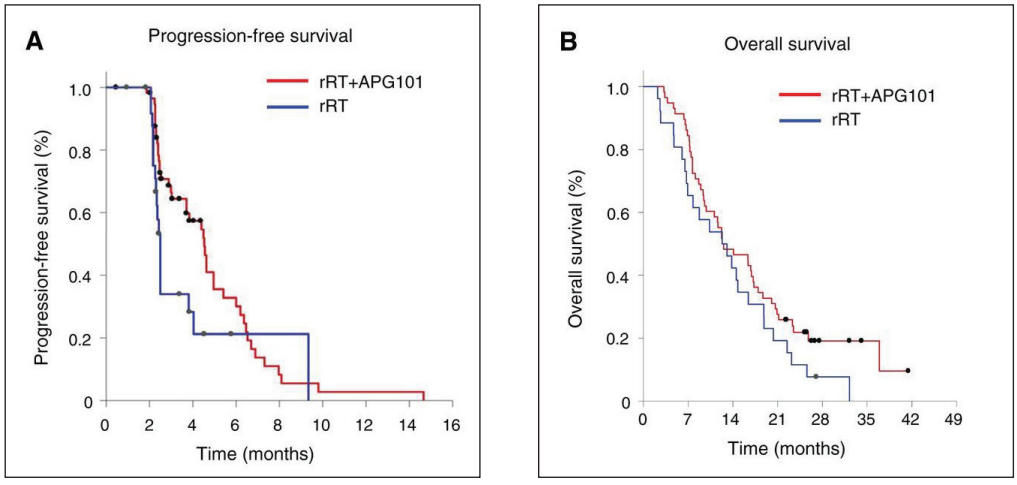
Overview: The Phase 2 trial was a multicenter, randomized and controlled study in recurrent GBM patients, and investigated the safety, tolerability and efficacy of APG101 (former name of CAN008 before in-licensing). The trial compared the efficacy and safety of a combination therapy of CAN008 (APG101) and radiotherapy versus radiotherapy (rRT) alone. Study results show statistically significant improvements in progression-free survival and quality of life as well as a positive trend in overall survival compared to treatment with radiotherapy alone, demonstrating the potential efficacy of CAN008 (APG101) in the treatment of recurrent GBM. During treatment with CAN008 (APG101) for up to two years, no drug-related serious adverse events were observed, affirming the excellent safety profile and very good tolerability of CAN008 (APG101).

Trial Design: A randomized control arm with rRT alone was added to avoid under- or overestimation of a signal from CAN008 (APG101). The study was approved by the ethics committees (EC) of all 25 participating sites. Patients were centrally randomised 1:2 to receive rRT (36 Gy) or rRT (36 Gy) + CAN008 (APG101) 400 mg weekly until progression. Treatment following disease progression was recorded. In this open-label, multinational trial, the first 9 patients constituted a predefined run-in phase to evaluate the safety of rRT + CAN008 (APG101). An independent Data and Safety Monitoring Board (DSMB) reviewed all relevant patient data after completion of the rRT and endorsed further accrual to the trial. The second meeting was held after 25 patients completed the reirradiation (rRT) and the third took place after 28 patients reached the primary endpoint, combined with a safety evaluation after the first 49 patients completed rRT. CAN008 (APG101) was given at 400 mg weekly as a 30-minute i.v. infusion until progression or undue toxicity.

Trial Status: The study was commenced in December 2009 and completed in September 2014.

Safety Data: Most patients tolerated both treatments well. 84.6% of patients in the rRT armed received the planned treatment while 98.3% in the rRT+ CAN008 (APG101) arm received the planned treatment.

Efficacy Data: In the control arm, rRT resulted in a PFS-6 rate of 3.8% (95% – CI: 0.1 – 19.6), i.e. one patient was free of progression, whereas PFS-6 in the rRT+ CAN008 (APG101) arm was 20.7% (95% – CI: 11.2 – 33.4), i.e. 12 patients, one less than prespecified, were free of progression. The difference in PFS-6 rates was 16.9% (95% – CI: 4.1 – 29.6, p=0.0485, Chi-Square test). The median PFS was 2.5 months in the rRT arm, as compared to 4.5 months in the rRT+ CAN008 (APG101) arm. As demonstrated by the charts below, CAN008 (APG101) achieved statistically significant improvements of over 50% in 4-month to 6-month progression-free survival, as well as a positive trend in overall survival in patients with relapsed GBM.



Souce: Clinical Cancer Research (October 2014)

Licensing

We entered into a license agreement with Apogenix on June 26, 2015 as amended by the First Addendum Agreement in December 2015, under which Apogenix granted us the exclusive rights to develop, manufacture and commercialize CAN008 (APG101) in Greater China. For details, please refer to "– Collaboration and Licensing Arrangements."

Our R&D Efforts since In-Licensing

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 chemistry and manufacturing and control (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;

    (ii) assessing 9 clinical trial 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.

Clinical Development Plan

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 a first-line Phase 2 clinical trial for CAN008 on 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.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN008 SUCCESSFULLY.

Hunterase® (CAN101) targeting MPS II/Hunter syndrome

Overview

Hunterase® (CAN101) is an enzyme replacement therapy for the treatment of mucopolysaccharidosis type II ("MPS II" or "Hunter syndrome"). 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 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 Hunter syndrome. We obtained a clinical trial waiver and the NDA approval for Hunterase® (CAN101) for MPS II from the NMPA in September 2020.

Mechanism of Action

MPS II, also known as Hunter syndrome, is an X-linked lysosomal storage disorder caused by deficient or defective activity of iduronate-2-sulfatase (IDS), which cleaves O-linked sulfate moieties from two human glycosaminoglycans (GAG), dermatan sulfate and heparan sulfate. In the absence of or with deficient activity of IDS, these GAGs accumulate in almost all body organs and tissues including the brain, heart, lung, bone, muscle, gut, and skin. Accumulation of GAG leads to cellular engorgement, organomegaly, tissue destruction, and organ system dysfunction.

Currently, there is no cure for Hunter syndrome. ERT is recommended as the standard of care by worldwide treatment guidelines and expert consensuses. ERT provides exogenous IDS enzyme for uptake into cellular lysosomes through the binding of M6P residues on its oligosaccharide chains to M6P receptors on the cell surface, leading to cellular internalization of the enzyme, targeting to intracellular lysosomes, and subsequent catabolism of accumulated GAG. ERT is effective in delaying disease progression, clearing accumulated GAG, controlling symptoms and disease manifestations, such as organ enlargement, decreased cardiac, respiratory system and bone functions, and has been proven to improve health outcomes of patients with Hunter syndrome.

Hunterase® (CAN101) is a purified form of recombinant human iduronate-2-sulfatase (rhIDS) produced in CHO DG44 cells using a serum-free process. It is an ERT that acts via specific uptake into lysosomes and subsequent degradation of GAGs that accumulate in the cells of patients with a deficiency in IDS enzyme.

Market Opportunity and Competition

Hunter syndrome or MPS II is a lysosomal storage disorder caused by the deficiency of iduronate-2-sulfatase (IDS), which leads to a massive accumulation of GAG and a wide variety of symptoms. MPS II is a rare, disabling and life-threatening genetic disease. Patients appear healthy at birth, with initial symptoms appearing between 18 months and 4 years of age. Life expectancy of patients with severe MPS II (60%-80% of cases) is significantly reduced, with death occurring generally before the age of 15 as a result of cardio-respiratory complications. In East Asian countries, MPS II is the most prevalent MPS disorder, occurring in an estimated 1.57/100,000 in newborn. According to Frost & Sullivan, the MPS II market in China remains stable as it is a genetically-related rare disease but highly underserved. The prevalence of MPS II in Greater China mainland reached 8,005 in 2020 and is estimated to reach 8,175 in 2030.

The treatment of MPS II was palliative prior to the introduction of ERT. The first ERT for MPS II is Elaprase approved by the FDA in 2006. While ERT is the standard of care, there is currently no treatment available in China, with Elaprase being added to the "Second list of drugs urgently needed in China" in March 2019. Compared to Elaprase, Hunterase® (CAN101) has shown higher specific enzyme activity with significant reduction in the urinary GAG

(uGAG) level and increase in the 6-MWT in clinical settings. We also believe that the serum-free production process of Hunterase® (CAN101) is more efficient than Elaprase, which eliminates the infectious agents transmitted in blood.

With Hunterase as the only approved treatment in China and an estimated number of over 8,000 patients countrywide in 2020, there is a high level of unmet need and the Chinese government has included MPS II on the "National Rare Disease List" as a disease group to target. For details on the competitive landscape of targeted therapies for MPS II, see "Industry Overview – Mucopolysaccharidosis Type II (MPS II or Hunter syndrome)".

Summary of Clinical Trial Data

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 and certain post-approval studies. The pivotal study indicated significant subject benefit, a significant decrease in uGAG level from baseline, and improvement in the primary endpoints. The ongoing trials continue to investigate the long-term safety and efficacy, and have obtained positive interim results.

Selected Completed trials: Phase 1/2 trial

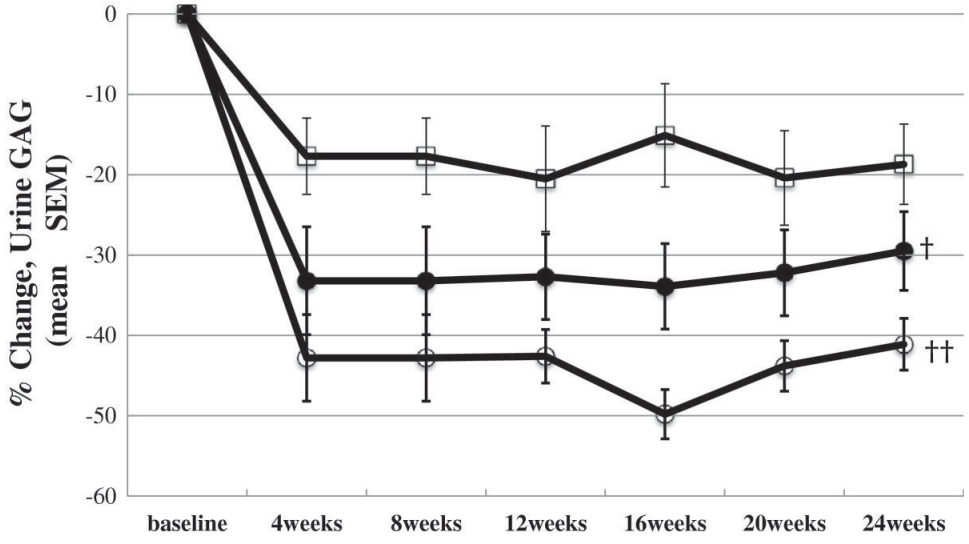
Overview: The Phase 1/2 trial indicated favorable efficacy of Hunterase® (CAN101) through a significant decrease in Urine GAG (uGAG) level from baseline, and improvements in the primary endpoints including the 6-MWT. It has also validated the safety profile of Hunterase® (CAN101) by the well tolerance in patients.

Trial Design: The Phase 1/2 trial was a randomized, single-blind, active-controlled study with the primary objective to evaluate the efficacy of Hunterase® (CAN101) based on the percentage change in uGAG from baseline to week 24, and the secondary objectives to evaluate the efficacy of Hunterase® (CAN101) based on the change and percentage change in the 6-minute walk test (6-MWT), liver volume, heart size, joint mobility, cardiac function and lung function, from baseline to week 24. 31 patients were randomized into one of three treatment arms: a comparator group, 0.5 mg/kg/week; a Hunterase® (CAN101) group, 0.5 mg/kg/week; and a Hunterase® (CAN101) group, 1.0 mg/kg/week. All the enrolled patients were previously treated with Elaprase, which also served as the active control in this trial.

Trial Status: The Phase 1/2 study was commenced in May 2010 and completed in March 2011.

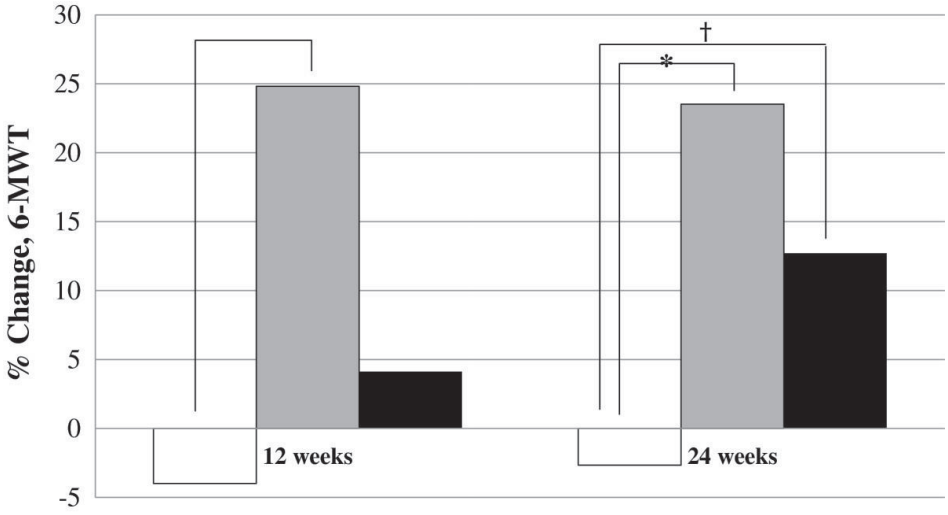
Safety Data: In the Phase 1/2 trial, Hunterase® (CAN101) was shown to be well-tolerated and elicited no serious adverse drug reactions in all three groups. The most frequent adverse events were urticaria and skin rash, which were easily controlled with administration of antihistamines.

Efficacy Data: Urinary GAG reduction has been used as the main efficacy measurement. The uGAG level is considered a reliable indicator of biologic activity *in vivo*, and in some cases is predictive of clinical efficacy. As shown in the table below, the Phase 1/2 trial has demonstrated statistically significant decrease in uGAG from baseline to 24 weeks. After 24 weeks of treatment, the percent changes in uGAG levels were significantly greater in Hunterase® (CAN101) groups treated at dosages of 0.5 mg/kg/week and 1.0 mg/kg/week, compared to the comparator group (†P = 0.043 and ††P = 0.002, respectively). Squares represent the comparator group (N = 11), closed circles represent the Hunterase® (CAN101) 0.5 mg/kg/week group (N =10), and open circles represent the Hunterase® (CAN101) 1.0 mg/kg/week group (N = 10).



Source: Orphanet Journal of Rare Diseases (March 2013)

The Six Minute Walk Test (6-MWT) is a functional endpoint that reflects the ability to walk a moderate distance that is important for normal community ambulation. This was the main secondary endpoint in the Phase 1/2 study. Patients with MPS II showed statistically significant and clinically meaningful improvements in the 6-MWT distance. At 24 weeks, the percent changes in 6MWT distance were significantly higher in Hunterase® (CAN101) groups treated at dosages of 0.5 mg/kg/week (*P = 0.003) and 1.0 mg/kg/week (†P = 0.015), compared to comparator group. White bars represent the comparator group (N= 8), grey bars represent the Hunterase® (CAN101) 0.5mg/kg/week group (N= 6), and black bars represent the Hunterase® (CAN101) 1.0mg/kg/week group (N= 7) in the chart below. The magnitudes of change are comparable to or exceed those seen in the pivotal clinical trials of ERTs for other MPS disorders.



Source: Orphanet Journal of Rare Diseases (March 2013)

Licensing

We obtained exclusive license rights in Hunterase® (CAN101) from South Korea-based Green Cross Corporation ("GC") through a license agreement dated January 3, 2019 to develop and commercialize Hunterase® (CAN101) in Greater China, and elected under the license agreement not to commercialize in Shanxi, Guizhou, Gansu, Qinghai, Xizang, Jilin and Yunnan. For details, please refer to "– Collaboration and Licensing Arrangements."

Clinical Development Plan

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

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). 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. An NDA and a marketing authorization application of maralixibat were submitted to the U.S. FDA for the treatment of ALGS and to the EMA for the treatment of PFIC, respectively. 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.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN108 SUCCESSFULLY.

CAN106 long-acting anti-C5 antibody for complement disorders

Overview

CAN106 is an innovative humanized long-acting 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 obtained 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 and received an IND acceptance notice from the NMPA for a Phase 1 study in April 2021.

Mechanism of Action

C3 and C5 are protease complexes in the complement system that protect against invading organisms. During their hydrolysis, C3 releases the anaphylatoxin C3a and the fragment C3b. C3b can form C3bBb and C3b2Bb, which catalyze the hydrolysis of C3 and C5, respectively. C5 releases the anaphylatoxin C5a and C5b that initiates assembly of membrane attack complex (MAC), a pore-like structure that inserts into the cell membranes, causing cell lysis.

C5 complement inhibitors block the complement cascade at the level of C5, so it can stop the immune responses that cause disease. C5 complement inhibitors preserve the generation of C3b, which is essential for the clearance of circulating immune complexes and the normal phagocytosis of bacterial and fungal pathogens. CAN106 is a humanized anti-C5 monoclonal antibody that binds to the α chain of C5, which prevents C5 from being cleaved into C5a and C5b by C5 convertase.

Market Opportunity and Competition

The unmet medical need and the treatments available vary depending on the continent. In Western countries, treatment with recombinant humanized anti-C5 monoclonal antibodies is the standard of care and there is limited unmet medical need. The prevalence of PNH has experienced steady growth both globally and in China. From 2016 to 2020, the prevalence of PNH have increased from 23.3 thousand to 23.8 thousand, and is predicted to reach 24.3 thousand in 2025 and 24.5 thousand in 2030. The recent acquisition and collaboration by other leading pharmaceutical companies regarding complement-mediated diseases also reflected the current market-heat in complement inhibitors. Alexion acquired Achillion Pharmaceuticals, Inc. in January 2020, adding two clinical-stage oral small molecule Factor D inhibitors to Alexion's pipeline and provides the foundation and expertise for a broader oral Factor D inhibition development platform with the potential to treat numerous additional complement-mediated diseases. In the same month, Argenx and Zai Lab Announce Strategic Collaboration for Efgartigimod, a treatment to generalized myasthenia gravis (gMG) in Greater China.

In Asian countries, and in China in particular, the unmet medical need remains high due to the inability to pay for high-priced Western treatments and lack of local drugs. We are developing CAN106 to be a less expensive treatment option in China, with a view to gaining approval in Western countries later in the clinical development program. In addition, complement C5 plays an important role in various rare diseases due to its function in inflammatory and cell killing processes, and China remains to be the largest untapped market.

For details on the competitive landscape of anti-C5 antibodies, see "Industry Overview – Complement Mediated Diseases".

Summary of Preclinical Data

We have completed the non-clinical studies to support our IND submission for CAN106 in China in March 2021.

Overview: The non-GLP nonclinical pharmacology and PK studies conducted with CAN106 demonstrated favorable properties of CAN106 and corresponding improved duration of PD effect on inhibiting hemolysis out to 35 days post administration of a single intravenous dose in mice supplemented with human C5 and the specific binding of CAN106 to human C5 is demonstrated.

In a study conducted on *in vitro* human wildtype C5 using surface plasmon resonance SPR, the results showed differential association and dissociation kinetics at pH 7.4 and pH 6.0, which can potentially improve the PK of CAN106 by addressing target-mediated drug disposition (TMDD).

The design of the structure of CAN106 enables differential association and dissociation kinetics of binding to FcRn at pH 7.4 and pH 6.0, and showed improved binding to human FcRn protein and permitted more efficient recycling of CAN106.

In a study conducted on chicken red blood cells (RBCs) *ex vivo* with CAN106, the dose-dependent inhibition of hemolysis of chicken RBCs in the presence of human serum C5 was observed (Figure 1).

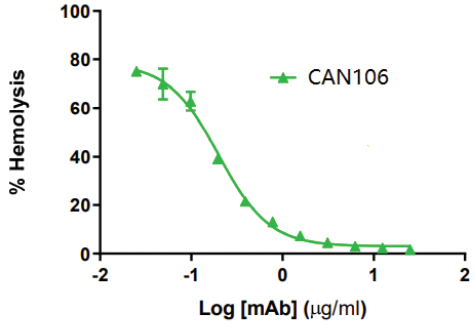


Figure 1. Hemolysis inhibition assay with CAN106 and wild-type human C5 protein

Source: Company data

Another study was conducted on nonobese diabetic (NOD)/severe combined immunodeficiency (SCID) mice with vehicle or CAN106 (5 or 15 mg/kg once IV by tail vein injection) with and without human C5 (250mcg loading dose on Day -1 with subsequent doses of 50mcg administered twice daily for 5 weeks). Results revealed that in the presence of human C5, CAN106 persisted for an extended period of 35 days with little to no TMDD. Mouse serum containing CAN106 inhibited hemolysis of chicken RBCs *ex vivo* over the course of the study (for up to 35 days) even in the presence of human C5 (Figure 2).

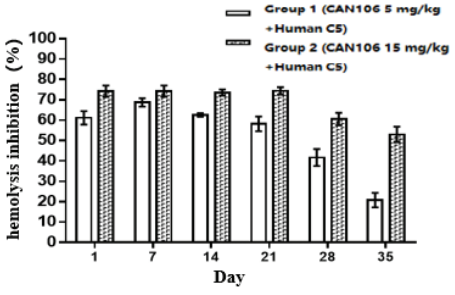


Figure 2: Pharmacodynamic effects (hemolysis inhibition percentage at different post-dosing days) of CAN106 in serum from NOD/SCID mice supplemented with human C5

Source: Company data

Other studies were conducted on Cynomolgus monkey to investigate the toxicology and safety pharmacology. The no-observed-adverse-effect level (NOAEL) in the 4-week repeated dose in Cynomolgus monkey for the off-target toxicity investigation was 150 mg/kg/week. The *in vitro* hemolysis, tissue cross reactivity and local tolerance test did not show any obvious abnormality or toxicity.

Conclusion: CAN106 exhibits pH-dependent binding to human C5 and FcRn that can result in improved CAN106 recycling and reduced TMDD, leading to improved PK and PD properties *in vivo*. Reduced TMDD was demonstrated in the NOD/SCID mouse model supplemented with human C5. Enhanced duration of PD effect (inhibition of C5-mediated hemolysis of chicken RBCs *ex vivo*) was demonstrated in the same model and correlated with the reduction in TMDD. CAN106 was well tolerated in the completed preclinical toxicity studies in Cynomolgus monkeys. These data indicate that CAN106 may have the potential to effectively inhibit C5 in patients with PNH with reduced dosing frequency.

Licensing

We entered into a licensing agreement with WuXi Biologics Ireland Limited (WuXi Biologics) on January 7, 2019, which granted us an exclusive, transferable and royalty-bearing right to the anti-C5 antibody owned by WuXi Biologics in Greater China. On May 9, 2020, we entered into another license agreement with Privus Biologics, LLC ("Privus"), wherein Privus granted to us an exclusive, transferable and royalty-bearing right to the anti-C5 antibody owned by Privus in worldwide except for Greater China. We have global rights to develop and commercialize the CAN106 with the strategic collaboration with WuXi Biologics and Privus to manufacture the drug products. For details, please refer to "– Collaboration and Licensing Arrangements."

Clinical Development Plan

This first-in-human study being conducted in Singapore in 2021 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. Subjects will initially be enrolled at the lowest dose level (0.25 mg/kg) and dose escalations will proceed after reviewing of the safety data by the Scientific Review Committee (SRC). A sentinel dosing strategy will be employed in cohort 3-6. The first 2 subjects in a cohort will be randomized to receive CAN106 or placebo at a 1:1 ratio, and the remaining subjects will be enrolled in the same cohort if tolerated. The remaining subjects will receive CAN106 or placebo at least 24 hours after the second sentinel subject has been dosed. A Phase 1 study is planned in China.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN106 SUCCESSFULLY.

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 fatty chemicals that accumulates 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 prototypitcal rare diseases in China with approximately 3,000 patients in 2020.

Completed in vitro and in vivo nonclinical pharmacology of CAN103 shows similar specific activity and uptake ability with Velaglucerase alfa. Animal data with a mouse model of Gaucher disease has shown that CAN103 has the efficacy on reduction the storage cells in liver, the decreasing levels of Lyso-GL-1 and glucocerebroside were also observed even in the low dose. The single dose toxicity study in rats and monkeys revealed no specific toxicity up to the highest dose at 20 mg/kg, and no test substance related changes in the 4-w repeated dose toxicity study in rats and monkeys.

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.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN103 SUCCESSFULLY.

CAN107

CAN107 is a 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 prevent 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, according to Frost & Sullivan.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN107 SUCCESSFULLY.

CAN105

CAN105 is a treatment 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.

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN105 SUCCESSFULLY.

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.

We obtained exclusive worldwide license rights in sL65 from LogicBio Therapeutics through a license agreement dated April 27, 2021 to develop and commercialize four gene therapy products in sL65, and an option to an exclusive license for LB-001 for the treatment of methylmalonic acidemia (MMA) in designated areas pursuant to the license agreement. LB-001 is an investigational in-vivo gene editing technology based on GeneRide™ platform, which is designed to precisely integrate corrective genes into albumin locus of the hepatocytes of patients to provide a durable therapeutic effect. For details, please refer to "– Collaboration and Licensing Arrangements."

WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET CAN201 AND CAN202 SUCCESSFULLY.

Collaboration and Licensing Arrangements

As of the Latest Practicable Date, all of our license partners are Independent Third Parties. We discuss and negotiate each license and/or collaboration arrangement on a case-by-case basis; therefore, the terms under each arrangement are customized. However, based on our understanding of the industry, and as advised by Frost & Sullivan, we also believe the overall arrangement under our collaboration agreements is consistent with general industry practice for similar kinds of products. As part of the global collaboration with our license partners, when applicable, we may participate in our license partners' global clinical studies by joining in the clinical studies with us taking the operational lead by conducting the screening, enrollment and treatment of patients and coordinating development, registration and commercialization in China and other specified territories where we have exclusive development and commercialization rights. Please see "Business" for detailed discussion on our products and late-stage clinical drug candidates and collaboration with our business partners. We plan to spend a portion of the [**REDACTED**] from this [**REDACTED**] on relevant development milestone fees under the collaboration 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.

In consideration of granting us such license under the Apogenix Agreement, we shall pay to Apogenix upfront aggregate payments of US$6 million, and in consideration for the amendment in December 2015 to add Taiwan, we must pay Apogenix 50% of the profits generated by us, our affiliates or our permitted sublicensees from the sale or other disposition of any Apogenix Licensed Products to a third party in Taiwan. Apogenix is eligible to receive up to an additional aggregate amount of US$8 million in regulatory milestone payments in mainland China for GBM, a US$5 million regulatory milestone payment in mainland China for another indication, such other indication to be agreed upon under a separate development plan by the parties, an aggregate amount of US$30 million in sales milestone payments in Greater China for GBM, and up to US$5 million in regulatory milestone payments in Taiwan. We also must pay to Apogenix tiered low teens percentage royalties based on net sales of the Apogenix Licensed Products in Greater China, including for indications other than GBM, if so agreed upon by the parties. Such royalties may be subject to certain reductions for lack of a valid patent claim in mainland China or competing generic products in Greater China.

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.

Subject to the terms of the Apogenix Agreement, in the development of the Apogenix Licensed Products, we and Apogenix will each solely own the entire right, title and interest in and to all inventions and discoveries related to Apogenix technology first developed, made or discovered solely by us or Apogenix, respectively. However, we possess the licensed rights within Greater China and Apogenix possesses such rights outside Greater China. In addition, we and Apogenix will jointly own an individual equal interest in certain inventions, patent rights and know-how based on jointly conceived intellectual property that relates to the Apogenix Licensed Products. We have the responsibility to file and prosecute our own patent rights and the jointly developed intellectual property in Greater China and Apogenix has the responsibility to file and prosecute our patent rights that relate to Apogenix technology and the jointly developed intellectual property outside Greater China.

Subject to the terms of the Apogenix Agreement, upon completion of the biomarker study to analyze CD95L expression and methylation patterns in the Chinese glioblastoma patient population Apogenix shall use its commercially reasonable efforts to transfer all data and information controlled by then to the extent necessary or useful for manufacturing and provide all relevant support. The manufacturing shall be conducted by a third party CMO or entity controlled by us.

The Apogenix Agreement may be terminated by us without cause upon 90 days' prior written notice to Apogenix, and by either us or Apogenix for cause in the event that (1) the biomarker study under the Apogenix Agreement is unsuccessful or (2) the other party commits a material uncured breach or default of its obligations under the Apogenix Agreement. Any

material breach which only affects Taiwan will only terminate the amendment granting license rights in Taiwan but not the entire Apogenix Agreement. Apogenix may terminate the Apogenix Agreement in the event that we, any of our affiliates, or a permitted sublicensee directly or indirectly challenges, or supports a third party to challenge, the validity of any Apogenix patent rights in a legal proceeding. Unless terminated earlier, the Apogenix Agreement will expire upon the fulfillment of relevant payment pursuant to the payment term, after which the license granted under the Apogenix Agreement shall survive and become non-exclusive, perpetual and royalty-free. Under the Apogenix Agreement, such royalty term with respect to an Apogenix Licensed Product expires on the later of (i) the expiry of the last-to-expire Apogenix patent with claims covering such Apogenix Licensed Product in mainland China, (ii) the expiry of major data or regulatory exclusivity for such Apogenix Licensed Product in mainland China, and (iii) the twelfth anniversary of the first commercial launch of such Apogenix Licensed Product in mainland China.

Apogenix is a private company based in Germany developing innovative immunotherapeutics for the treatment of cancer and viral infections. Since its inception in 2005, Apogenix has developed a promising portfolio of innovative immuno-oncology therapeutics for the treatment of cancer and viral infections. Apogenix' drug candidates target different TNFSF-dependent signaling pathways, thereby restoring the anti-tumor immune response in cancer patients and reducing lymphopenia and inflammatory cell death in patients with viral infections.

As of the Latest Practicable Date, Apogenix is an Independent Third Party.

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 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.

Subject to the terms of the GC Pharma Agreement, in the development of the GC Pharma Licensed Products, GC Pharma will own the entire right, title and interest in and to all intellectual property rights relating to the GC Pharma Licensed Products or the licensed rights under the GC Pharma Agreement, whether solely created by GC Pharma or by us or jointly created, and GC Pharma shall grant a royalty-free license to CANbridge under such rights to develop, commercialize the licensed products in the field. We will own any intellectual property rights created solely by us not related to the GC Pharma Licensed Products or the licensed rights, but grant to GC Pharma a perpetual, irrevocable, royalty-free, worldwide, sublicensable license under such intellectual property rights for GC Pharma to research, develop, manufacture, use, and commercialize the GC Pharma Licensed Products. Each party has rights for prosecution of its intellectual property rights, subject to a step-in right by us should GC Pharma choose not to prosecute a licensed patent. GC Pharma has the first right, but not the obligation, to enforce licensed patents in the licensed territory, subject to our step-in right should GC Pharma not diligently pursue an infringement action.

Pursuant to the GC Pharma Agreement, we shall pay GC Pharma an aggregate total of US$10 million for the upfront payment and development milestones. In addition, we are obligated to pay GC Pharma a fixed double digit percentage royalty on net sales of GC Pharma Licensed Products generated in each of Greater China. Such royalties are subject to a reduction in the event of generic competition. The royalty term with respect to a GC Pharma Licensed Product in any region expires on the later of (i) the expiry of the last-to-expire valid claim of a licensed patent covering such GC Pharma Licensed Product in such region, and (ii) the fifteenth anniversary of the first commercial sale of such GC Pharma Licensed Product in such region.

The GC Pharma Agreement may be terminated by us, without cause, upon prior written notice. GC Pharma may terminate the agreement upon certain conditions such as our failure to meet certain development timeline as agreed. In addition, either party may terminate the GC Pharma Agreement upon bankruptcy, a change of control, or material uncured breach of the agreement of or by the other party.

GC Pharma is a biopharmaceutical company headquartered and listed in South Korea (stock code: 006280.KS) that delivers protein therapeutics and vaccines. It is a leading global protein products manufacturers and has been dedicated to quality healthcare solutions more than half a century.

As of the Latest Practicable Date, GC Pharma is an Independent Third Party.

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 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. The supply price of the the WuXi Biologics Licensed Product is based on manufacturing cost at a specified fixed rate, plus a bonus payment of US$500,000 for completion of clinical trial application and clinical batches.

Subject to the terms and conditions of the WuXi Biologics Agreement, we shall pay WuXi Biologics an upfront payment of US$0.1 million, and are obligated to pay up to an aggregate of US$15.5 million in pre-clinical, clinical development and regulatory milestone payments and up to an aggregate of US$65 million in commercial milestone payments. In addition, we are obligated to pay WuXi Biologics a tiered mid-single digit royalty on total aggregate net sales of the WuXi Biologics Licensed Product. Such royalties are subject to a reduction in the event of blocking third-party intellectual property and/or biosimilar competition. The royalty term for the WuXi Biologics Licensed Product in a specific country or region commences upon the first commercial sale in such country or region and expires on the later of (i) the expiry of the last-to-expire valid claim of a licensed patent covering the WuXi Biologics Licensed Product in such country or region, and (ii) the tenth anniversary of the first commercial sale of the WuXi Biologics Licensed Product in such country or region.

Subject to the terms of the WuXi Biologics Agreement, we and WuXi Biologics will each solely own the entire right, title and interest in and to all inventions and discoveries first made or discovered solely by us or WuXi Biologics, respectively, and will jointly own all inventions or discoveries jointly made or discovered. We have the sole right, at our expense, for the prosecution and maintenance of the licensed patent rights. We also have the first right, but not the obligation, to enforce the licensed patent rights.

Unless terminated earlier, the WuXi Biologics Agreement will expire, for each WuXi Biologics Licensed Product, upon the expiration of the royalty term on a country-by-country or region-by-region basis. The WuXi Biologics Agreement may be terminated by us, without cause, upon 90 days' prior written notice to WuXi Biologics. WuXi Biologics may terminate the WuXi Biologics Agreement if we directly or indirectly challenge any of the licensed patent rights. Either party may terminate the WuXi Biologics Agreement upon the insolvency of, or material uncured breach of the agreement by, the other party.

WuXi Biologics Ireland Limited is a subsidiary of WuXi Biologics (Cayman) Inc., a Hong Kong-listed company (stock code: 2269.HK) with an open-access biologics technology platform offering end-to-end solutions to empower organizations to discover, develop and manufacture biologics since 2000.

As of the Latest Practicable Date, WuXi Biologics Ireland Limited is an Independent Third Party.

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.

Subject to the terms and conditions of the Privus Agreement, we shall pay Privus an upfront payment of US$6.0 million, and are obligated to pay up to an aggregate of US$73.0 million in regulatory, clinical development, additional indication, and up to an aggregate of US$118.0 million in commercial milestone payments. In addition, we are obligated to pay Privus a tiered mid-single digit royalty on total aggregate net sales of the Privus Licensed Product. Such royalties are subject to a reduction in the event of blocking third-party intellectual property and/or biosimilar competition.

Subject to the terms of the Privus Agreement, we and Privus will each solely own the entire right, title and interest in and to all inventions and discoveries first made or discovered solely by us or Privus, respectively, and will jointly own all inventions or discoveries jointly made or discovered. We have the sole right, at our expense, for the prosecution and maintenance of the licensed patent rights. We also have the first right, but not the obligation, to enforce the licensed patent rights.

Unless terminated earlier, the Privus Agreement will expire, for each Privus Licensed Product, upon the expiration of the royalty term on a country-by-country or region-by-region basis. The Privus Agreement may be terminated by us, without cause, upon 90 days' prior written notice to Privus. Privus may terminate the Privus Agreement if we (ii) cease all development activities prior to receipt of regulatory approval for the Privus Licensed Product in any of the U.S, E.U. or Japan for a period of six consecutive months and does not cure such cessation within 90 days or receiving written notice thereof from Privus or (ii) directly or indirectly challenge any of the licensed patent rights. Either party may terminate the Privus Agreement upon the insolvency of, or material uncured breach of the agreement by, the other party.

Privus is a limited liability company organized under the law of the State of Delaware, U.S., focusing on the business of discovering, manufacturing and developing biologics to treat rare diseases and conditions.

As of the Latest Practicable Date, Privus is an Independent Third Party.

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, 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.

Located in Worcester, Massachusetts, U.S., UMass was founded in 1962 and is consistently ranked by U.S.News & World Report as one of the leading medical schools in the U.S. for primary care education. Its mission is to advance the health and well-being of the people of the Commonwealth and the world through pioneering education, research, public service and health care delivery.

As of the Latest Practicable Date, UMass is an Independent Third Party located in Worcester, Massachusetts.

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 gene therapy candidates for two targets for the treatment of Fabry and Pompe diseases, such 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.

The agreement contains intellectual property provisions customary for this type of agreement.

Under the agreement, we paid a one-time, non-refundable upfront payment of US$10 million. Upon exercising the option for LB-001, we would assume responsibility and costs for all future development of LB-001 in Greater China, including regulatory and commercial activities and, potentially, manufacturing. The agreement also includes payments, including opt-in fees triggered upon the exercise of these options, as well as clinical, regulatory, and commercial milestone payments for up to US$591 million, and up to a tiered double-digit royalties on net sales.

The royalty term for the LogicBio Licensed Product in a specific country commences upon the first sale in such country and expires on a licensed product-by-licensed product and country-by-country basis on the later of (i) the expiration of the last-to-expire valid claim of a licensed patent covering the LogicBio Licensed Product in such country, (ii) the expiration of all regulatory exclusivity for such LogicBio Licensed Product in such country, and (iii) the tenth anniversary of the first sale of the LogicBio Licensed Product in such country. In addition, LogicBio may enter into new license agreements with third parties during the term of the agreement and should we opt to receive a sublicense to patents, know-how or LB-001 technology under such agreements, we will be responsible for certain payments, subject to the terms of the agreement.

Unless terminated earlier, the agreement will expire, for each LogicBio Licensed Product, upon the expiration of the royalty term on a country-by-country or region-by-region basis. The agreement may be terminated by us, without cause, subject to a notice period. LogicBio may terminate the agreement if we (i) directly or indirectly challenge the validity, enforceability or scope of any licensed rights; or (ii) on a target-by-target basis cease development and commercialization activates regarding the LogicBio Licensed Products. In addition, either party may terminate the agreement upon insolvency of, or material uncured breach of the agreement by, the other party.

LogicBio is based in Lexington, Massachusetts, U.S., and listed on the NASDAQ stock exchange (Stock Symbol: LOGC). LogicBio is a clinical-stage genetic medicine company pioneering gene delivery and gene editing platforms to address rare and serious diseases from infancy through adulthood.

As of the Latest Practicable Date, LogicBio is an Independent Third Party.

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 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.

Under the terms of the licensing agreement, we have obtained the exclusive right to develop and commercialize maralixibat within the Greater China regions for ALGS, PFIC, and BA. In exchange, Mirum is entitled to receive an $11.0 million upfront payment, R&D funding, and up to $109.0 million for the achievement of future regulatory and commercial maralixibat milestones, with significant double-digit tiered royalties based on product net sales. The royalty term for the Mirum Licensed Product in a specific country commences upon the first sale in such country and expires on a licensed product-by-licensed product and region-by-region basis on the later of (i) the expiration of the last-to-expire valid claim of a licensed patent covering the Mirum Licensed Product in such region, or expiration of the applicable upstream license agreement royalty term, (ii) the expiration of regulatory exclusivity for such Mirum Licensed Product in such region, or (iii) the twelve (12) anniversary of the first sale of the Mirum Licensed Product in such region.

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.

Subject to the terms of the agreement, we and Mirum will each solely own the entire right, title and interest in and to all inventions and discoveries first made or discovered solely by us or Mirum, respectively, and will jointly own all inventions or discoveries jointly made or discovered in connection with the performance of activities under this agreement. Mirum has

the first right, at its expense, for the prosecution and maintenance of the licensed patent rights in the licensed territory. We have the first right, but not the obligation, to enforce the licensed patent rights in the licensed territory.

Mirum is based in Foster City, California, U.S. and listed on the NASDAQ stock exchange (Stock Symbol: MIRM). Mirum is a clinical-stage biopharmaceutical company focused on the development and commercialization of a late-stage pipeline of novel therapies for debilitating liver diseases.

As of the Latest Practicable Date, Mirum is an Independent Third Party.

OUR PLATFORM

We have developed a fully-integrated platform for the research, development, and commercialization of rare disease therapies. The integration of our platform enables smooth collaboration among different functional groups at key points in the lifecycle of a product candidate with the goal of increasing the speed of development and likelihood of success while at the same time reducing the cost of development. In addition, our platform has been stress tested throughout the development of our product candidates by requiring each functional group to improve their process, approach and collaboration skills.

RESEARCH AND DEVELOPMENT

We believe that R&D is key to driving our therapies 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

Our R&D team members have extensive early research, 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 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 and Development Committee of Joint Institute of Peking University Health Science Center and University of Michigan Medical School.

We promote company-wide cross-function collaboration to identify and mitigate inherent risks early in the development of innovative therapies with massive market potential. For example, in implementing such approach, our senior R&D members serve across different functional teams, and our medical team will be involved from the project inception and throughout the preclinical development of our research projects. This enables our team to be familiar with the assets at an early stage so that they can formulate development ideas early on and provide feedback to the internal R&D team.

In addition, to empower our R&D team, achieve a lean operation and optimize the effectiveness and efficiency the drug development efforts for our innovative pipeline assets, we strategically combine internal research and global collaborations with top biotechnology institutions worldwide. See "Our Strengths – Extensive strategic partnerships to source innovative therapies globally" and "– Collaboration with CROs." In particular, we continue to invest in gene therapy as our next-generation technology development and expand our in-house R&D activity to generate promising leads for treatment of rare diseases. See "Our Strategies – Maximize value creation through partnership and collaboration." Our R&D efforts are also supported by a scientific advisory board with reputable key opinion leaders in the pharmaceutical industry, covering rare disease and gene therapy.

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 respectively.

Preclinical Research

Our preclinical research effort is led by Dr. Yunxiang Zhu (PhD), our Vice President and Head of Global Research. Dr. Zhu has nearly 20 years of R&D leadership experience in the biotechnology industry, during which time he designed more than five first-in-class bispecific and trifunctional antibody lead candidates, and contributed greatly to the invention of the second-generation enzyme replacement therapy. Our R&D teams currently base in Shanghai, China and Greater Boston area.

We have a streamlined our preclinical research process in identifying and validating potential therapeutic compounds. Our R&D team makes proposals on the drug target and modality for further investigation. Then, the R&D leaders from our preclinical research, clinical development and medical research teams review the proposals to assess the proposed therapeutic targets based on unmet clinical needs, competitive landscape and their fit with our corporate strategy. Our senior management will then approve the further investigation/in-house development, acquisition or in-licensing after such feasibility assessment.

In addition to biologics and small molecules, we are internally developing an AAV delivery platform targeting different tissues such as central nervous system (CNS) and muscles. We have also entered into collaborations with top medical companies and institutions including LogicBio Therapeutics and UMass to explore the gene therapy solutions for treatment of LSDs, MMA, and certain neuromuscular disorders based on novel AAV capsids. We are building gene therapy CMC operations with AAV research process development laboratory and pilot plants enabling translational studies in the Greater Boston area. We believe our full-fledged platform and collaboration partnerships also afford us with opportunities to pursue rare disease drug development in neglected diseases and quickly generate clinical proof-of-concept and data for global development. As we grow and scale up our infrastructure, we expect to enjoy a cost advantage which enables us to optimize our pricing and bring our rare disease therapies to as many overseas markets as possible.

Clinical Development

Our clinical development team is led by Dr. Gerald Cox (MD, PhD), our Chief Development Strategist and interim CMO. Each of our clinical development projects involves a joint and collaborative process involving clinical development, science and pipeline strategy teams and is initiated only after a comprehensive study on product profile, clinical/preclinical data, existing and anticipated treatment and competitive landscape, as well as commercial potential. For each proposed clinical development project, a feasibility assessment led by our medical team is conducted. A feasibility report is generated in the process and submitted to our review committee (composed of functional representatives from medical, clinical operations, CMC, preclinical, regulatory affairs and our project leadership teams), and a clinical development project meeting will be organized to assess factors such as the project's compatibility with our strategy, project feasibility, filing strategy, execution timetable, market and commercialization prospects and R&D resources available to either approve or reject the project. After approval, we assign a project lead for each of our clinical development project who formulates the study timetable and budget, and a medical lead who develops a detailed study protocol based on the compound's MoA and oversees the trial execution.

Collaboration with CROs

To efficiently and effectively achieve our R&D targets, we adopt a distributed drug development model, where we select the most suitable partners to optimize the effectiveness and efficiency of our drug development efforts, including working with industry-leading CROs to manage, conduct and support our preclinical research and clinical trials. For example, we engaged PAREXEL China Co., Ltd., a leading clinical CRO in China, to conduct pharmacovigilance, data management, regulatory management, biometric analysis, project management and center reading for the Phase 1 trial of CAN008, and PPC China Corporation Limited, another leading clinical CRO in China, to provide pharmacovigilance, data management, regulatory management, biometric analysis and project management for the ongoing Phase 1 trial of CAN106.

We select CROs based on various factors, such as their professional qualifications, research experience, therapeutic area experience, industry reputation, project specialty, project track record and data management system. In addition, we consider their ability to facilitate site selection, timely recruit patients and conduct complex clinical trials efficiently with high quality. We typically enter into a general service agreement with a CRO for clinical trial management services under which we execute separate work orders for each clinical development project. We closely supervise these CROs to ensure their performance in a manner that complies with our protocols and applicable laws, which in turn protects the integrity and authenticity of the data from our trials and studies.

Below is a summary of the key terms of an agreement that we typically enter into with our CROs:

- Services. The CRO provides us with services such as the implementation and management of a clinical research project as specified in the master agreement or a work order.

- Term. The CRO is required to perform its services within the prescribed time limit set out in each work order and in accordance with the KPIs agreed by both parties.

- Payments. We are required to make payments to the CRO in accordance with the payment schedule agreed by the parties.

- Risk allocation. Each party should indemnify the other party for losses caused by its negligence, recklessness, intentional misconduct or material breach of the master agreement or the work order.

MANUFACTURING

We currently outsource the production of drug candidates to a limited number of highly reputable CDMOs. For example, WuXi Biologics is the CDMOs we have engaged to provide small and large molecule manufacturing services. We have adopted procedures to ensure that the production qualifications, facilities and processes of our CDMOs comply with the relevant regulatory requirements and our internal guidelines. We select our CDMOs by reviewing a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability in meeting delivery schedules, and the financial terms offered by them. We commission these CDMOs to develop and manufacture active pharmaceutical ingredients to support our clinical development. To monitor and evaluate the services performed by our CDMOs, we set a series of predefined specifications on in-process control and release tests, and review manufacturing related documents, including batch records and quality control test results, to ensure specifications are met. In addition, we conduct annual audits and when there is deviation from process protocol, ad hoc special audits, on our CDMOs.

In an effort to scale up our gene therapy development, we are in the process of building our AAV process development lab in Greater Boston area, which is expected to be opened in 2022. In addition, we are also establishing our manufacturing facilities in Suzhou, which is designed to comply with cGMP with several production lines.

SALES AND MARKETING

Our Sales Capabilities

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.

As we successfully received the marketing approval from China's NMPA and commercially launched Hunterase® (CAN101) in China in May 2021, we are currently building a dedicated in-house commercialization team to support its initial launch and expect to expand to a team of over 300 members in the next five years, comprising three major functions including marketing and sales, medical affairs and patient advocacy and assistance, with the mission to execute medical engagement plan for KOL development, promote entire community awareness and explore industry insights for better drug development strategy.

With our late-stage drug candidates entering into the commercialization stage, we have established our key operation hubs in both Beijing and Shanghai, with offices in other locations in Great China, and plan to expand to each of the key target provinces with local offices. See "Our Strategies – Drive commercialization of our late-stage assets in Greater China."

Our Marketing Model and Sales Arrangements

We employ a strategic marketing model to promote and sell our products. Under this model, we promote our products to hospitals and physicians in Greater China through academic marketing, establishing center of excellence and referral network, and providing trainings to physicians.

Sales to Distributors and Direct Sales

In line with industry practice, we sold a significant portion of our products to distributors during the Track Record Period, who then sold the products to hospitals, physicians, pharmacies, medical centers or sub-distributors. We do not rely on the distributors to develop or expand our sales network, but benefit from their established nationwide or regional resources. During the Track Record Period, we sold Caphosol™ (CAN002) in mainland China and Nerlynx® (CAN030) in Greater China. We also started commercialization of Hunterase® (CAN101) in mainland China in May 2021. We engaged one distributor for the sales of Caphosol™ (CAN002) and one distributor for the sales of Nerlynx® (CAN030) respectively in mainland China, each of which is an Independent Third Party. During the Track Record Period, we also sold Caphosol™ (CAN002) in mainland China directly to a healthcare company and sold Nerlynx® (CAN030) directly to hospitals, physicians, pharmacies and medical centers in Hong Kong and Taiwan via a sales and marketing service provider.

Caphosol™ (CAN002) is a mouth rinse for temporary or persistent dryness of the mouth and throat used as an adjunct to standard oral care for the prevention and treatment of oral mucositis caused by radiotherapy or high dose chemotherapy. Nerlynx® (CAN030) is an anti-HER2 treatment as extended adjuvant therapy for early-stage HER2-positive breast cancer. As we strategically shift our business focus to rare disease and rare oncology, we have simplified our sales arrangements for Caphosol™ (CAN002) and Nerlynx® (CAN030).

Our collaboration with the distributor for Caphosol™ (CAN002) expired by the end of 2019. In February 2020, we entered into an agreement with a healthcare company for the direct sales of Caphosol™ (CAN002), with a term of seven years since the first commercial order in mainland China, with an automatic renewal of a further period of three years unless otherwise agreed by the parties. Such healthcare company is an Independent Third Party as of the Latest Practicable Date.

Our collaboration with the distributor for Nerlynx® (CAN030) expired by the end of March 2021. Our commercialization right of Nerlynx® (CAN030) in Greater China was granted by Puma Biotechnology, Inc. (Nasdaq: PBYI) ("Puma") under a collaboration and license agreement in January 2018. In February 2021, we have reached an agreement with Puma to terminate such license agreement and Puma has agreed with Pierre Fabre Médicament SAS ("Pierre Fabre") to grant transfer the exclusive commercialization right of Nerlynx® (CAN030) in Greater China to Pierre Fabre. We have simultaneously 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 until December 31, 2022, with an option to renew. For details, please see "Business – Legal Proceedings and Compliance".

For the commercialization of Hunterase® (CAN101) in mainland China, we entered into a distribution agreement in September 2020 with a distributor who, to the best of our Directors' knowledge, is an Independent Third Party, for the distribution of Hunterase® (CAN101) in mainland China, for a term of two years commencing from the date of the agreement with an automatic renewal of a further period of three years unless otherwise agreed by the parties.

For the sales of Nerlynx® (CAN030) in Hong Kong and Taiwan, we enter into arrangements with a sales and marketing service provider, pursuant to which the title to the products we deliver to such provider remains with us until these products are sold to end consumers. Such provider provides us with services, including among others, product storage, delivery/transportation and invoicing, and pays us the purchase price of the underlying products within 90 days after the products are invoiced and delivered to the end customers, but they have the right to return to us for a full refund any product that is returned by end consumers, any stock of products expire, or the remaining stock upon termination of the agreement.

Revenue under the above arrangements is recognized when a sale is made to the end customer and control is transferred to the end customer upon their acceptance in accordance with the sales report provided by the service provider. Such revenues reflect the consideration paid by end consumers and do not take into account the sales commissions we pay to the service provider, which are recorded as sales and marketing expenses.

Goods Return Policy

We generally do not accept product returns or exchanges except for products with quality defects, or in the situation that the distributor has obtained our written consent for such return or exchange. Our distributors are required to inspect the quality and package of products on delivery.

Pricing

As of the Latest Practicable Date, we had three commercialized products in the market. We sold products to our distributors, directly to a healthcare company in mainland China and directly to hospitals, physicians, pharmacies and medical centers in Hong Kong and Taiwan via a sales and marketing service provider at the price determined by us from time to time. When determining the price of our products sold, we consider factors such as clinical value, product quality, product marketing, competitiveness, patient affordability and competitors' pricing strategy. For details on other factors related to the pricing of our products, see "Indutry Overview – Rare Disease Therapies Reimbursement and Pricing".

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. Please see below a summary of the sales to our five largest customers for the periods indicated:

Five Largest Customers for the year ended December 31, 2019	**Background**	**Covered Region**	**Sales Amount** *RMB'000*	**Percentage of Revenue**
Customer A	Distributor	Mainland China	1,061	72.2%
Customer B	Physician	Hong Kong	408	27.8%
–	–		–	–
–	–		–	–
–	–		–	–
Total:			1,460	100.0%

Five Largest Customers for the year ended December 31, 2020	**Background**	**Covered Region**	**Sales Amount** *RMB'000*	**Percentage of Revenue**
Customer C	Distributor	Mainland China	5,324	44.2%
Customer D	Physician	Hong Kong	2,173	18.1%
Customer E	Hospital	Hong Kong	854	7.1%
Customer F	Hospital	Hong Kong	512	4.3%
Customer B	Physician	Hong Kong	491	4.1%
Total:			9,354	77.7%

Five Largest Customers for the three months ended March 31, 2021	Background	Covered Region	Sales Amount *RMB'000*	Percentage of Revenue
Customer C	Distributor	Mainland China	2,172	33.1%
Customer G	Hospital	Taiwan	1,030	15.7%
Customer H	Healthcare company	Mainland China	843	12.9%
Customer F	Hospital	Hong Kong	321	4.9%
Customer D	Physician	Hong Kong	253	3.9%
Total:			4,619	70.5%

RAW MATERIALS AND SUPPLIERS

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.

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.

Five Largest Suppliers for the year ended December 31, 2019	Purchases	Purchase Amount *(RMB'000)*	Percentage of Total Purchases
Supplier A	License agreement	34,881	42.8%
Supplier B	License agreement	6,209	7.6%
Supplier C	Research and development services	4,403	5.4%
Supplier D	Medical device products	3,153	3.9%
Supplier E	Research and development services	2,742	3.4%
Total		51,388	63.1%

Five Largest Suppliers for the year ended December 31, 2020	Purchases	Purchase Amount *(RMB'000)*	Percentage of Total Purchases
Supplier F	License agreement and finished drug products	131,236	55.6%
Supplier G	Research and development services	34,560	14.6%
Supplier A	License agreement	16,312	6.9%
Supplier B	License agreement	8,622	3.7%
Supplier H	License agreement	6,898	2.9%
Total		197,628	83.7%

Five Largest Suppliers for the three months ended March 31, 2020	Purchases	Purchase Amount *RMB'000*	Percentage of Total Purchases
Supplier H	License agreement	37,595	59.6%
Supplier G	Research and development services	9,205	14.6%
Supplier F	License agreement and finished drug products	2,306	3.7%
Supplier A	License agreement and finished drug products	1,832	2.9%
Supplier I	Research and development services	1,401	2.2%
Total:		52,339	83.1%

Raw Materials

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

INVENTORY

Our inventories consist of finished goods. We currently store all our inventories in warehouses in Beijing, Guangzhou, Taipei, and Hong Kong.

All our products are subject to expiry. Our finished products generally have an effective period of approximately 36 months. We regularly monitor our inventories to reduce the risk of overstocking. We have in place internal policies which require a physical count of all our finished goods once every 12 to identify products that are damaged, expired or soon-to-be expired.

Our Directors confirm that our inventory control policies have been effective and we did not experience any material shortage in supply or overstocking of inventories during the Track Record Period and up to the Latest Practicable Date.

As of December 31, 2019 and 2020, and 31 March 2021, our inventories amounted to RMB1.4 million, RMB0.6 million and 1.8 million, respectively.

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.

We operate in the segments of the pharmaceutical, biotechnology and other related markets that address rare diseases. There are other companies working to develop similar therapies in these fields. These companies include divisions of large pharmaceutical companies and biotechnology companies of various sizes. Many of the companies we are competing against or with which we may compete in the future have significantly 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. Mergers and acquisitions in the pharmaceutical and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies or products complementary to, or necessary for, our research and development.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer or more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain NMPA or other regulatory approval for their drugs earlier than we obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience and price.

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

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. Our insurance policies cover adverse events in our clinical trials, but we do not maintain property loss insurance, product liability insurance or key person insurance. We maintain social welfare insurance for our employees in accordance with relevant PRC laws and regulations.

EMPLOYEES

As of the Latest Practicable Date, we had 151 employees in total. The following table sets forth the number of our employees categorized by function as of the Latest Practicable Date.

Function	Number	% of Total
Commercialization	73	48.3%
Product Development (R&D, clinical, regulatory, IP)	47	31.1%
Quality Control	3	2.0%
General	28	18.6%
Total	151	100%

We plan to further expand our commercialization team to have over 300 full time employees in the next five years. See the sub-section headed "Commercialization" in this section for more details.

Employment Agreements with Key Management and Research Staff

We enter into standard confidentiality and non-compete and employment agreements with our key management and research staff. Our standard confidentiality and non-compete agreement prohibits the employee from competing with us, directly or indirectly, during his or her employment and for up to 24 months after the termination of his or her employment. The standard confidentiality and non-compete agreement also includes undertakings regarding the assignment of inventions and discoveries made during the course of the employee's employment. For further details regarding the terms of the confidentiality and non-compete and employment agreements with our key management, please refer to the section headed "Directors and Senior Management" in this document.

We believe that we maintain a good working relationship with our employees. We have not experienced any material labor disputes or any significant difficulty in recruiting staff for our operations.

Training and Development

We conduct new staff training regularly to guide new employees and help them adapt to the new working environment. In addition, we provide on-line and in-person formal and comprehensive company-level and department-level training to our employees on a quarterly basis in addition to on-the-job training. We also encourage our employees to attend external seminars and workshops to enrich their technical knowledge and develop competencies and skills. We also provide training and development programs to our employees and external training sessions from time to time to improve their technical skills and ensure their awareness and compliance with our various policies and procedures.

Employee Benefits

Our employees' remuneration consists of salaries, bonuses, share-based incentive plans, an employees' provident fund, and social security contributions and other welfare payments. In accordance with applicable laws in China and other relevant jurisdictions, we have made contributions to social security insurance funds (including pension plans, unemployment insurance, work-related injury insurance, medical insurance and maternity insurance) and housing funds for our employees. For more information, please refer to the section headed "Risk Factors – Risks Relating to Extensive Government Regulations – Failure to comply with relevant regulations relating to social insurance and the housing provident fund may subject us to penalties and adversely affect our business, financial condition, results of operations and prospects."

LAND AND PROPERTIES

As of the latest Practicable Date, we had a total of approximately 4,300 sq.m leased office space as our clinical and business development center in Greater China. We also have leased offices in the United States, which are used as our overseas offices in Greater Boston. The relevant lease agreements generally provide a duration of up to five years.

We do not have any property interest with a carrying amount of 15% or more of our consolidated total assets as of March 31, 2021. 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 of the Laws of Hong Kong), this document is exempted from compliance with the requirements of section 38(1) 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 requires a valuation report with respect to all of our Group's interests in land or buildings.

During the Track Record Period, we did not experience any dispute arising out of our leased properties. For details of risks relating to our leased properties, see the section headed "Risk Factors – Risks Relating to Our Operations – We do not own the real property for our current major operation sites and may be subject to risks relating to leased properties." in this document.

INTELLECTUAL PROPERTY

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 table below lists the portfolio of patent applications material to our business operations as of the Latest Practicable Date:

Summary of patents and patent applications of our product candidates

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

Product	Scope of Patent Protection	Patent Applicant/ Holder	Jurisdiction	Status	Patent Expiration*
Hunterase® (CAN101)	Human iduronate-2-sulfatase and preparation method thereof	GC Pharma	China, Hong Kong	Granted	2032
CAN108	Pediatric compositions for cholestatic liver disease, Use of composition for treatment	Shire HGT	China	Granted	2032
		Shire HGT	China, Hong Kong	Pending	N/A
	Genotype and Dose-Dependent Response to an Asbti in Patients with Bile Salt Export Pump Deficiency	Mirum	Worldwide (PCT stage)	Pending	N/A
	Methods for Treating Cholestasis	Mirum	Worldwide (PCT stage)	Pending	N/A
	Methods for Increasing Growth in Pediatric Subjects Having Cholestatic Liver Disease	Mirum	Worldwide (PCT stage)	Pending	N/A
CAN106	Antibody Molecules to Complement Component 5 and Uses Thereof	Atarga	AE, AU, BR, CA, CL, CN, CO, EP, ID, IL, IN, JP, KR, MX, NZ, PE, PH, RU, SA, SG, TW, ZA**	Pending	2039

* Patent expiration does not include any applicable patent term extensions

** Australia, Brazil, Canada, Chile, China, Colombia, Europe, Indonesia, Israel, India, Japan, South Korea, Mexico, New Zealand, Peru, Philippines, Russia, Saudi Arabia, Singapore, South Africa, Taiwan, United Arab Emirates

LEGAL PROCEEDINGS AND COMPLIANCE

We entered into a collaboration and license agreement (the "2018 License Agreement") with Puma Biotechnology, Inc. (Nasdaq: PBYI) ("Puma"), a biopharmaceutical company, in January 2018, in which Puma granted us exclusive rights to develop and commercialize neratinib in Greater China. Neratinib is a drug developed by Puma and approved for marketing in the U.S. for both the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and HER2-positive metastatic breast cancer. Neratinib is marketed in the U.S. as NERLYNX® (neratinib) tablets.

Pierre Fabre Médicament SAS ("Pierre Fabre"), a global pharmaceutical and healthcare products company, entered into a license agreement (the "2019 License Agreement") with Puma in March 2019, pursuant to which Puma granted Pierre Fabre certain rights and licenses to develop and commercialize neratinib in Europe, Turkey, Middle East and Africa.

In July 2020, Puma initiated an arbitration proceeding against us in connection with the 2018 License Agreement (the "Arbitration") before the International Chamber of Commerce. We filed a response in August 2020 and asserted counterclaims against Puma. To settle the Arbitration, we have reached an agreement with Puma in February 2021 to terminate the 2018 License Agreement. Simultaneous to the termination of the 2018 License Agreement, Puma has agreed with Pierre Fabre, to amend the terms of the 2019 License Agreement to extend Pierre Fabre exclusive rights to develop and commercialize neratinib to also include Greater China.

We have also simultaneously entered into a distribution agreement with Pierre Fabre (the "Distribution Agreement") pursuant to which Pierre Fabre appoints us as its distributor with exclusive rights to register, import, market, distribute and sell neratinib for Pierre Fabre with commercially reasonable efforts in Hong Kong, Macau, and Taiwan until December 31, 2022, with an option to renew.

Pursuant to the terms of the various agreements implementing this transaction among the three companies, Puma received an upfront payment of US$50 million from Pierre Fabre in consideration for the amendment to their 2019 License Agreement, and we received a one-time US$20 million termination fee from Puma to return all rights to neratinib in Greater China back to Puma. Finally, both parties have agreed to dismiss the Arbitration with prejudice, and not to pursue any further actions against the other party related to the claims asserted in the Arbitration. We recorded a net transaction gain out of the termination fee from Puma and as we strategically shift our business focus to rare disease and rare oncology, the termination of the 2018 License Agreement, the settlement with Puma and various agreements implementing this transaction are not expected to have any material adverse impact on our future business operations or financial results.

ENVIRONMENTAL MATTERS AND WORKPLACE SAFETY

We strive to operate our facilities in a manner that protects the environment and the health and safety of our employees, patients and communities. Our operations in the future, particularly after the completion and initiation of manufacturing in our manufacturing facility in Suzhou and Greater Boston, will involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. We have drafted and plan to implement in the manufacturing facility environmental, health and safety manuals, policies and standard operating procedures that include management systems and procedures relating to emissions of air, water and other media; waste water generation and treatment; process safety management; handling, use, storage, treatment and disposal of hazardous substances; worker health and safety requirements; third-party safety management; emergency planning and response; and product stewardship.

We have not had any significant workplace accidents in our history.

PERMITS, LICENSES AND OTHER APPROVALS

As of the Latest Practicable Date, we had obtained all requisite licenses, approvals and permits from relevant authorities that are material to our operations. For more details, please see the section headed "Risk Factors – Risks Relating to Extensive Government Regulation – Our and/or others' failure to obtain or renew certain approvals, licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations" in this document.

RISK MANAGEMENT AND INTERNAL CONTROL

Risk Management

We recognize that risk management is critical to the success of our business operations. Key operational risks faced by us include changes in the general market conditions and the regulatory environment of the PRC and global pharmaceutical markets, our ability to develop, manufacture and commercialize our drug candidates, and our ability to compete with other oncology pharmaceutical companies. See "Risk Factors." We also face various market risks. In particular, we are exposed to credit, liquidity, interest rate and currency risks that arise in the normal course of our business. See "Financial Information – Market Risk Disclosure."

We have adopted a comprehensive set of risk management policies, which set out a risk management framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis. Our senior management, and ultimately our Directors, supervise the implementation of our risk management policies. Risks identified by management will be analyzed on the basis of likelihood and impact, and will be properly followed up and mitigated and rectified by our Group and reported to our Directors.

The following key principles outline our Group's approach to risk management and internal control:

- Our Audit Committee oversees and manages the overall risks associated with our business operations, including (i) reviewing and approving our risk management policy to ensure that it is consistent with our corporate objectives; (ii) monitoring the most significant risks associated with our business operations and our management's handling of such risks; and (iii) ensuring the appropriate application of our risk management framework across our Group.

- The relevant departments, including but not limited to the business operations, finance and general administration departments, are responsible for developing and implementing our risk management policy and carrying out our day-to-day risk management practice, such as assessing risks on key business operations, advising risk responses and optimizing risk management policies. In order to formalize risk management across our Group and set a common level of transparency and risk management performance, the relevant departments will (i) gather information about

the risks relating to their operation or function; (ii) conduct risk assessments, which include the identification, evaluation, prioritization, and categorization of all key risks that could potentially affect their objectives; (iii) continuously monitor the key risks relating to their operations or functions; (iv) implement appropriate risk responses where necessary; and (v) develop and maintain an appropriate mechanism to facilitate the application of our risk management framework.

Internal Control

Our Board of Directors is responsible for establishing and maintaining appropriate and effective internal control system to safeguard our Shareholders' investment at all times. Our internal control policies set out a framework to identify, assess, evaluate and monitor key risks associated with our strategic objectives on an ongoing basis.

Below is a summary of the internal control policies, measures and procedures we have implemented or plan to implement:

- We have adopted various measures and procedures regarding our business operations, and we provide training about these measures and procedures to new employees. We also constantly monitor the implementation of these measures and procedures.

- We maintain strict anti-corruption policies on personnel with external communication functions. We will also ensure that our commercialization team complies with applicable promotion and advertising requirements, which include restrictions on promoting drugs for unapproved uses or patient populations and limitations on industry-sponsored scientific and educational activities.

- Our Directors (who are responsible for monitoring the corporate governance of our Group), with help from our Compliance Adviser, will also periodically review our compliance status with all relevant laws and regulations after the [**REDACTED**].

- We plan to establish an audit committee, which will (i) make recommendations to our Directors on the appointment and removal of external auditors; and (ii) review the financial statements and render advice in respect of financial reporting, as well as (iii) oversee the financial reporting system and internal control and risk management systems of our Group.

During the Track Record Period, we have regularly reviewed and enhanced our risk management and internal control systems. We believe that our Directors and members of our senior management possess the necessary knowledge and experience in providing good corporate governance oversight in connection with risk management and internal control.

QUALITY CONTROL

We have a quality management department that devotes resources to quality management of our products. We have our own quality control system and devote significant attention to quality control for the designing, R&D manufacturing, testing and transportation of our products and product candidates. Our management team is actively involved in setting quality policies and managing our internal and external quality performance. We have established a strict quality control system in accordance with ICH Q10 and NMPA regulations.

As of the Latest Practicable Date, our quality management department consists of three employees. The department is divided into a quality control team and a quality assurance team. Our quality control team is responsible for inspecting raw materials, production process and the quality of finished goods. Our quality assurance team focuses on the establishment, implementation and maintenance of our quality management system, as well as monitoring our operation in real time throughout the entire development and production process to ensure its compliance with the applicable regulatory and industry requirements.

AWARDS AND RECOGNITIONS

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

Award/Grant	Awardee	Award/ Completion Date	Award Authority
Key Overseas Chinese Entrepreneurial Team (重點華僑華人創業團隊)	CANbridge Life Sciences Limited	2015	State Council for Overseas Chinese Affairs Office
2018 Future Medicine 100 Forum	CANbridge Life Sciences Limited	2018	VCBeat Network and VCBeat Research Institute
China Future Healthcare Rankings 2019 – Top 100 Pharma & Biotech Companies	CANbridge Pharmaceuticals, Inc	2019	VCBeat Network and VCBeat Research Institute
HSBC Pioneer Corporation Member	CANbridge Life Sciences Limited	2019	Hongkong and Shanghai Banking Corporation Limited

Award/Grant	Awardee	Award/ Completion Date	Award Authority
Cancer Frontier Diagnosis and Treatment-Beijing International Science and Technology Cooperation Base (腫瘤前沿診治–北京市國際科技合作基地)	CANbridge Life Sciences Limited	2019-2020	Beijing Municipal Science and Technology Commission
Zhongguancun Science Part High and New Technology Enterprise (中關村高新技術企業)	CANbridge Life Sciences Limited	2019	Administrative Committee of Zhongguancun Science Part
Director member of China Pharmaceutical Innovation and Research Development Association	CANbridge Pharmaceuticals, Inc	2019	China Pharmaceutical Innovation and Research Development Association
Member of China Alliance for Rare Disease	CANbridge Life Sciences Limited	2018	China Alliance for Rare Disease
Top 30 Most Growing Companies in China's New Economy of Chinese Venture	CANbridge Life Sciences Limited	2021	Chinese Venture Magazine