



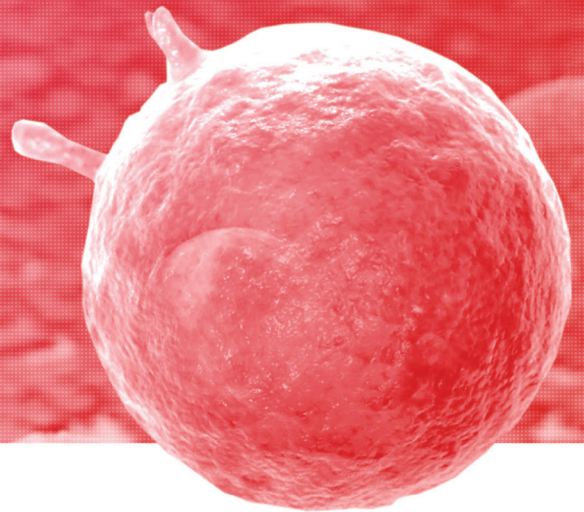
BeiGene

BeiGene, Ltd.
百濟神州有限公司

(incorporated in the Cayman Islands with limited liability)

Stock Code : NASDAQ : BGNE HKEX : 06160

**CANCER HAS
NO BORDERS
NEITHER
DO WE**



**2020
ANNUAL
REPORT**

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CORPORATE INFORMATION

BOARD OF DIRECTORS

Executive Director

Mr. John V. Oylar
(Chairman and Chief Executive Officer)

Non-Executive Directors

Mr. Anthony C. Hooper
Dr. Xiaodong Wang

Independent Non-Executive Directors

Mr. Timothy Chen
Mr. Donald W. Glazer
Mr. Michael Goller
Mr. Ranjeev Krishana
Mr. Thomas Malley
Dr. Corazon (Corsee) D. Sanders
Mr. Jing-Shyh (Sam) Su
Mr. Qingqing Yi

AUDIT COMMITTEE

Mr. Thomas Malley *(Chairman)*
Mr. Anthony C. Hooper
Dr. Corazon (Corsee) D. Sanders

COMPENSATION COMMITTEE

Mr. Qingqing Yi *(Chairman)*
Mr. Timothy Chen
Mr. Ranjeev Krishana

NOMINATING AND CORPORATE GOVERNANCE COMMITTEE

Mr. Donald W. Glazer *(Chairman)*
Mr. Michael Goller
Mr. Anthony C. Hooper^{*(Note 1)*}
Mr. Jing-Shyh (Sam) Su^{*(Note 1)*}

SCIENTIFIC ADVISORY COMMITTEE

Dr. Xiaodong Wang *(Co-Chair)*
Dr. Corazon (Corsee) D. Sanders *(Co-Chair)*^{*(Note 1)*}
Mr. Michael Goller
Mr. Thomas Malley
Mr. Qingqing Yi

COMMERCIAL AND MEDICAL AFFAIRS ADVISORY COMMITTEE^{*(Note 2)*}

Mr. Anthony C. Hooper *(Chairman)*
Mr. Timothy Chen
Mr. Ranjeev Krishana
Dr. Corazon (Corsee) D. Sanders^{*(Note 1)*}
Mr. Jing-Shyh (Sam) Su

COMPANY SECRETARY

Ms. Chau Hing Ling (FCG, FCS) of
Vistra Corporate Services (HK) Limited

AUTHORIZED REPRESENTATIVES

Mr. Scott A. Samuels
Dr. Howard Liang

Note:

1. The relevant appointment with effect from February 24, 2021.
2. The Commercial Advisory Committee of the Board has been renamed the Commercial and Medical Affairs Advisory Committee with the effect from February 24, 2021.

CORPORATE INFORMATION

AUDITORS

As to Hong Kong financial reporting audit
Ernst & Young, Registered Public Interest Entity Auditor

As to United States financial reporting audit
Ernst & Young Hua Ming LLP

REGISTERED OFFICE

The offices of Mourant Governance Services
(Cayman) Limited
94 Solaris Avenue
Camana Bay
Grand Cayman KY1-1108
Cayman Islands

HEAD OFFICE AND PRINCIPAL PLACE OF BUSINESS IN CHINA

No. 30 Science Park Road
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Beijing
PRC

PRINCIPAL PLACE OF BUSINESS IN HONG KONG

Room 1901, 19/F, Lee Garden One
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Causeway Bay
Hong Kong

LEGAL ADVISORS

As to Hong Kong law and United States law
Skadden, Arps, Slate, Meagher & Flom

As to PRC law
Fangda Partners

As to Cayman Islands law
Mourant Ozannes

HONG KONG SHARE REGISTRAR

Computershare Hong Kong Investor Services Limited
Shops 1712-1716, 17th Floor
Hopewell Centre
183 Queen's Road East
Wanchai, Hong Kong

PRINCIPAL SHARE REGISTRAR AND TRANSFER OFFICE

Mourant Governance Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman KY1-1108
Cayman Islands

STOCK CODE

06160

COMPANY WEBSITE

www.beigene.com

FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this annual report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected growth, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

Forward looking statements are often identified by the use of words such as, but not limited to, “aim,” “anticipate,” “believe,” “can,” “continue,” “could,” “estimate,” “expect,” “goal,” “intend,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would” or the negative of these terms or similar expressions or variations intended to identify forward-looking statements, although not all forward-looking statements contain those identifying words. These forward-looking statements include, among other things, statements about:

- our ability to successfully commercialize our approved medicines and to obtain approvals in additional indications and territories for our medicines;
- our ability to successfully develop and commercialize our in-licensed medicines and drug candidates and any other medicines and drug candidates we may in-license;
- our ability to further develop sales and marketing capabilities and launch and commercialize new medicines, if approved;
- our ability to maintain and expand regulatory approvals for our medicines and drug candidates, if approved;
- the pricing and reimbursement of our medicines and drug candidates, if approved;
- the initiation, timing, progress and results of our preclinical studies and clinical trials and our research and development programs;
- our ability to advance our drug candidates into, and successfully complete, clinical trials and obtain regulatory approvals;
- our reliance on the success of our clinical stage drug candidates;
- our plans, expected milestones and the timing or likelihood of regulatory filings and approvals;
- our expectations about the successful restoration of supply of ABRAXANE® (paclitaxel albumin-bound particles for injectable suspension) in China;
- the implementation of our business model, strategic plans for our business, medicines, drug candidates and technology;

FORWARD-LOOKING STATEMENTS

- the scope of protection we (or our licensors) are able to establish and maintain for intellectual property rights covering our medicines, drug candidates and technology;
- our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights and proprietary technology of third parties;
- costs associated with enforcing or defending against intellectual property infringement, misappropriation or violation, product liability and other claims;
- regulatory developments in the United States, China, the United Kingdom, Switzerland, the European Union (“EU”) and other jurisdictions;
- the accuracy of our estimates regarding expenses, revenues, capital requirements and our need for additional financing;
- the potential benefits of strategic collaboration and licensing agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations or licensing agreements;
- our reliance on third parties to conduct drug development, manufacturing and other services;
- our ability to manufacture and supply, or have manufactured and supplied, drug candidates for clinical development and medicines for commercial sale;
- the rate and degree of market access and acceptance and the pricing and reimbursement of our medicines and drug candidates, if approved;
- developments relating to our competitors and our industry, including competing therapies;
- the size of the potential markets for our medicines and drug candidates and our ability to serve those markets;
- our ability to effectively manage our growth;
- our ability to attract and retain qualified employees and key personnel;
- statements regarding future revenue, hiring plans, key milestones, expenses, capital expenditures, capital requirements and share performance;
- the future trading price of our American Depositary Shares (“ADS”) and ordinary shares and impact of securities analysts’ reports on these prices;

FORWARD-LOOKING STATEMENTS

- the impact of the COVID-19 pandemic on our clinical development, regulatory, commercial and other operations; and
- other risks and uncertainties, including those listed under the section headed “Risk Factors” in this annual report.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this annual report, particularly in “Risk Factors,” that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

Since actual results or outcomes could differ materially from those expressed in any forward-looking statements, we strongly caution investors against placing undue reliance on any such forward-looking statements. Any forward-looking statement speaks only as of the date on which such statement is made, and, except as required by the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “HK Listing Rules”), we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. Statements of or references to our intentions or those of any of our Directors are made as of the date of this annual report. Any such intentions may change in light of future developments.

This annual report includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, you are cautioned not to give undue weight to this information. All forward-looking statements in this annual report are expressly qualified by reference to this cautionary statement.

Unless the context requires otherwise, in this annual report, the terms “BeiGene,” the “Company,” “we,” “us” and “our” refer to BeiGene, Ltd. and its subsidiaries, on a consolidated basis.

OVERVIEW

We are a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and expand access for patients worldwide.

Our research organization has delivered ten molecules into the clinic in our first ten years, including our two lead commercial medicines, BRUKINSA[®], a small molecule inhibitor of Bruton’s Tyrosine Kinase (“BTK”) for the treatment of various blood cancers, and tislelizumab, an anti-PD-1 antibody immunotherapy for the treatment of various solid tumor and blood cancers. We are marketing BRUKINSA[®] in the world’s two largest pharmaceutical markets, the United States and China, and tislelizumab in China, with an established, science-based commercial organization. We have built state-of-the-art biologic and small molecule manufacturing facilities in China to support the potential future demand of our products, and we also work with high quality contract manufacturing organizations (“CMOs”) to manufacture our internally developed clinical and commercial products.

We are a leader in China-inclusive global clinical development, which we believe can facilitate faster and more cost-effective development of innovative medicines. Our internal clinical development capabilities are deep, including a more than 1,600-person global clinical development team that is running more than 60 ongoing or planned clinical trials. This includes more than 25 pivotal or registration-enabling trials for three product candidates that have enrolled more than 12,000 patients and healthy volunteers, of which approximately one-half have been outside of China, as of January 2021. We have over 45 products and product candidates in commercial stage or clinical development, including 7 approved medicines, 5 pending approval, and over 30 in clinical development.

Supported by our development and commercial capabilities, we have entered into collaborations with world-leading biopharmaceutical companies such as Amgen Inc. (“Amgen”) and Novartis Pharma AG (“Novartis”) to develop, manufacture and commercialize innovative medicines globally. Since our inception in 2010 in Beijing, we have become a fully integrated global organization of over 5,300 employees in 14 countries and regions, including China, the United States, Europe and Australia.

BUSINESS

OUR STRATEGY

Our mission is to provide access to high-quality, innovative, impactful, and affordable medicines to billions more people globally. We believe that we have built competitive advantages in research, clinical development, manufacturing and commercialization that will drive our business into the future. We intend to continue to develop and expand our competitive advantages and become a global leader by focusing on the following key strategic imperatives:

1. **Research And Innovation Focus.** We have built one of the largest research teams in China with more than 450 people and a robust suite of capabilities that fuel our innovation pipeline. To date, our research organization has advanced more than 10 internally discovered molecules into the clinic and, of those programs, two medicines have been approved for commercial use in multiple indications. Our team has discovered promising new drug candidates, including our investigational TIGIT antibody and Bcl-2 inhibitor currently in development. We plan to continue to invest in research and innovation with the aim of discovering additional innovative product candidates for patients.
2. **World Class Clinical Development.** We believe that leveraging our leadership position in China-inclusive clinical development will enable us to develop products with advantages in speed and cost efficiency, while maintaining quality. We plan to continue to invest to in-source our clinical capabilities to mitigate the challenges associated with relying on third-party contract research organizations (“CROs”), with the intention of becoming one of the best clinical development organizations in the world.








3. **China Commercial Leadership.** We have built a large commercial team in China, with over 2,200 colleagues spread across the country and organized under experienced executive leadership. We believe that we have established BeiGene as a high-quality, science-driven, leading provider of innovative and affordable medicines in China. We aspire to grow our commercial portfolio through both internal discovery efforts and through in-licensing additional products and product candidates, striving to be a partner of choice and creating mutual benefits with our partners wherever possible. We believe that our commercial capabilities in China, coupled with our China-inclusive clinical development capabilities conducted at global-quality standards, enable us to attract favorable in-licensing opportunities. We plan to further invest in our China commercial organization and create advantages in scale, speed, and quality to establish our commercial leadership in China.
4. **Global Leadership, Access, and Reputation.** We have launched BRUKINSA® in the United States and built a targeted commercial team focused on medical thought leaders in blood cancer treatments. This competitive foothold is based on the clinical differentiation of our approved products and product candidates and our deep relationships. We aspire to establish our reputation globally as a leading biotechnology company by delivering highly effective and differentiated medicines in the United States, China, Europe and new markets.
5. **Broad Accessibility.** We believe that our commercial scale in China, potentially lower upfront development costs through China-inclusive clinical development, sizeable portfolio of innovative therapies, and overall commercial expertise in serving large, underserved populations give us a unique advantage and create an opportunity for us to be an early mover in providing innovative medicines at affordable prices to many geographies that are not traditionally the focus for pharmaceutical or biotechnology companies. We plan to focus our long-term strategy on seeking approvals of our portfolio compounds globally and building clinical development and commercial capabilities in these markets, either alone or through our collaborators.

BUSINESS

OUR COMMERCIAL AND REGISTRATION STAGE PRODUCTS

The following table summarizes the status of our commercial products and new products that are pending approval as of February 25, 2021:

PRODUCT	LEAD INDICATIONS	MECHANISM OF ACTION	REGULATORY STATUS	BEIGENE COMMERCIAL RIGHTS	PARTNER
 Brukinsa™ <small>zanubrutinib</small>	R/R MCL (U.S.) ¹ /R/R MCL ² and R/R CLL/SLL ² (China)	BTK inhibitor	Approved in the U.S. and China	Global	N/A
tislelizumab ⁴	1L Squamous NSCLC/ R/R classical Hodgkin's lymphoma ² /R/R PD-L1+ urothelial carcinoma ²	Anti-PD-1 antibody	Approved in China	Outside North America, Japan, EU and six other European countries ⁴	 NOVARTIS
pamiparib	2L+ BRCA-mutated ovarian cancer	PARP inhibitor	NDA accepted in China	Global	N/A
 XGEVA <small>(denosumab) injection</small>	Giant cell tumor of bone ² / Skeletal Related Events (SREs) ²	Anti-RANK ligand antibody	Approved in China	Mainland China	 AMGEN
 BLINCYTO <small>(blinatumomab) injection</small>	Acute lymphocytic leukemia	Anti-CD19 x anti-CD3 bispecific T-cell engager (BiTE)	Approved in China	Mainland China	 AMGEN
 Kyprolis <small>(carfilzomib) injection</small>	Multiple myeloma	Proteasome inhibitor	NDA accepted in China	Mainland China	 AMGEN
 Abraxane <small>nanoparticle albumin bound paclitaxel</small>	Breast cancer	Microtubule inhibitor	Approved in China ³	Mainland China	 Bristol Myers Squibb
 Revlimid <small>(lenalidomide) capsules</small>	R/R adult multiple myeloma, newly diagnosed multiple myeloma, previously treated follicular lymphoma	Anti-angiogenesis, immuno-modulation	Approved in China	Mainland China	 Bristol Myers Squibb

PRODUCT	LEAD INDICATIONS	MECHANISM OF ACTION	REGULATORY STATUS	BEIGENE COMMERCIAL RIGHTS	PARTNER
	Myelodysplastic syndromes, acute myeloid leukemia, chronic myelomonocytic leukemia	DNA hypomethylation	Approved in China	Mainland China	
	Idiopathic multicentric Castleman disease	IL-6 antagonist	BLA accepted in China	Greater China	
	High-risk neuroblastoma	Anti-GD2 antibody	BLA accepted in China	Mainland China	
BAT1706 (Avastin biosimilar)	Colorectal, lung, liver cancers	Anti-VEGF antibody	BLA accepted in China	Greater China	

1. Approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. 2. Conditionally approved. Full approval for these indications is contingent upon results from ongoing randomized, controlled confirmatory clinical trials. 3. As announced previously, the NMPA suspended the importation, sales and use of ABRAXANE® (nanoparticle albumin-bound paclitaxel) in China supplied to BeiGene by Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company. 4. Tislelizumab collaboration with Novartis announced January 2021. The transaction was closed on February 26, 2021. Abbreviations: CLL = chronic lymphocytic leukemia; MCL = mantle cell lymphoma; NSCLC = non-small cell lung cancer; R/R = relapsed/refractory; RT = radiotherapy; SLL = small lymphocytic lymphoma.

We commercialize the following internally developed cancer medicines:

BRUKINSA

BRUKINSA® is a second-generation small molecule BTK inhibitor designed to maximize BTK occupancy and minimize off-target binding effects. We are marketing BRUKINSA® in the U.S. and China. BRUKINSA® received accelerated approval in the United States as a treatment for mantle cell lymphoma (“MCL”) in adult patients who have received at least one prior therapy (November 2019), as well as conditional approval in China for adult patients with MCL who have received at least one prior therapy and adult patients with chronic lymphocytic leukemia (“CLL”) or small lymphocytic lymphoma (“SLL”) who have received at least one prior therapy (June 2020).

In China, we have filed a supplemental new drug application (“sNDA”) for BRUKINSA® for the treatment of patients with relapsed/refractory (“R/R”) Waldenström’s macroglobulinemia (“WM”), and that application is pending under priority review. We have also filed additional applications for approval in the EU, Australia and Canada, for R/R WM and Australia, Canada and Israel for R/R mantle cell lymphoma (“MCL”). In December 2020, we announced inclusion of BRUKINSA® in the updated National Reimbursement Drug List (“NRDL”) by the China National Healthcare Security Administration (“NHS”) for BRUKINSA®’s approved indications.

BUSINESS

Market Opportunity and Competition

Lymphomas are blood-borne cancers involving lymphatic cells of the immune system. They can be broadly categorized into non-Hodgkin's lymphoma ("NHL") and Hodgkin's lymphoma ("HL"). Depending on the origin of the cancer cells, lymphomas can also be characterized as B-cell or T-cell lymphomas. B-cell lymphomas make up approximately 85% of NHLs and comprise a variety of specific diseases involving B-cells at differing stages of maturation or differentiation. According to statistics from the Surveillance, Epidemiology and End Results (SEER) program of the U.S. National Cancer Institute, there were 77,240 new NHL cases and 19,940 deaths in 2020 in the United States, and of these NHL cases the incidence of CLL was 21,040 cases and there were 4,060 deaths from CLL. Similar SEER analyses calculated U.S. incidence rates of 3,000 for MCL and 1,350 for WM. According to the China National Central Cancer Registry ("NCCR"), International Agency for Research on Cancer ("IARC"), and Frost and Sullivan ("F&S") research, in China, the number of new cases of NHL reached 90,000 in 2019. The compound annual growth rate from 2015 to 2019 was 2.6%, and the number of new cases of NHL is expected to reach 102,000 and 116,000 in 2024 and 2030, respectively. In China, diffuse large B-cell lymphoma ("DLBCL") is the most common NHL subtype, accounting for 41.0%, while follicular lymphoma and MCL are the other two largest subtypes of lymphoma, accounting for 6.1% and 3.4%, respectively.

Conventional methods of treating lymphomas vary according to the specific disease or histology, but generally include chemotherapy, antibodies directed at CD20, a molecular marker found on the surface of B-cells, and, less frequently, radiation. Recently, significant progress has been made in the development of new therapies for lymphomas, including BTK inhibitors, the phosphoinositide 3-kinase ("PI3K") inhibitors, idelalisib, copanlisib and duvelisib, and the Bcl-2 inhibitor, venetoclax.

The BTK inhibitor IMBRUVICA® (ibrutinib) was first approved by the U.S. Food and Drug Administration ("FDA") in 2013 for the treatment of patients with MCL who have received at least one prior therapy. Since that time, ibrutinib has received supplemental FDA approvals for the treatment of patients with CLL/SLL, CLL/SLL patients with 17p deletion, patients with WM, patients with marginal zone lymphoma ("MZL") who have received at least one prior anti-CD20-based therapy, patients with chronic graft versus host disease after failure of one or more lines of systemic therapy, in combination with rituximab in WM, and in combination with obinutuzumab in CLL/SLL. Ibrutinib is also approved by the European Medicines Agency ("EMA") for the treatment of patients with MCL, CLL and WM. Ibrutinib has been approved in over 90 countries and regions, and it was approved and launched in China at the end of 2017 for the treatment of patients with R/R CLL/SLL and R/R MCL. Subsequently, in July 2018, ibrutinib was also approved for first-line CLL/SLL. Another BTK inhibitor, CALQUENCE® (acalabrutinib), was approved by the FDA in 2017 under accelerated approval for the treatment of patients with MCL who have received at least one prior therapy, and in November 2019 for use in adults with CLL/SLL as a single agent or in combination with obinutuzumab. In 2020, global revenues for BTK inhibitors were approximately US\$7.1 billion according to published reports.

Tislelizumab

Tislelizumab is a humanized IgG4 monoclonal antibody against the immune checkpoint receptor programmed cell death protein 1 (“PD-1”) that we specifically designed to minimize binding to Fc receptor gamma (“FcγR”), which is believed to play an essential role in activating phagocytosis in macrophages, to minimize its negative impact on T effector cells. We are evaluating tislelizumab in a broad pivotal clinical program for both solid tumor and hematological indications, both globally and in China. Tislelizumab is approved in China for the treatment of patients with classical Hodgkin’s Lymphoma (“cHL”) who have received at least two prior therapies (December 2019); the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (April 2020); and the first-line treatment of patients with advanced squamous non-small cell lung cancer (“NSCLC”) in combination with chemotherapy (January 2021). In addition, we have filed sNDAs in China for tislelizumab for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy and for previously treated patients with unresectable hepatocellular carcinoma (“HCC”). In December 2020, we announced the inclusion of tislelizumab in the updated NRDL by the China NHSA in tislelizumab’s approved cHL and UC indications.

In January 2021, we announced a collaboration and license agreement with Novartis to develop, manufacture and commercialize tislelizumab in the United States, Canada, Mexico, the EU, UK, Norway, Switzerland, Iceland, Liechtenstein, Russia and Japan (the “Novartis Territory”). The transaction was closed on February 26, 2021. We received an upfront payment of US\$650 million and are eligible to receive up to US\$1.3 billion in regulatory milestones, US\$250 million in potential sales milestones and royalties on future sales of tislelizumab in the Novartis Territory. We retained worldwide rights to commercialize our proprietary products in combination with tislelizumab.

BUSINESS

Market Opportunity and Competition

A number of PD-1 or PD-L1 antibody medicines have been approved by the FDA. These include Merck's KEYTRUDA® (pembrolizumab), BMS's OPDIVO® (nivolumab), Roche's TECENTRIQ® (atezolizumab), AstraZeneca's IMFINZI® (durvalumab), Pfizer and Merck Sereno's BAVENCIO® (avelumab), and Regeneron and Sanofi's LIBTAYO® (cemiplimab). In the global setting, several PD-1 or PD-L1 antibody agents are in late-stage clinical development in addition to tislelizumab, such as GlaxoSmithKline's dostarlimab and Pfizer's sasanlimab. In China, as of February 1, 2021, there are five other approved PD-1 antibodies, OPDIVO® (nivolumab) and KEYTRUDA® (pembrolizumab), as well as Junshi's TUOYI® (toripalimab), Innovent's TYVYT® (sintilimab), and Hengrui's AIRUIKA® (camrelizumab), and there are two approved PD-L1 antibody agents AstraZeneca's IMFINZI® (durvalumab) and Roche's TECENTRIQ® (atezolizumab). There are approximately 40 more PD-1 and PD-L1 agents in clinical development in China.

Globally, the top four PD-1/PD-L1 antibody medicines had sales of approximately US\$26.5 billion in 2020 based on public reports. We believe that there is a large commercial opportunity in China for PD-1 and PD-L1 antibody medicines. Currently available clinical data suggest that some of the most prevalent cancers in China, such as lung, gastric, liver and esophageal cancer, are responsive to this class of agents. According to the World Health Organization's GLOBOCAN online database, in 2018 China suffered 39%, 50%, 47%, and 56% of all deaths from lung, gastric, liver, and esophageal cancers, respectively, in the world. Collectively, these four tumor types comprised over 2.3 million new cases in 2016 in China alone, according to Chen et al. 2016. In addition, China has a higher proportion of PD-1 responsive tumors in its total annual cancer incidence in comparison to other geographies like the United States or Europe. According to Chen et al. 2016, the annual incidence of the top ten PD-1 responsive tumors in China is estimated to be 3.0 million out of 4.3 million in total annual cancer incidence. In comparison, the estimated annual incidence of the top ten PD-1 responsive tumors is 0.9 million out of 1.7 million in total annual cancer incidence in the United States, and 0.9 million out of the 1.8 million total in the EU5 countries (United Kingdom, France, Germany, Spain and Italy) according to the SEER program of the U.S. National Cancer Institute and the World Health Organization.

Pamiparib

Pamiparib is an investigational, selective small molecule inhibitor of poly ADP-ribose polymerase 1 ("PARP1") and PARP2 enzymes. Pamiparib has demonstrated pharmacological properties such as brain penetration and PARP-DNA complex trapping in preclinical models. We are evaluating pamiparib as a potential monotherapy and in combinations for the treatment of various solid tumors. A new drug application ("NDA") for pamiparib for patients with ovarian cancer ("OC") has been accepted and granted priority review in China by the Center for Drug Evaluation ("CDE") of the China National Medical Products Administration ("NMPA"), and is currently pending approval.

Market Opportunity and Competition

Many tumor types have been shown to be responsive to PARP inhibitors, including OC, breast cancer, prostate cancer, and gastric cancer (“GC”). PARP inhibitors have demonstrated encouraging activity both in R/R patients as well as in the maintenance setting. In the United States, in 2020 there were approximately 21,750 new cases of OC, 276,480 new cases of breast cancer, and 27,600 new cases of GC, according to the U.S. National Cancer Institute’s SEER online database. In China, there were approximately 52,000 new cases of OC, 326,000 new cases of breast cancer, and 456,000 new cases of GC in 2019, according to NCCR, IARC and F&S research.

A number of PARP inhibitors have been approved by the FDA. These include AstraZeneca’s LYNPARZA® (olaparib), Clovis Oncology’s RUBRACA® (rucaparib), GlaxoSmithKline’s ZEJULA® (niraparib), and Pfizer’s TALZENNA® (talazoparib). AbbVie’s veliparib is in late-stage development. In 2020, global sales of the PARP class were approximately US\$2.4 billion according to company reports. In China, AstraZeneca received approval for olaparib in August 2018. Zai Labs obtained development and commercial rights for niraparib in China, and its NDA was approved by the NMPA in December 2019. Fluzoparib from Hengrui/Hansoh was approved in December 2020.

We are currently commercializing, or plan to commercialize, the following cancer medicines in China under an exclusive license from Amgen:

XGEVA

XGEVA® (denosumab) is an antibody-based RANK ligand inhibitor that was approved globally for the prevention of skeletal-related events (“SREs”) in patients with bone metastases from solid tumors and in patients with multiple myeloma (“MM”), and for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone (“GCTB”). XGEVA® is approved in over 70 countries worldwide. In China, XGEVA® received conditional approval in the GCTB indication in May 2019 and received conditional approval for the SRE indications in November 2020. We began marketing XGEVA® in China in July 2020. In December 2020, we announced the inclusion of XGEVA® in the NRDL for the treatment of GCTB.

GCTB is a relatively rare, benign, but locally aggressive osteolytic skeletal neoplasm of young adults. The patients experience pain, swelling, and limitation of joint movement at the primary site. In China, there were 2,086 new cases of GCTB in 2019, according to the China NCCR, IARC, and F&S research. To date, XGEVA® is the only approved therapy for the treatment of GCTB. For patients with aggressive forms of GCTB, who are not candidates for locoregional therapy, e.g., therapy or radiotherapy, XGEVA® is the preferred treatment option over bisphosphonate, chemotherapy, or interferon.

Metastases to bone are a common site of cancer recurrence for many solid tumors. Bone metastases cause pain, compromised quality of life, and SREs, which include pathologic fracture, the need for radiation or surgery to bone, hypercalcemia of malignancy, and spinal cord compression. Both XGEVA® and bisphosphonates reduce the morbidity of metastatic bone disease, mainly by decreasing SREs. Similar to bone metastases in patients with solid tumors, MM has a major feature of osteolytic bone disease that can lead to severe disability and morbidity, including SREs. XGEVA® is also indicated for the prevention of SREs in patients with MM.

BUSINESS

In China, there are a number of biosimilars for denosumab in clinical development, including from Shandong Boan Biotechnology Co., Qilu Pharmaceutical Co., and Shanghai Henlius Biotech Co.

BLINCYTO

BLINCYTO® (blinatumomab), a bispecific CD-19 directed CD3 T-cell engager, is the first and only approved bi-specific T-cell engager (“BiTE”) immunotherapy. It has been approved in 60 countries for use in patients with acute lymphoblastic leukemia (“ALL”). In China, BLINCYTO® received conditional approval as a treatment for adult patients with R/R ALL in December 2020. We expect to begin commercializing BLINCYTO® in the first half of 2021.

ALL is the most common childhood malignancy and accounts for approximately one-quarter of all childhood malignancies. It is estimated that there are 0.69 cases of ALL in 100,000 people in China, according to the China NCCR, IARC, and F&S research. Approximately 15 percent of children fail initial treatment and advance to R/R stage, and BLINCYTO is indicated for the treatment of patients with R/R B-cell precursor ALL. There are CAR-T therapies being developed for this indication, and tisagenlecleucel from Novartis has been approved by the FDA for treatment of patients including and under 25 years of age with B-cell precursor ALL that is refractory or in second or later relapse. Clofarabine from Sanofi is also approved in this indication by the FDA. Neither of these two agents have been approved in China.

KYPROLIS

KYPROLIS® (carfilzomib), a proteasome inhibitor, has been approved in over 60 countries for use in patients with R/R MM. It has been filed in China as a treatment for patients with MM, and the NDA has been accepted by the NMPA and is pending approval. In the class of proteasome inhibitors, VELCADE® has been marketed by Johnson & Johnson in China since 2006 and NINLARO® (ixazomib) has been marketed by Takeda in China since 2018. There are a number of generic forms of carfilzomib being developed in China by local manufacturers, including Jiangsu Hansoh Pharmaceutical Group Co., Ltd., Chia Tai Tianqing Pharmaceutical Group Co., Ltd., and Yangtze River Pharmaceutical Group Co., Ltd.

We commercialize the following cancer medicines in China under an exclusive license from BMS:

ABRAXANE

ABRAXANE® (paclitaxel albumin-bound particles for injectable suspension) is a solvent-free chemotherapy product which was developed using a proprietary nanoparticle albumin-bound (nab®) technology platform. This protein-bound chemotherapy agent combines paclitaxel with albumin. Globally, ABRAXANE® is approved for uses in breast cancer, NSCLC, pancreatic cancer, and GC, with geographic differences in labeling. In China, ABRAXANE® is approved for use in metastatic breast cancer after failure of combination chemotherapy for metastatic disease or relapse within six months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated. It is also approved for use in metastatic adenocarcinoma of the pancreas in combination with gemcitabine.

There were approximately 326,000 new cases of breast cancer and 108,000 new cases of pancreatic cancer in China in 2019, according to the China NCCR, IARC, and F&S research. Targeted therapy, hormone therapy and chemotherapy are three main strategies to treat different types of breast cancer. The taxanes marketed in China include two branded solvent-based formulations of paclitaxel (TAXOL® and ANZATAX®), one branded formulation of docetaxel (TAXOTERE®), one paclitaxel liposome (LIPUSU®), one albumin-bound paclitaxel (ABRAXANE®), and a number of generic forms of solvent-based taxanes and ABRAXANE®, including albumin-bound paclitaxel products from CSPC Pharmaceutical Group Limited, Jiangsu Hengrui Medicine Co., Ltd., Qilu Pharmaceutical Co., Ltd., and Sichuan Kelun Pharmaceutical Co., Ltd.

On March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. We did not have any sales of ABRAXANE® in 2020 following the suspension and do not expect revenue from ABRAXANE® until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE® and qualified medicine is manufactured and available for sale in China. We are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. We do not know when the NMPA suspension of ABRAXANE® will be lifted and when we will be able to re-commence sales of ABRAXANE® in China.

BUSINESS

REVLIMID

REVLIMID® (lenalidomide) is an oral immunomodulatory medicine that was approved in China in 2013 for the treatment of MM in combination with dexamethasone in adult patients who have received at least one prior therapy. In February 2018, REVLIMID® received NMPA approval of a new indication for the treatment of MM in combination with dexamethasone in adult patients with previously untreated MM who are not eligible for transplant.

In 2019, there were approximately 20,700 new cases of MM in China in 2019, according to the China NCCR, IARC, and F&S research. With a growing aging population and improving diagnosis, China has seen a steady increase in MM incidence. The main treatments for MM in China include VELCADE®, which is a proteasome inhibitor marketed by Johnson & Johnson in China since 2006, REVLIMID®, NINLARO® (ixazomib), an oral proteasome inhibitor developed by Takeda, DARZALEX® (daratumumab), an infusion CD38 monoclonal antibody marketed by Johnson & Johnson since 2019, and a number of generic forms of VELCADE® and REVLIMID®, including generic lenalidomide from Shuanglu Pharmaceutical Co., Ltd., Chia Tai Tianqing Pharmaceutical Group Co., Ltd., Qilu Pharmaceutical Co., Ltd., and Yangtze River Pharmaceutical Group Co., Ltd. Chinese guidelines recommend lenalidomide as a standard of care for the treatment of R/R and newly diagnosed MM as well as in the maintenance setting.

REVLIMID® was listed on the NRDL in June 2017. In November 2019, we announced that REVLIMID® received formal inclusion on the NRDL in China for R/R MM. In November 2020 our sNDA for the use of REVLIMID® in combination with rituximab in adult patients with previously treated follicular lymphoma was approved by the NMPA.

VIDAZA

VIDAZA® (azacitidine for injection) is a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression. VIDAZA® was approved in China in April 2017 for the treatment of intermediate-2 and high-risk myelodysplastic syndromes (“MDS”), chronic myelomonocyte leukemia and acute myeloid leukemia (“AML”) with 20% to 30% blasts and multi-lineage dysplasia. In January 2018, VIDAZA® became commercially available in China.

MDSs are among the most common hematological malignant diseases. In 2019, there were approximately 22,100 new cases of MDS in China in 2019, according to the China NCCR, IARC, and F&S research. The typical age of onset is 70 years. The higher-risk MDS (intermediate-2 and high-risk MDS) is considered fatal because the median overall survival is only 0.4-1.1 years, and nearly 30% of these patients progress to AML. In China, the main treatments for intermediate-2 and high-risk MDS are conventional care regimen (“CCR”) (best supportive care, low-dose cytarabine and intensive chemotherapy), and hypomethylating agents (“HMAs”). DACOGEN® (decitabine), marketed by Johnson & Johnson, was the first HMA agent approved in China in 2009. In the past several years, at least nine decitabine generics have become available. In 2017, decitabine was listed in the NRDL. There are also two approved generic forms of azacitidine from manufacturers Chia Tai Tianqing Pharmaceutical Group Co., Ltd. and Sichuan Huiyu Pharmaceutical Co., Ltd. Nevertheless, there are still over 50% of higher-risk MDS patients treated with CCR, and the unmet need remains large. VIDAZA® is a first-line recommended treatment in the Chinese MDS treatment guidelines. VIDAZA® was listed in the NRDL in October 2018.

We are planning to commercialize the following cancer medicines in China under an exclusive license from EUSA Pharma:

SYLVANT

SYLVANT® (siltuximab), an interleukin-6 (“IL-6”) antagonist, was approved as a treatment for patients with idiopathic multicentric Castleman disease (“iMCD”) who are human immunodeficiency virus (“HIV”) negative and human herpesvirus-8 (HHV-8) negative. We announced on January 25, 2021 that the biologics license application (“BLA”) for siltuximab was accepted by the NMPA and granted priority review. It is estimated that approximately 6,500 to 7,700 new cases of Castleman disease (“CD”) are diagnosed each year in the United States, of which approximately 75% are estimated to be unicentric and the remaining 25% are estimated to be HHV-8-associated multicentric Castleman disease (“MCD”) or HHV-8- negative/idiopathic MCD. In Japan, the incidence appears to be similar to that seen in the United States; however, in contrast, MCD appears to be more common than unicentric CD, and HHV-8-associated MCD is rare. There are few published data regarding the epidemiology in China, but there are no clear associations between epidemiology and particular ethnicities. SYLVANT® is the preferred treatment for patients with iMCD according to the NCCN guidelines, and when SYLVANT® is not available, tocilizumab, a monoclonal antibody targeted against the IL6 receptor, could be used to treat iMCD.

BUSINESS

QARZIBA

QARZIBA[®]▼ (dinutuximab beta), a mouse-human chimeric monoclonal GD2 antibody, was approved as a treatment of high-risk neuroblastoma in patients aged 12 months and above who have previously received induction chemotherapy and achieved at least a partial response (PR). We announced on November 9, 2020 that the BLA for dinutuximab was accepted by the NMPA and granted priority review. Neuroblastoma is almost exclusively a disease of children. It is the third most common childhood cancer, after leukemia and brain tumors, and is the most common solid extracranial tumor in children. There are limited publications on the epidemiology of the disease, and it is estimated there are 5-9 cases of neuroblastoma in one million children under the age of 19. High-risk neuroblastoma patients are managed with induction chemotherapy, surgical resection, tandem autologous hematopoietic stem cell transplantation, radiotherapy, and maintenance with biologic/immunologic therapy, e.g., dinutuximab.

We are planning to commercialize the following product in China under an exclusive license from Bio-Thera:

BAT1706

BAT1706 is an investigational biosimilar to Avastin[®] (bevacizumab) that is in development by Bio-Thera Solutions, Ltd., a commercial-stage biopharmaceutical company located in Guangzhou, China. In China, Avastin[®] is approved for the treatment of patients with metastatic colorectal cancer, liver cancer and NSCLC.

We have acquired the right to develop, manufacture and commercialize BAT1706 in China, including Hong Kong, Macau, and Taiwan. BAT1706 is an investigational compound and has not received regulatory approval in any country. The NMPA accepted the BLA for BAT1706 in June 2020. Bio-Thera has submitted a marketing authorization application to the EMA and submitted a BLA to the FDA in November 2020. In China, two bevacizumab biosimilars have been approved, marked by Qilu Pharmaceutical Co., Ltd. and Innovent Biologics, Inc., and there are also a number of bevacizumab biosimilars in development, including by Sunshine Guojian Pharmaceutical Co., Ltd. and Shanghai Henlius Biotech Inc.

Reimbursement and Market Access

Our sales are largely dependent on the availability and extent of coverage and reimbursement by third party payors. In many markets these third parties are government health systems and in some markets such as the United States there are also private payors such as private health insurers and health systems. During 2020 we commercialized our products in two markets, China and the United States.

In China there is one main payor, the government's national health care coverage system, which provides Basic Medical Insurance ("BMI") to the majority (greater than 95%) of China's approximate 1.4 billion people. There are three types of coverage plans in China at the national level that depend on if a resident lives in an urban versus rural setting and if they are employed. The different plans have different characteristics in terms of how the plan is paid for and what it covers. Coverage and reimbursement of pharmaceuticals in China comes under the purview of the NHSA, the National Healthcare Security Administration, which oversees the NRDL. The NRDL is composed of three lists. The 'A' and 'B' list are commonly referred to as the 'regular' lists. The A list generally includes older, off-patent medicines, while the B list generally includes newer medicines, some with remaining patent protection, which are reimbursed at a lower rate compared to the A list. In 2017 a third list was added to the system, often referred to as the 'C' list or the 'negotiation' list. This list generally includes newer innovative medicines which are accepted on the list after successful negotiation between the NHSA and the company. Typically, inclusion on the C list is accompanied by a discount to the prevailing list price in China for the medicine at the time of inclusion. The NRDL price for a medicine is its prevailing price in China, but the actual price that is used can be modified at the provincial level. In addition to the NRDL, there are provincial reimbursement drug lists, or PRDLs. Provinces have been allowed to omit reimbursement for 10-15% of the products on the NRDL in order to direct resources to other products to better serve their specific populations. This ability is being phased out by 2022 according to a July 2019 NHSA policy memo. The PRDLs are thus, at this time, the official list of what is available to China's citizens. In addition to insurance reimbursement, patients can elect to self-pay for needed medicines.

BUSINESS

Several of BeiGene's medicines are listed on the NRDL. In the most recent NRDL list announced in December 2020, the following medicines were included in the NRDL, effective March 1, 2021:

- Tislelizumab for the treatment of patients with cHL who received at least two prior therapies (approved in December 2019);
- Tislelizumab for the treatment of patients with locally advanced or metastatic UC with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (approved in April 2020);
- BRUKINSA® for the treatment of adult patients with MCL who have received at least one prior therapy (approved in June 2020);
- BRUKINSA® for the treatment of adult patients with CLL/SLL who have received at least one prior therapy (approved in June 2020); and
- XGEVA® for the treatment of adults and skeletally mature adolescents with GCTB that is unresectable or where surgical resection is likely to result in severe morbidity (Amgen obtained approval of XGEVA in China in May 2019).

Additionally, two of our medicines were listed in past NRDLs: REVLIMID® was included in the 2017 NRDL negotiation list and later received formal inclusion in the 2019 B list, while VIDAZA® was listed in the 2018 NRDL negotiation list and later received formal inclusion to the 2020 B list.

In 2018, China started a new program to centrally purchase generic medicines for the nation's health care system called "volume-based procurement", or GPO (group purchasing organization) or "4+7" (4 municipalities and 7 provincial cities) when the program was first piloted in 11 major cities. After the 2018 pilot program, it was implemented nationally in 2019. It is a tender-based system that provides guaranteed volume for lowered pricing. Participation in the program requires a product to have passed a quality consistency evaluation ("QCE"), which in turn requires passing a bioequivalence ("BE") comparison often to the originator product. The system offers a major portion of a market's volume to winning bidders. More than one company can win a given tender, and more guaranteed volume is awarded as more bidders win. The system is still evolving and, as such, the exact terms of how many bidders win and what amount of volume are won and at what price is also evolving.

It is common in China for pharmaceutical companies to employ patient assistance programs to help patients afford their innovative medicines. Usually these programs have been offered to patients who are self-paying. A typical program provides a certain number of free doses to patients after a certain number of doses have been paid for. Usually these programs end when a medicine is included in the NRDL. We offer these types of patient assistance programs to our patients.

In the United States most health insurance coverage is provided by private insurers, often accessed via employer-sponsored plans, and the two main public insurance programs, Medicare and Medicaid. All three types of programs usually have some type of coverage for pharmaceutical products. Often this is through a PBM, or pharmacy benefit manager. The structure of the pharmacy benefit can be quite different for different beneficiaries depending on the negotiations between plan sponsors and plan purchasers. There is no central list of covered pharmaceuticals in the United States, as there is no single payer system. As such, the prices paid for pharmaceuticals in the United States can vary.

We offer patient assistance programs in the United States under our myBeiGene program. This program seeks to enhance access to BRUKINSA[®] by assisting with obtaining reimbursement, co-pay assistance when allowed, temporary supply of free product for insurance delays, and free product assistance for some uninsured and underinsured patients. The programs also seek to support patients and caregivers by providing education and information about BRUKINSA[®] and its approved indications, nurse advocates, and connecting patients to sources of support such as support groups and transportation/lodging assistance.

BUSINESS

OUR PIPELINE PRODUCTS

The following table summarizes the status of our internally-discovered drug candidates as of February 25, 2021:

DRUG CANDIDATES	PROGRAMS	DOSE ESC.	DOSE EXPANSION		PIVOTAL		FILED	MARKETED
		Phase 1a	Phase 1b	Phase 2*	Phase 2**	Phase 3		
zanubrutinib (BTK)	monotherapy	R/R MCL (Accelerated Approval in the U.S. Nov. 14, 2019)						
		WM (filings accepted in multiple geographies)						
		R/R MCL, R/R CLL/SLL (approved by NMPA in China June 3, 2020)						
		R/R WM						
		1L CLL/SLL, R/R CLL/SLL						
		R/R MZL						
	combination	Previously treated CLL/SLL (ibrutinib, acalabrutinib intolerant)						
		+rituximab 1LMCL						
		+obinutuzumab R/R FL						
		+ lenalidomide +/- rituximab R/R DLBCL						
tislelizumab (PD-1)	monotherapy	R/R cHL (approved December 26, 2019), 2L + UC (approved April 10, 2020)						
		2L/3L HCC						
		2L NSCLC, 1L HCC, 2L ESCC						
		R/R NK/T-cell lymphoma						
	+ chemo	1L Sq. NSCLC (approved January 13, 2021)						
		1L Non-Sq. NSCLC (sNDA accepted June 19, 2020)						
		1L NPC, 1L SCLC, Stage II/III NSCLC, Localized ESCC						
	1L GC, 1L ESCC							
	+ pamiparib (PARP)	Solid tumors						
	+ zanubrutinib (BTK)	B-cell malignancies						
pamiparib (PARP)	monotherapy	3L gBRCA+ OC						
		2L platinum-sensitive OC maintenance						
		1L platinum-sensitive GC maintenance						
		HER2-BRCA mutated breast cancer						
	Solid tumors							
+ TMZ (chemo)	Solid tumors							
+ RT/TMZ (RT/chemo)	Glioblastoma							
ociperlimab (BGB-A1217, TIGIT)	+ tislelizumab	Solid tumors						
lifirafenib (RAF Dimer)	+ mirdametinib	B-Raf- or K-RAS/N-RAS-mutated solid tumors						
BGB-A333 (PD-L1)	monotherapy + tislelizumab	Solid tumors						
BGB-A425 (TIM-3)	monotherapy + tislelizumab	Solid tumors						
BGB-A445 (OX40)	+ tislelizumab	Solid tumors						
BGB-11417 (Bcl-2)	monotherapy + zanubrutinib	B-cell malignancies						
BGB-10188 (PI3-ko)	mono; + tislelizumab; + zanubrutinib	B-cell malignancies; Solid tumors						
BGB-15025 (HPK1)	monotherapy & + tislelizumab	IND accepted						

Global
China

* Some indications will not require a non-pivotal Phase 2 clinical trial prior to beginning pivotal Phase 2 or Phase 3 clinical trials. **Confirmatory clinical trials post approval are required for accelerated or conditional approvals.

Abbreviations: 1L = first line; 2L = second line; 3L = third line; AML = acute myeloid leukemia; Bcl-2 = B-cell lymphoma 2; BTK = Bruton’s tyrosine kinase; cHL = classical Hodgkin’s lymphoma; CLL = chronic lymphocytic leukemia; Dose Esc = dose escalation; ESCC = esophageal squamous cell carcinoma; FL = follicular lymphoma; gBRCA = germline BRCA (Breast Cancer); GC = gastric cancer; HCC = hepatocellular carcinoma; MCL = mantle cell lymphoma; MZL = marginal zone lymphoma; NSCLC = non-small cell lung cancer; NDA = new drug application; NK = natural killer; NMPA = National Medical Products Administration; NPC = nasopharyngeal carcinoma; OC = ovarian cancer; PARP = poly ADP-ribose polymerase; PD-1 = programmed cell death protein 1; PH = Phase; R/R = relapsed/refractory; RT = radiotherapy; SLL = small lymphocytic lymphoma; SCLC = small cell lung cancer; Sq = squamous; TIGIT = T-cell immunoreceptor with Ig and ITIM domains; TMZ = temozolomide; UC = urothelial carcinoma; WM = Waldenström’s macroglobulinemia.

The following table summarizes the status of our in-licensed drug candidates as of February 25, 2021:

DRUG CANDIDATES	DESCRIPTION	DOSE ESCALATION / EXPANSION		PIVOTAL		COMMERCIAL RIGHTS	
		Phase 1	Phase 2*	Phase 2^	Phase 3		
sotorasib ¹	(KRAS G12C, SM)	Solid tumors, NSCLC, CRC					China ¹
AMG 701 ¹	(BCMA, HLE BiTE)	MM					
AMG 176 ¹	(Mcl-1, SM (i.v.))	Hematologic					
AMG 397 ¹	(Mcl-1, SM (oral))	Hematologic					
AMG 330 ¹	(CD33, BiTE)	AML					
AMG 673 ¹	(CD33, HLE BiTE)	AML					
AMG 427 ¹	(FLT3, HLE BiTE)	AML					
AMG 757 ¹	(DLL3, HLE BiTE)	SCLC					
AMG 160 ¹	(PSMA, HLE BiTE)	Prostate					
AMG 509 ¹	(STEAP1 XmAb, BiTE)	Prostate					
AMG 199 ¹	(MUC17)	GC/GEJC					
AMG 910 ¹	(Anti-CLDN18.2, BiTE)	GC/GEJC					
AMG 650 ¹	(oral small molecule)	Solid tumors					
AMG 506 ¹	(FAP x 4-1BB, DARPIn [®])	Solid tumors					
AMG 256 ¹	(Anti-PD-1 x IL21 mutein)	Solid tumors					
Sitravatinib ²	(multi-kinase inhibitor) + tislelizumab	NSCLC, RCC, OC, MEL				Asia ex-Japan, NZ, AU	
	Mono + tislelizumab	HCC, GC/GEJC					
zanidatamab ³	(bispecific HER2 antibody)	Breast cancer, GEA				Asia ex-Japan, NZ, AU	
		Biliary tract cancers					
ZW49 ³	(bispecific anti-HER2 ADC)	HER2-expressing cancers				Asia ex-Japan, NZ, AU	
BGB-3245 ⁴	(B-RAF)	Solid tumors				Asia ex-Japan	
BA3071 ⁵	(CTLA4) Mono, + tislelizumab	Tech transfer in progress					Global
SEA-CD70 ⁶	(anti-CD70)	MDS, AML				Asia ex-Japan, AU, NZ	
DKN-01 ⁷	(DKK1) + tislelizumab +/- chemo	GC/GEJC				Asia ex-Japan, AU, NZ	
ABI-H0731 ⁸	(HBV core inhibitor)	Chronic Hepatitis B virus				China	
ABI-H2158 ⁸		Chronic Hepatitis B virus					
ABI-H3733 ⁸		Chronic Hepatitis B virus					

Global
China

BUSINESS

- * Some indications will not require a non-pivotal Phase 2 clinical trial prior to beginning pivotal Phase 2 or Phase 3 clinical trials. ^Confirmatory clinical trials post approval are required for accelerated or conditional approvals. 1. Collaboration with Amgen. BeiGene also receives royalties on sales outside China except for sotorasib. 2. Collaboration with Mirati Therapeutics, Inc. 3. Collaboration with Zymeworks. ZW49 study conducted by Zymeworks. 4. Study conducted by MapKure, a JV with SpringWorks. 5. Licensed from BioAtla. 6. Collaboration with SeaGen. 7. Collaboration with Leap Therapeutics (option to license). 8. Collaboration with Assembly Biosciences.

Abbreviations: ADC = antibody drug conjugate; AML = acute myeloid leukemia; AU = Australia; BCMA = B-cell maturation antigen; BiTE = Bi-specific T- cell engager; B-RAF = B-version Rapidly Accelerated Fibrosarcoma; BTK = Bruton's tyrosine kinase; CD## = cluster of differentiation; CTLA4 = cytotoxic T- lymphocyte-associated protein 4; DKK1 = Dickkopf protein 1; DLL3 = delta-like ligand 3; FAP = familial adenomatous polyposis; FLT3 = fms-like tyrosine kinase 3; GEJC = gastro-esophageal junction cancer; HER2 = human epidermal growth factor receptor 2; HBV = hepatitis B virus; HCC = hepatocellular carcinoma; HLE = half-life extended; i.v. = intravenous; IL21 = interleukin 21; KRAS = gene for K version of Ras (rat sarcoma) protein; Mcl-1 = Myeloid cell leukemia-1; MEL = melanoma; MM = multiple myeloma; NSCLC = non-small cell lung cancer; NZ = New Zealand; OC = ovarian cancer; PD-1 = Programmed cell death protein 1; PH = Phase; PSMA = prostate-specific membrane antigen; RCC = renal cell carcinoma; SCLC = small cell lung cancer; SM= small molecule.

OUR COMMERCIAL- AND CLINICAL-STAGE DRUG CANDIDATES

A description of our commercial- and clinical-stage drug candidates and clinical data from selected clinical trials is set forth below. Historically, we have made available, and we intend to continue to make available, clinical data and/or topline results from clinical trials of our drug candidates in our press releases and/or filings with the U.S. Securities and Exchange Commission ("SEC") and the Stock Exchange of Hong Kong Limited ("HKEx"), copies of which are available on the Investors section of our website.

BRUKINSA (zanubrutinib), a BTK Inhibitor

We are currently evaluating zanubrutinib in a broad pivotal clinical program globally and in China as a monotherapy and in combination with other therapies to treat various lymphomas. Zanubrutinib has demonstrated higher selectivity against BTK than IMBRUVICA (ibrutinib), an approved BTK inhibitor, based on our biochemical assays; higher exposure than ibrutinib based on their respective Phase 1 experience in separate studies; and sustained 24-hour BTK occupancy in both the peripheral blood and lymph node compartments in patients. We reported data from our Phase 3 ASPEN study, which compared zanubrutinib with ibrutinib in WM. While the trial did not achieve statistical significance on its primary endpoint of superiority in complete response and very good partial response ("VGPR") rates for zanubrutinib compared to ibrutinib, zanubrutinib demonstrated a numerically higher VGPR rate as well as improvements in safety and tolerability.

Mechanism of Action

BTK is a key component of the B-cell receptor ("BCR") signaling pathway and is an important regulator of cell proliferation and cell survival in various lymphomas. BTK inhibitors block BCR-induced BTK activation and its downstream signaling, leading to growth inhibition and cell death in certain malignant white blood cells called B-cells. Zanubrutinib is an orally active inhibitor that covalently binds to BTK, resulting in irreversible inactivation of the enzyme.

Overview of Clinical Development Program and Regulatory Status

We received accelerated approval from the FDA in November 2019 for zanubrutinib for the treatment of adult MCL patients who have received at least one prior therapy. We announced approval from China's NMPA in June 2020 for use in two indications – the treatment of adult patients with CLL/SLL who have received at least one prior therapy, and the treatment of adult patients with MCL who have received at least one prior therapy.

We have announced filings of BRUKINSA[®] with regulatory authorities globally, including in the United States, China, the EU, Canada, and Australia for WM, and in Canada, Australia and Israel for MCL. As of February 2021, more than 20 marketing authorization applications for BRUKINSA[®] have been submitted outside of the United States and China, covering 45 countries and regions, including by BeiGene in the EU and Canada and with support from our five distribution partners: Adium Pharma S.A. in Latin America and the Caribbean, NewBridge Pharmaceuticals in the Middle East and North Africa, Erkim in Turkey, Nanolek in Russia, and Medison in Israel.

Based on the clinical data to date, we believe that BRUKINSA[®] has a potentially best-in-class profile, and we are running a broad global pivotal program in multiple indications, including nine registration or registration-enabling clinical trials. Four of the nine studies are Phase 3 and five are designed to be registration-enabling Phase 2 trials.

We have reported results from the monotherapy head-to-head Phase 3 trial versus ibrutinib in WM (ASPEN, NCT03053440), which are being included in several filings globally. We are also conducting an ongoing Phase 3 trial comparing BRUKINSA[®] to bendamustine and rituximab in patients with treatment-naïve ("TN") CLL/SLL (SEQUOIA, NCT03336333) and a head-to-head Phase 3 trial in R/R CLL/SLL versus ibrutinib (ALPINE, NCT03734016). We have completed patient enrollment in SEQUOIA and ALPINE. Our fourth Phase 3 trial is an ongoing Phase 3 confirmatory trial in patients with TN MCL (NCT04002297). Additionally, we have five filed or ongoing Phase 2 trials that are designed to be registration-enabling, including four monotherapy studies in R/R MCL, R/R WM, R/R CLL/SLL (NCT03206970, NCT03332173, NCT03206918), and R/R MZL (MAGNOLIA, NCT03846427) and an ongoing pivotal Phase 2 trial in combination with GAZYVA[®] (obinutuzumab) in patients with R/R FL (ROSEWOOD, NCT03332017), which is designed as a pivotal trial for accelerated or conditional approval and will require a confirmatory study if approved. Finally, we are also investigating zanubrutinib in several combination studies in DLBCL and CLL/SLL, including two studies in CLL/SLL investigating venetoclax combinations.

We continue to pursue regulatory approvals for BRUKINSA[®] globally. We expect regulatory decisions for some of the filings this year, including those for certain patients with MCL in the EU, Middle East, South America, Canada, Australia, and Russia, and for patients with WM in the United States, EU, Canada and Australia. We expect topline results to be available from two of our Phase 3 studies in CLL/SLL, SEQUOIA (as early as 2021) and ALPINE (first half 2022). The former is examining BRUKINSA[®] in 1L CLL/SLL against bendamustine plus rituximab, and the latter is a head-to-head study comparing BRUKINSA[®] versus ibrutinib in second line CLL/SLL. Finally, we expect to complete enrollment in the pivotal Phase 2 ROSEWOOD trial comparing BRUKINSA[®] plus obinutuzumab to obinutuzumab alone in R/R follicular lymphoma patients in 2021.

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Summary of Clinical Results

As of January 2021, we had enrolled more than 3,100 patients in clinical trials of zanubrutinib, including trials of zanubrutinib in combination with other therapies. Our first-in-human study is a multi-center, open-label Phase 1 trial being conducted in Australia, New Zealand, the United States, South Korea and Europe to assess the safety, tolerability, pharmacokinetic properties and preliminary activity of zanubrutinib as a monotherapy in patients with different subtypes of B- cell malignancies, such as WM, CLL/SLL, follicular lymphoma (“FL”), and MCL. The initial results of the dose-escalation phase and dose-expansion phase of this trial demonstrated that, consistent with zanubrutinib’s pharmacokinetic profile, complete and sustained 24-hour BTK occupancy in the blood was observed in all tested patients, starting at the lowest dose of 40 mg once daily (“QD”). In addition, sustained full BTK occupancy was observed in the lymph nodes with the 160 mg twice- daily (“BID”) dosing regimen. We substantially expanded the clinical development program for zanubrutinib based on these early results to include late stage clinical studies in WM, CLL/SLL, MCL, FL and MZL. In addition, we have several studies ongoing in DLBCL, both monotherapy and combinations, and we have several combination studies in CLL, including combinations with the Bcl-2 inhibitor venetoclax and a planned study with our internally-discovered BCL-2 inhibitor, BGB-14417. All of the studies discussed below were presented at major medical conferences and were included in press releases issued at the time of the medical conferences and included in our current reports or announcements filed with the SEC and HKEx, respectively. Those sources have further details on each study.

Waldenström’s Macroglobulinemia – ASPEN Study

In December 2019, we announced topline results from our Phase 3 ASPEN trial of zanubrutinib compared to ibrutinib for the treatment of patients with WM. We presented the results of the trial at the 2020 Annual Meeting of the American Society of Clinical Oncology (“ASCO”).

The ASPEN trial is a randomized Phase 3 trial in 229 patients with WM conducted in 61 centers in Europe, Australia, and the United States. ASPEN was the largest Phase 3 trial yet conducted in WM and the first comparative trial readout for two BTK inhibitors. Cohort 1 enrolled 201 patients and randomized 102 to receive zanubrutinib and 99 to receive ibrutinib.

The trial did not achieve statistical significance on its primary endpoint of superiority in CR and VGPR rates for zanubrutinib compared to ibrutinib, but zanubrutinib demonstrated numerically more frequent VGPRs, higher PFS and OS at 12 months, and advantages in safety and tolerability.

	R/R		Overall	
	Zanubrutinib (N = 83)	Ibrutinib (N = 81)	Zanubrutinib (N = 102)	Ibrutinib (N = 99)
Efficacy				
VGPR + CR Rate	28.9% ¹	19.8% ¹	28.4% ²	19.2% ²
PFS (12 month)	92.4%	85.9%	89.7%	87.2%
OS (12 month)	98.8%	92.5%	97.0%	93.9%

Data cutoff of August 31, 2019, with a median follow-up of 19.4 months. 1. 2-sided p=0.1160, no patients achieved a CR in either arm. 2. 2-sided descriptive p=0.0921, no patients achieved a CR in either arm.

Zanubrutinib showed a more favorable safety profile overall compared to ibrutinib, as shown in the table below, including overall fewer grade >3 events and less incidence of AEs known to be of interest in BTK inhibitor usage such as atrial fibrillation or flutter.

Safety	Zanubrutinib Overall (n = 101)	Ibrutinib Overall (n = 98)
Grade >3 AEs	58.4%	63.3%
Treatment discontinuation due to AEs	4 (4.0%)	9 (9.2%)
Fatal AEs	1 (1.0%)	4 (4.1%)
Atrial fibrillation/flutter of any grade	2.0%	15.3%
Minor bleeding	48.5%	59.2%
Major hemorrhage	5.9%	9.2%
Diarrhea	20.8%	31.6%
Neutropenia	29.7%	13.3%

Waldenström’s Macroglobulinemia – ASPEN Study – MYD88^{WT} Cohort

ASPEN enrolled patients with the wild type MYD88 gene, which is believed to result in lower response rates and shorter progression-free survival rates when treated with BTK inhibitors. This cohort of 26 MYD88^{WT} patients were all treated with zanubrutinib (160mg bid). The overall response rate was 80.8%, with a major response rate of 50.0%, including a VGPR rate of 26.9%. The progression-free survival event-free rate at 12 months was 72.4%. The most frequently reported AEs were diarrhea, anemia, contusion, pyrexia, and upper respiratory tract infection. Major hemorrhage was reported in 2 patients, and atrial fibrillation was reported in 1 patient. There were no fatal AEs.

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – SEQUOIA 17p Deletion Arm C

We presented updated results from Arm C of the SEQUOIA trial (NCT03336333). Patients who have the 17p13.1 deletion [del(17p)] have a poor prognosis and respond poorly to standard chemo-immunotherapy. A total of 109 of these patients were enrolled into Arm C of the SEQUOIA trial, a non-randomized arm due to the unfavorable response of these patients to bendamustine plus rituximab. With median follow-up of 21.9 months, the overall response rate was 94.5%, including a CR/CRi rate of 6.4% and a PR/nPR rate of 87.1%. The 18-month PFS rate was 90.6%. Adverse events of interest that were the most common included infections, minor bleeding, bruising and neutropenia (65%, 28%, 25% and 19%).

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Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma – BOVen

Zanubrutinib has been tested in investigator-sponsored studies. One study, called the BOVen study (NCT03824483), investigated the use of zanubrutinib in combination with obinutuzumab and venetoclax in 39 previously untreated CLL/SLL patients. The study investigated if the combination would be able to produce frequent uMRD (undetectable minimal residual disease), thus allowing for an MRD-driven treatment discontinuation approach. At a median follow up time of 11 months, the rate of uMRD in peripheral blood and bone marrow was 84% and 73%, respectively, and 62% of patients were able to stop therapy. The most common TEAEs were neutropenia, thrombocytopenia, infusion reactions, bruising, and diarrhea (51%, 46%, 41%, 41%, 41%). There was one death of a patient experiencing an intracerebral hemorrhage on cycle 1 after receiving intravenous heparin for pulmonary emboli.

Marginal Zone Lymphoma – MAGNOLIA

Zanubrutinib is also being investigated for use in marginal zone lymphoma, a rare and heterogeneous disease in which it has been difficult to define optimal therapeutic strategies. This Phase 2 single arm study (NCT03846427) enrolled 68 patients who received zanubrutinib monotherapy (160mg BID) after having received at least one prior line of anti-CD20-directed therapy. The overall response rate seen with a median follow up of 11 months was 74%, including 24% complete response based on investigator assessment. The nine-month PFS rate was 67%. In the study 96% of patients had at least one treatment-emergent adverse event (“TEAE”) and 38% experienced a TEAE of grade 3 or higher. TEAEs of interest in at least 10% of patients included: infection, hemorrhage, diarrhea, neutropenia and thrombocytopenia (40%, 32%, 21%, 13%, 10%).

Other Lymphomas

We are also investigating zanubrutinib for the treatment of patients with other lymphomas. We have studies ongoing in MCL, FL, and DLBCL.

Analysis of Safety Data from Monotherapy Trials

Pooled safety data from 682 patients enrolled in six Phase 1 and Phase 2 clinical trials of zanubrutinib as a monotherapy for WM, MCL, CLL/SLL, DLBCL and other B-cell malignancies were presented at the 2019 European Hematology Association (“EHA”). The majority of patients had R/R disease; almost all patients received zanubrutinib at a dose of 320mg QD or 160mg BID. The median duration of zanubrutinib exposure was 13.4 months (0.1-49.7). This analysis included an evaluation of the frequency and severity of AEs, AEs of special interest (“AESIs”), and AEs leading to death, dose reduction, or treatment discontinuation. Ninety-seven percent of patients reported at least one AE, which were primarily grade 1 or 2. The most common AEs of all grades included upper respiratory tract infection (32.4%), neutrophil count decreased (25.2%), diarrhea (19.4%), cough (19.1%), contusion (18.6%), and rash (18%). The most common grade ≥ 3 AEs included neutrophil count decreased (14.4%), anemia (7.6%), neutropenia (6.6%), pneumonia (4.5%), platelet count decreased (4.3%), and lung infection (4.1%). Serious AEs (“SAEs”), consisting primarily of infectious complications such as pneumonia/lung infection, were reported in 36% of patients. AESIs such as atrial fibrillation/flutter (1.9%), major hemorrhage (2.5%), and grade ≥ 3 hypertension (3.4%) were infrequent, and treatment discontinuation due to AEs was uncommon (9.1% overall, including 3.5% for whom the event(s) were treatment-related).

Tislelizumab, an anti-PD-1 Antibody

Tislelizumab is a humanized monoclonal antibody against the immune checkpoint receptor PD-1 that is currently being evaluated in pivotal clinical trials globally and in China and for which we plan to commence additional pivotal trials as a monotherapy and in combination with standard of care to treat various solid and hematological cancers.

Mechanism of Action

Cells called cytotoxic T-lymphocytes (“CTLs”) provide an important self-defense mechanism against cancer, patrolling the body, recognizing cancer cells due to immunogenic features that differ from normal cells, and killing cancer cells by injecting deleterious proteins into them. T-lymphocytes have various mechanisms that prevent them from damaging normal cells, among which is a protein called PD-1 receptor, that is expressed on the surface of T-lymphocytes. PD-L1 is an important signaling protein that can engage PD-1. PD-L1 binding to PD-1 sends an inhibitory signal inside the T-lymphocyte and suppresses its cytotoxic effects. Many types of cancer cells have hijacked the PD-L1 expression system that normally exists in healthy cells. By expressing PD-L1, cancer cells protect themselves from being killed by CTLs. Anti-PD-1 therapies are designed to bind to and block downstream activity of PD-1, allowing the immune system to combat cancer cells.

Tislelizumab is a monoclonal antibody designed to specifically bind to PD-1, thereby blocking engagement of PD-1 by its ligands PD-L1 and PD-L2. Tislelizumab has demonstrated high affinity and specificity for PD-1 in preclinical studies. It is differentiated mechanistically from the currently approved PD-1 antibodies by an engineered Fc region designed to minimize binding to FcγR on macrophages, thereby abrogating antibody-dependent phagocytosis, a potential mechanism of T-cell clearance, which we believe may minimize potentially negative interactions with other immune cells based on preclinical data.

Clinical Development Program, Regulatory Status and Collaboration

Tislelizumab has received conditional approval in China for the treatment of: (i) cHL patients who have received at least two prior therapies (December 2019); and (ii) 2L+ UC PD-L1 positive patients (April 2020). Tislelizumab has also received full approval in China for the treatment of 1L squamous NSCLC patients in combination with chemotherapy (January 2021). It is currently under review by the NMPA for use in front line non-squamous NSCLC and second or third line HCC.

In January 2021, we announced a collaboration with Novartis to develop, manufacture and commercialize tislelizumab in North America, Japan, the EU, and six other European countries. We and Novartis have agreed to jointly develop tislelizumab in these licensed countries, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals. In addition, both companies may conduct clinical trials globally to explore combinations of tislelizumab with other cancer treatments, and we have an option to co-detail the product in North America, funded in part by Novartis. The transaction was closed on February 26, 2021.

We have a broad development program for tislelizumab, including 16 filed, approved or registration-enabling clinical trials. These include global pivotal trials in Asia-prevalent cancers, NSCLC, HCC, GC, and ESCC, which are intended to support regulatory submissions globally and in China.

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Our trials in lung cancer include:

- A global Phase 3 trial evaluating tislelizumab as a second- or third-line treatment compared to docetaxel in patients with locally advanced or metastatic NSCLC (NCT03358875);
- Two Phase 3 trials in China evaluating tislelizumab plus chemotherapy versus chemotherapy in squamous and non- squamous NSCLC (NCT03594747 and NCT03663205, respectively); and
- A Phase 3 trial in China in 1L SCLC evaluating tislelizumab plus chemotherapy versus chemotherapy (NCT04005716).

Our trials in liver cancer include:

- A global Phase 3 trial comparing tislelizumab with sorafenib as first-line treatment for patients with HCC (NCT03412773); and
- A global single-arm pivotal Phase 2 trial evaluating tislelizumab in second or third line unresectable HCC (NCT03419897).

Our trials in gastric cancer include:

- A global Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment for patients with gastric cancer (NCT03777657).

Finally, our trials in ESCC include:

- A global Phase 3 trial comparing tislelizumab with chemotherapy as second-line treatment for patients with advanced ESCC (NCT03430843);
- A global Phase 3 trial of tislelizumab in combination with chemotherapy as first-line treatment for patients with ESCC (NCT03783442); and
- A Phase 3 trial in China of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590).

We are also evaluating tislelizumab in registration-enabling trials in UC, MSI-high or dMMR solid tumors, and NPC. We have two China studies in UC, including a pivotal Phase 2 (NCT04004221) in second-line UC evaluating tislelizumab as monotherapy that was the basis for our UC approval in China in May 2020, and a Phase 3 trial (NCT03967977) in first line UC comparing tislelizumab plus chemotherapy versus chemotherapy alone. In MSI-high or dMMR solid tumors we have an ongoing pivotal Phase 2 trial (NCT03736889) in China examining tislelizumab as monotherapy, and in NPC we have a Phase 3 trial (NCT03924986) in China in first line evaluating tislelizumab plus chemotherapy versus chemotherapy alone.

We have announced that four of Phase 3 trials for tislelizumab have met their respective primary endpoints, in 1L squamous NSCLC, 1L non-squamous NSCLC, 2L NSCLC, and 2L ESCC. In 1L NSCLC, tislelizumab in combination with chemotherapy has shown improved PFS when compared to PFS in both squamous and non-squamous patients. In 2L NSCLC and 2L ESCC, tislelizumab has shown improved overall survival compared to chemotherapy.

We expect several milestones from the tislelizumab program in 2021. Submission of the first BLA outside of China is expected during the year. Submission of supplemental biologics license applications (“sBLAs”) in China for 2L/3L NSCLC and MSI-H/dMMR solid tumors is expected in the first half of 2021, and for 2L ESCC in mid-2021. Regulatory decision on sBLAs in 1L non-squamous NSCLC and 2L/3L HCC are expected in China in 2021. We expect to announce topline results of the Phase 3 trial of 1L treatment combined with chemotherapy in patients with NPC in 2021. Completion of enrollment of the Phase 3 trial in 1L SCLC is expected in the first half of 2021. Completion of enrollment in the Phase 3 trial versus placebo in combination with chemoradiotherapy in patients with localized ESCC is expected in 2021.

Summary of Clinical Results

As of January 2021, we had enrolled over 7,700 patients in clinical trials of tislelizumab, including combination trials. Data from our trials thus far suggested that tislelizumab was generally well-tolerated and exhibited anti-tumor activity in a variety of tumor types. All of the studies discussed below were presented at major medical conferences and were included in press releases issued at the time of the medical conferences and included in our current reports or announcements filed with the SEC and HKEx, respectively. Those sources have further details on each study.

Non-Small Cell Lung Cancer

In January 2020, we announced that our Phase 3 clinical study evaluating tislelizumab plus two chemotherapy regimens versus chemotherapy alone in first-line treatment of squamous NSCLC patients (NCT03594747) met the primary endpoint of progression-free survival at the planned interim analysis, as determined by independent review committee. In this study, patients with previously untreated advanced squamous NSCLC were randomized to receive either tislelizumab in combination with paclitaxel and carboplatin, tislelizumab in combination with nanoparticle albumin-bound (nab) paclitaxel (ABRAXANE®) and carboplatin, or paclitaxel and carboplatin alone. Based on the pre-planned interim analysis, both tislelizumab treatment arms crossed the pre-specified efficacy boundary compared to chemotherapy alone.

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The data from this trial were presented at the 2020 annual meeting of ASCO and are briefly summarized below.

	Arm A Tislelizumab + PC (n = 120)	Arm B Tislelizumab + <i>nab</i> -PC (n = 119)	Arm C PC (n=121)
PFS, median in months	7.6	7.6	5.5
Stratified hazard ratio versus placebo	0.524	0.478	
p-value	0.0001	<0.0001	
ORR, %	73	75	50

PC: paclitaxel and carboplatin.

Safety data from the study are briefly summarized below.

	Arm A Tislelizumab + PC (n = 120)	Arm B Tislelizumab + <i>nab</i> -PC (n = 119)	Arm C PC (n=121)
Patients with ≥ 1 TEAE, %	100	99	100
Serious TEAE, %	37	38	25
TEAE leading to permanent discontinuation of any study treatment component, %	13	30	15
TEAE leading to death, n	4	5	5

In April 2020, we announced that our Phase 3 clinical study evaluating tislelizumab plus platinum doublet chemotherapy versus chemotherapy alone in first-line treatment of non-squamous NSCLC patients (NCT03663205) met the primary endpoint of progression-free survival at the planned interim analysis, as determined by independent review committee. In this study, patients with previously untreated advanced non-squamous NSCLC were randomized to receive either tislelizumab in combination with pemetrexed and investigator's choice of platinum chemotherapy (either carboplatin or cisplatin) versus pemetrexed and platinum chemotherapy alone. Based on the pre-planned interim analysis, the tislelizumab treatment arm crossed the pre-specified efficacy boundary compared to chemotherapy alone.

The data from this trial were presented at the 2020 virtual congress of the European Society for Medical Oncology (“ESMO”) and are briefly summarized below.

	Arm A Tislelizumab + PP (n = 223)	Arm B PP (n = 111)
PFS, median in months	9.7	7.6
Stratified hazard ratio versus chemotherapy alone	0.645	
p-value	0.004	
ORR, %	57	37

Safety data from the study are briefly summarized below.

	Arm A Tislelizumab + PP (n = 223)	Arm B PP (n = 111)
Patients with ≥ 1 TEAE, %	100	99
Grade ≥ 3 TEAE, %	68	54
TEAE leading to permanent discontinuation of any study treatment component, %	26	9
TEAE leading to death, n	7	2

In Arm A, fatal TEAEs were pneumonitis (n=3), asphyxia, atrial fibrillation, cerebellar hemorrhage, and unspecified death (n=1 each); in Arm B, fatal TEAEs were pneumonitis and embolism (n=1 each); four patients experienced AEs leading to death that were considered by the investigator to be treatment-related.

Two reports of preliminary efficacy and safety from a clinical trial (NCT03493451) investigating use of tislelizumab in lymphoma were reported at the 2020 virtual congress of EHA. The two reports were each from one arm of the study, one in natural killer/T-cell lymphoma and one in peripheral T-cell lymphoma.

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Safety Results

The safety results of tislelizumab in clinical trials to date have been consistent with its therapeutic class, having a relatively low rate of drug-related grade 3 or above toxicity. The safety data of tislelizumab described below was obtained from 934 patients treated with tislelizumab monotherapy from the following four clinical studies as of April 2020: BGB-A317-001 (N=451), BGB-A317-102 (N=300), BGB-A317-203 (N=70) and BGB-A317-204 (N=113). Types of tumors studied included: urothelial carcinoma (N=152), non-small cell lung cancer (N=105), esophageal carcinoma (N=81), gastric cancer (N=78), classical Hodgkin lymphoma (N=70), hepatocellular carcinoma (N=69), colorectal cancer (N=54), ovarian cancer (N=51), renal cell carcinoma (N=37), melanoma (N=36), breast cancer (N=32), head and neck squamous cell carcinoma (N=29), nasopharyngeal carcinoma (N=27), cholangiocarcinoma (N=18), pancreatic cancer (N=10), small cell neuroendocrine carcinoma (N=10), sarcoma (N=10), mesothelioma (N=9), cervical cancer (N=7), and others (N=49). In the above studies, 496 patients received tislelizumab 200 mg once every 3 weeks, 355 patients received tislelizumab at a dose of 5 mg/kg once every 3 weeks, 26 patients received 2 mg/kg once every 2 weeks, 26 patients received 5 mg/kg once every 2 weeks, 21 patients received 2 mg/kg once every 3 weeks, 7 patients received 10 mg/kg once every 2 weeks, and 3 patients received 0.5 mg/kg once every 2 weeks. The median duration of treatment was 16 weeks (range: 0.6 – 160.4 weeks); 36.1% patients received treatment with tislelizumab for ≥ 6 months and 20.6% for ≥ 12 months.

The incidence of adverse reactions of all grades was 70.8% in 934 patients treated with tislelizumab. Those occurring in $\geq 10\%$ of patients included rash, fatigue, and alanine aminotransferase increased.

The incidence of Grade 3 or higher AEs was 21.8%. Those occurring in $\geq 1\%$ of patients included: gamma-glutamyl transferase increased, anemia, aspartate aminotransferase increased, alanine aminotransferase increased, pneumonitis, severe skin reactions, and hypokalemia.

irTEAEs and Deaths

The specific irAE rates listed below are from the four studies of tislelizumab in 934 patients summarized above. These irAEs have well-established algorithms for treatment and are considered manageable. irAEs seen in >1.0% of patients were as follows:

	All Grades, n	Grade ≥ 3, n
Immune-related pneumonitis	25	14
Immune-related diarrhea and colitis	10 (3 diarrhea, 7 colitis)	6 (2 diarrhea, 4 colitis)
Immune-related hepatitis	20	13
Immune-related hypothyroidism	70	0
Immune-related hyperthyroidism	35	0
Immune-related thyroiditis	9	0
Immune-related skin adverse reactions	67	10

In total, there were four deaths in the pooled data set of 934 patients across the four studies. The four deaths occurred in one patient experiencing immune-related pneumonitis, two patients experiencing immune-related hepatitis, and one patient experiencing immune-related nephritis (all-grade immune-related nephritis incidence was 0.6%).

Pamiparib, a PARP1 and PARP2 Inhibitor

Pamiparib is an investigational, selective small molecule inhibitor of poly ADP-ribose polymerase 1 (“PARP1”) and PARP2 enzymes that is being evaluated as a potential monotherapy and in combinations for the treatment of various solid tumors. We believe that pamiparib has the potential to be differentiated from other PARP inhibitors because of its brain penetration, greater selectivity, strong DNA-trapping activity, and good oral bioavailability demonstrated in preclinical models.

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Mechanism of Action

PARP family members PARP1 and PARP2 play essential roles in cell survival in response to DNA damage. Inhibition of PARPs prevents the repair of common single-strand DNA breaks, which leads to formation of double-strand breaks during DNA replication. Cancer cells with mutations in the breast cancer susceptibility gene, or BRCA1/2 genes, are highly sensitive to PARP inhibition. This phenomenon is called “synthetic lethality” and is the foundation of the therapeutic utility of PARP inhibitors as a monotherapy for BRCA mutant cancers. In addition to hereditary BRCA1/2 mutations, the synthetic lethality concept has been broadened to include sporadic tumors that display homologous recombination deficiency (“HRD”, a double stranded DNA repair mechanism), a gene expression profile that resembles that of a BRCA deficient tumor.

Another potential therapeutic utility of PARP inhibitors is in combination therapy. PARP inhibitors are hypothesized to potentiate cytotoxicity of DNA-alkylating agents such as platinum compounds, temozolomide and ionizing radiation, and may be used in combination with these agents in treating various cancers.

Summary of Clinical Results

We presented preliminary results from a Phase 2 registration trial at ESMO 2020. The data are from a Phase 2 dose-expansion portion of a Phase 1/2 trial of pamiparib in patients with advanced ovarian cancer, fallopian cancer, and primary peritoneal cancer or advanced triple negative breast cancer (NCT03333915). A total of 113 patients in China with high-grade, non-mucinous, epithelial OC (including fallopian or primary peritoneal cancer), harboring germline BRCA1/2 mutation, following at least two prior lines of standard chemotherapy were enrolled in the pivotal Phase 2 portion of the trial, including 90 patients with advanced platinum-sensitive OC (PSOC) in Cohort 1, and 23 patients with advanced platinum-resistant OC (PROC) in Cohort 2.

As of the data cutoff on February 2, 2020, there was a median follow-up time of 12.2 months. In Cohort 1, the patients with PSOC, the ORR was 65%. In Cohort 2, the patients with PROC, the ORR was 32%. Pamiparib was generally tolerated in patients with PSOC and PROC, which is similar to other PARP inhibitors. Across the trial, the most common ($\geq 20\%$) TEAEs of any grade included anemia (89%), nausea (68%), decreased neutrophil count (61%), decreased white blood cell count (60%), vomiting (50%), decreased platelet count (31%), decreased appetite (30%), asthenia (28%), diarrhea (22%), increased AST (21%), decreased lymphocyte count (21%), increased ALT (20%), and leukopenia (20%).

Clinical Development Program and Regulatory Status

In July 2020, we filed an NDA for pamiparib in China for use in third-line BRCA-mutated ovarian cancer based on the pivotal study results described above. In addition to this study, our clinical development program includes a Phase 3 trial as a maintenance therapy in patients with platinum-sensitive recurrent OC (NCT03519230), a Phase 2 trial in BRCA-mutated HER2-negative breast cancer (NCT03575065), a Phase 2 trial in first-line platinum-sensitive GC maintenance (NCT03427814), and a Phase 1b/2 trial in combination with temozolomide in glioblastoma multiforme (NCT03150862).

We expect to announce top-line results from the Phase 3 maintenance study in patients with platinum-sensitive recurrent OC in 2021 or the first half of 2022.

Ociperlimab (BGB-A1217), an TIGIT Inhibitor

Ociperlimab (BGB-A1217) is an investigational humanized IgG1-variant monoclonal antibody directed against TIGIT. We have an ongoing Phase 1a/1b trial (NCT04047862) in Australia investigating the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of BGB-A1217 in combination with tislelizumab in patients with advanced solid tumors. The molecule has exhibited high potency in our experiments, and possesses a competent Fc moiety which our experiments suggest is required for optimal efficacy. Further, no DLTs have been observed and full target occupancy has been seen in PBMCs at the lowest dose tested. We have selected the randomized Phase 2 dose for ociperlimab and are studying the molecule in combination with tislelizumab. We plan to present Phase 1a/1b data in 2021, and a registrational program is expected to begin in the first half of 2021.

Lifirafenib (BGB-283) and BGB-3245, Inhibitors of RAF

Lifirafenib is an investigational novel small molecule inhibitor with RAF monomer and dimer inhibition activities. Lifirafenib has shown antitumor activities in preclinical models and in cancer patients with tumors harboring BRAF V600E mutations, non-V600E BRAF mutations or KRAS/NRAS mutations. We have been developing lifirafenib for the treatment of cancers with aberrations in the mitogen-activated protein kinase ("MAPK"), pathway, including BRAF gene mutations and KRAS/NRAS gene mutations where first generation BRAF inhibitors are not effective. We believe that lifirafenib as monotherapy or in combination with other agents may have potential for treating various malignancies such as melanoma, NSCLC, and endometrial cancer.

Currently approved BRAF inhibitors include Roche's ZELBORAF® (vemurafenib), Novartis' TAFINLAR® (dabrafenib) and Pfizer/Array BioPharma's BRAFTOVI® (encorafenib). The combination of BRAF and MEK inhibitors is approved in patients with BRAF V600E/K mutation-positive metastatic melanoma, such as Novartis' dabrafenib and MEKINIST® (trametinib), Roche's vemurafenib and COTELLIC® (cobimetinib), and Pfizer/Array Biopharma's BRAFTOVI® (encorafenib) and MEKTOVI® (binimetinib). We are aware of several other BRAF inhibitors in clinical development, such as Roche's belvarafenib and Novartis' LXH254.

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BeiGene is working together with SpringWorks Therapeutics, Inc. (“SpringWorks”) in a global clinical collaboration and has initiated a Phase 1b clinical trial (NCT03905148) to evaluate the safety, tolerability, and preliminary efficacy of lifirafenib in combination with SpringWorks’ investigational MEK inhibitor, mirdametinib (PD-0325901), in patients with advanced solid tumors.

In addition to the collaboration, BeiGene and SpringWorks formed a separate company, MapKure, LLC, to develop BGB-3245, an investigational, selective next-generation RAF kinase inhibitor discovered by BeiGene scientists. MapKure has an ongoing Phase 1 clinical trial of BGB-3245 (NCT04249843) in patients with advanced or refractory tumors harboring specific v-RAF murine sarcoma viral oncogene homolog B (“B-RAF”) genetic mutations.

Sitravatinib (MGCD-0516), a Multi-Kinase Inhibitor

In January 2018, we entered into an exclusive license agreement with Mirati Therapeutics, Inc. (“Mirati”) for the development, manufacturing and commercialization of Mirati’s sitravatinib in Asia (excluding Japan and certain other countries), Australia and New Zealand. Sitravatinib is an investigational spectrum-selective kinase inhibitor, which potently inhibits receptor tyrosine kinases, including RET, TAM family receptors (TYRO3, Axl, MER), and split family receptors (VEGFR2, KIT). Sitravatinib is being evaluated by Mirati in multiple clinical trials to treat patients who are refractory to prior immune checkpoint inhibitor therapy, including a Phase 3 trial of sitravatinib in NSCLC initiated in 2019. Sitravatinib is also being evaluated as a single agent in patients with NSCLC, melanoma and other solid tumor types whose tumors harbor specific genetic alterations in the CBL protein. In recent data readouts by Mirati, sitravatinib has demonstrated durable responses in lung cancer patients who progressed after treatment with checkpoint inhibitors. We have an ongoing Phase 1 trial (NCT03666143) of sitravatinib in combination with tislelizumab in various solid tumors in Australia and China, and a Phase 1/2 trial (NCT03941873) is investigating sitravatinib monotherapy and combining sitravatinib with tislelizumab focused on HCC or gastroesophageal junction cancer.

BGB-11417, a Small Molecule Bcl-2 Inhibitor

BGB-11417 is an investigational small molecule Bcl-2 inhibitor. We have completed preclinical and investigational new drug (“IND”) -enabling studies of BGB-11417, which demonstrated potent activity and high selectivity against the pro- apoptotic protein Bcl-2. The molecule appears to be more potent than venetoclax and shows the potential to overcome resistance to venetoclax. Further, it is more selective than venetoclax for Bcl-2 relative to Bcl-xL. Finally, we believe that it is well-positioned to be combined with BRUKINSA®. We have an ongoing Phase 1 trial (NCT04277637) in Australia and the United States to investigate the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of BGB-11417 and its combination with zanubrutinib in patients with mature B-cell malignancies.

BGB-A445, an OX40 Agonist Antibody

BGB-A445 is an investigational agonistic antibody directed to the OX40 antigen. BGB-A445 is a non-ligand competing antibody that does not disrupt OX40 to OX40 ligand engagement. Preclinical experiments showed that our antibody has increasing effectiveness at higher doses versus an antibody that was ligand-competing, which showed falling effectiveness at higher doses. BGB-A445 has also showed in preclinical tests the potential to be combined with several agents, such as tislelizumab, as well as a TLR9 agonist, a PI3K inhibitor, sitravatinib, and chemotherapy. We have an ongoing Phase 1 trial (NCT04215978) of our OX40 antibody in combination with tislelizumab in patients with advanced solid tumors.

Zanidatamab (ZW25), a bispecific HER2 inhibitor

Zanidatamab (ZW25), a novel investigational Azymetric™ bispecific antibody against HER2, is currently in late-stage clinical development with Zymeworks Inc. BeiGene has development and commercial rights to zanidatamab in Asia (excluding Japan), Australia, and New Zealand. We have two clinical studies ongoing with zanidatamab. The first is a phase 1/2 study (NCT04215978) in HER2 positive breast and gastric cancer. The breast cancer arm combines zanidatmab with docetaxel, and the gastric arm combines zanidatamab with our PD-1 inhibitor tislelizumab and chemotherapy. The second study (NCT04466891) is a Phase 2b study in patients with advanced or metastatic HER2-amplified biliary tract cancers (BTC) in which zanidatamab is being used as monotherapy. We expect to initiate a Phase 3 study examining zanidatamab in combination with chemotherapy with and without tislelizumab in HER2 positive gastroesophageal cancer in 2021.

BGB-A333, a PD-L1 Inhibitor

BGB-A333 is an investigational humanized IgG1-variant monoclonal antibody against PD-L1, the ligand of PD-1. We have investigated BGB-A333 as a monotherapy and in combination with other cancer therapies, such as tislelizumab, to treat various cancers. We recently completed a Phase 1 clinical trial (NCT03379259) in Australia to assess the safety and antitumor effect of BGB-A333 alone and in combination with tislelizumab in patients with advanced solid tumors.

BGB-A425, a TIM-3 Inhibitor

BGB-A425 is an investigational humanized IgG1-variant monoclonal antibody against T-cell immunoglobulin and mucin- domain containing-3 ("TIM-3"). We have an ongoing Phase 1/2 trial (NCT03744468) of BGB-A425 in combination with tislelizumab in various solid tumors.

BGB-15025, a Small Molecule HPK1 Inhibitor

BGB-15025 is an investigational small molecule inhibitor of HPK1, which is a key negative feedback regulator of TCR signaling. Inhibition of HPK1 leads to enhanced T-cell activation pre-clinically. In addition, preclinical studies showed that BGB-15025 exhibits combination activity with tislelizumab and has a wide therapeutic window. We plan to initiate clinical studies in the first quarter of 2021.

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OUR PRECLINICAL PROGRAMS

We have a proprietary biology research platform that has allowed us to research and develop both small molecules and biologic molecules. In the last decade, this platform has generated more than 10 clinical stage assets, including two internally- developed molecules that have been approved by regulatory bodies in the United States and China and in China, respectively, with other filings pending globally and planned to be submitted. The platform is a full-process technology system spanning from early discovery to commercialization of oncology medicines based on multiple drug technology platforms that can be applied to oncology and other fields. We have core technology platforms for the development of small molecule and antibody medicines and the manufacturing of our own and potentially other medicines.

We anticipate advancing multiple our preclinical drug candidates into the clinic in the next 12 months. We believe that we have the opportunity to combine tislelizumab with our preclinical candidates to target multiple points in the cancer immunity cycle. We also may seek to develop companion diagnostics that will help identify patients who are most likely to benefit from the use of our medicines and drug candidates.

MANUFACTURING AND SUPPLY

We manufacture our medicines and drug candidates internally and with the help of third-party CMOs. The manufacturing of our medicines and drug candidates is subject to extensive regulations that impose various procedural and documentation requirements governing recordkeeping, manufacturing processes and controls, personnel, quality control, and quality assurance, among others. Our manufacturing facilities and the facilities of the CMOs we use to manufacture our medicines and drug candidates operate under current good manufacturing practice regulations (“GMP”) conditions. GMP regulations are requirements for the production of pharmaceuticals that will be used in humans.

Our Manufacturing Facilities

We have manufacturing facilities for small molecule drugs and large molecule biologics in Suzhou and Guangzhou, China, respectively, to support the commercialization and potential future demand of our internally developed products.

Our manufacturing facility in Suzhou is over 13,000 square meters and consists of a manufacturing base for small molecule drug products with an annual production capacity of about 100 million tablets and a pilot test biologics production facility with 500 liters capacity. In addition, our Suzhou facility produces biologics candidates for clinical supply. It is aligned with the design criteria of the United States, EU, and China regulatory requirements. The facility has a manufacturing license, which is required for the commercial manufacture of zanubrutinib in China.

We are also building a state-of-the-art commercial-scale manufacturing facility of approximately 100,000 square meters in Guangzhou for the manufacturing of large molecule biologics. Phase I and Phase II of the facility have been completed in September 2019 and December 2020, respectively, with biologics capacity of 24,000 liters, and Phase III is expected to be completed by the end of 2021 with capacity of 40,000 liters. Upon completion, the total capacity will reach 64,000 liters. In the future, we intend to expand the production capacity of the Guangzhou facility to exceed 120,000 liters and to reach up to 200,000 liters. We have received a manufacturing license for drug substances and drug products for this facility and approval from NMPA to manufacture commercial product has been received in April 2021. Following regulatory inspection and approval, the first commercial product to be manufactured at this facility is expected to be tislelizumab.

We are also looking to expand our biologics manufacturing capabilities to include a future manufacturing facility in the United States, with multiple sites currently under review.

We also have pilot scale (approximately 140 square meter) manufacturing capabilities at our research facility in Beijing, China, which produces preclinical and clinical trial materials for some of our small molecule drug candidates.

Contract Manufacturing Organizations

We currently rely on, and expect to continue to rely on, a limited number of third-party CMOs and CROs for the production of some drug products and drug substances and the supply of raw materials to meet the commercial, clinical, and preclinical needs of our medicines and drug candidates. We have adopted procedures to ensure that the production qualifications, facilities, and processes of the third-party suppliers engaged by us comply with relevant regulatory requirements and our internal quality and operational guidelines. We select our third-party suppliers carefully by considering a number of factors, including their qualifications, relevant expertise, production capacity, geographic proximity, reputation, track record, product quality, reliability in meeting delivery schedules, and business terms.

We have commercial supply and related agreements with most of our manufacturing service providers. For example, we entered into a commercial supply agreement with Catalent Pharma Solutions, LLC (“Catalent”) to produce BRUKINSA[®] at Catalent’s Kansas City, MO site for clinical and commercial use in the United States and other countries outside of China. We currently source the active pharmaceutical ingredient (“API”) for BRUKINSA[®] from a supplier in China and are in the process of bringing an additional source of supply online outside of China. In addition, we entered into a commercial supply agreement with Boehringer Ingelheim Biopharmaceuticals (China) Ltd. (“Boehringer Ingelheim”) for tislelizumab, which is being manufactured at Boehringer Ingelheim’s facility in Shanghai, China as part of a Marketing Authorization Holder (“MAH”) project pioneered by us and Boehringer Ingelheim. Additionally, our collaboration and license agreement with Novartis includes the right for Novartis to manufacture tislelizumab for the licensed territory, to be managed by Novartis following tech transfer. For our commercial and clinical stage products licensed from Amgen and BMS, we rely on Amgen and BMS and their manufacturing facilities or CMOs outside of China for the supply of those medicines and drug candidates.

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Our agreements with the outsourced suppliers engaged by us generally set out terms, including product quality or service details, technical standards or methods, delivery terms, agreed price and payment, and product inspection and acceptance criteria. We are generally allowed to return any products that fail to meet specified quality standards. Our outsourced suppliers procure raw materials themselves. Typically, outsourced suppliers request settlement of payment within 30 days from the date of invoice. Either party may terminate the agreements by serving notice to the other party under certain circumstances.

We generally obtain raw materials for our manufacturing activities from various suppliers who we believe have sufficient capacity to meet our demands. Raw materials and starting materials used at our facilities in Beijing and Suzhou include active pharmaceutical ingredients custom-made by our third-party CROs and excipients, which are commercially available from well-known vendors that meet the requirements of the relevant regulatory agencies. The core raw materials used in manufacturing at our Guangzhou facility are genetically modified cell lines that we have co-developed and licensed from Boehringer Ingelheim and other third parties.

We typically order raw materials on a purchase order basis and do not enter into long-term, dedicated capacity or minimum supply arrangements. We pay for our purchases of raw materials on credit. Credit periods granted to us by our suppliers generally range from 30 to 60 days. Our suppliers are generally not responsible for any defects in our finished products.

AMGEN COLLABORATION

Collaboration Agreement

On October 31, 2019, our wholly-owned subsidiary, BeiGene Switzerland GmbH (“BeiGene Switzerland”), entered into a Collaboration Agreement with Amgen, which became effective on January 2, 2020 (the “Amgen Collaboration Agreement”). Pursuant to the terms of the Amgen Collaboration Agreement, we are responsible for commercializing Amgen’s oncology products XGEVA[®], BLINCYTO[®] and KYPROLIS[®] in China (excluding Hong Kong, Macao and Taiwan) for a period of five or seven years following each product’s regulatory approval in China, as specified in the Amgen Collaboration Agreement, with the commercialization period for XGEVA[®] commencing following the transition of operational responsibilities for the product. In addition, as specified in the agreement, we have the option to retain one of the three products to commercialize for as long as the product is sold in China. The parties have agreed to equally share profits and losses for the products in China during each product’s commercialization period. After expiration of the commercialization period for each product, the products not retained will be transitioned back to Amgen and we will be eligible to receive tiered mid-single to low-double digit royalties on net sales in China of each product for an additional five years.

Additionally, pursuant to the terms of the Amgen Collaboration Agreement, we and Amgen have agreed to collaborate on the global development and commercialization of a portfolio of Amgen clinical- and late-preclinical-stage oncology pipeline products. Starting from the commencement of the Amgen Collaboration Agreement, we and Amgen will co-fund global development costs, with BeiGene contributing up to US\$1.25 billion worth of development services and cash over the term of the collaboration. We will be eligible to receive tiered mid-single digit royalties on net sales of each product globally outside of China, other than sotorasib (AMG 510), on a product-by-product and country-by-country basis, until the latest of the expiration of the last valid patent claim, the expiration of regulatory exclusivity, or the earlier of eight years after the first commercial sale of such product in the country of sale and 20 years from the date of first commercial sale of such product anywhere in the world.

For each pipeline product that is approved in China, we will have the right to commercialize the product for seven years, with the parties sharing profits and losses for the product in China equally. In addition, we will have the right to retain approximately one of every three approved products, up to a total of six, other than sotorasib (AMG 510), to commercialize for as long as each such product is sold in China. After the expiration of the seven-year commercialization period, each product will be transitioned back to Amgen and we will be eligible to receive tiered mid-single to low-double digit royalties on net sales in China for an additional five years. The parties are subject to specified exclusivity requirements in China and the rest of the world.

We have guaranteed certain obligations of BeiGene Switzerland under the Amgen Collaboration Agreement pursuant to the terms of a separate Guarantee Agreement.

The Amgen Collaboration Agreement contains customary representations, warranties and covenants by the parties. The agreement will continue in effect on a product-by-product basis unless terminated by either party pursuant to its terms. The agreement may be terminated by mutual written consent of the parties, or by either party upon the other party's uncured material breach, insolvency, failure to comply with specified compliance provisions, or subject to a specified negotiation mechanism, certain adverse economic impacts or the failure to meet commercial objectives. In addition, Amgen may terminate the agreement with respect to a pipeline product in the event it suspends development of such pipeline product on specified terms, subject to the parties determining whether to continue development of the pipeline product in China.

Share Purchase Agreement

In connection with the Amgen Collaboration Agreement, pursuant to a share purchase agreement dated October 31, 2019, as amended, by and between BeiGene, Ltd. and Amgen (the "Share Purchase Agreement"), we issued to Amgen 206,635,013 ordinary shares in the form of 15,895,001 ADSs of BeiGene, Ltd. on January 2, 2020, representing approximately 20.5% of our then outstanding shares, for an aggregate purchase price of US\$2.78 billion, or US\$13.45 per ordinary share, or US\$174.85 per ADS.

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Pursuant to the Share Purchase Agreement, Amgen has agreed to (i) a lock-up on sales of its shares until the earliest of (a) the fourth anniversary of the closing, (b) the expiration or termination of the Collaboration Agreement and (c) a change of control of BeiGene, Ltd., (ii) a standstill until the later of (a) the first anniversary of the date as of which it ceases to have the right to appoint a director and (b) the date on which it holds less than 5% of our then outstanding shares, and (iii) a voting agreement to vote its shares on certain matters presented for shareholder approval until the later of (a) the fifth anniversary of the closing and (b) the expiration of the standstill period, all under specified circumstances and as set forth in the agreement. Following the later of (i) the expiration of the lock-up period and (ii) the expiration of the standstill period, Amgen has agreed not to sell shares representing more than 5% of our then outstanding shares in any rolling 12-month period, subject to specified exceptions. In addition, Amgen will have the right to designate an independent director to serve on our board of directors until the earlier of (a) the date on which Amgen holds less than 10% of our then outstanding shares as a result of Amgen's sale of ordinary shares or Amgen's failure to participate in future offerings and (b) the third anniversary of the date of the expiration or termination of the Amgen Collaboration Agreement. Under the terms of the Share Purchase Agreement, Amgen will also have specified registration rights upon expiration of the lock-up. Additionally, we have agreed to use reasonable best efforts to provide Amgen with an opportunity to participate in subsequent new securities offerings upon the same terms and conditions as other purchasers in the offering in an amount needed to allow Amgen to hold up to 20.6% of our shares, subject to applicable law and HKEx rules and other specified conditions.

On March 17, 2020, BeiGene, Ltd. and Amgen entered into an Amendment No. 2 (the "Second Amendment") to the Share Purchase Agreement in order to account for periodic dilution from the issuance of shares by us, which agreement was restated in its entirety on September 24, 2020 (the "Restated Second Amendment"). Pursuant to the Restated Second Amendment, Amgen has an option (the "Direct Purchase Option") to subscribe for additional ADSs in an amount necessary to enable it to increase (and subsequently maintain) its ownership at approximately 20.6% of our outstanding shares. The Direct Purchase Option is exercisable on a monthly basis, but only if Amgen's interest in our outstanding shares at the monthly reference date is less than 20.4%. The Direct Purchase Option (i) is exercisable by Amgen solely as a result of dilution arising from issuance of new shares by us under our equity incentive plans from time to time, and (ii) is subject to annual approval by our independent shareholders each year during the term of the Restated Second Amendment. The exercise period of the Direct Purchase Option commenced on December 1, 2020 and will terminate on the earliest of: (a) the date on which Amgen and its affiliates collectively own less than 20% of the outstanding share capital of the Company as a result of Amgen's sale of shares; (b) at least 60-day advance written notice from either Amgen or the Company that such party wishes to terminate the Direct Purchase Option; or (c) December 1, 2023. The Direct Purchase Option has no vesting period.

NOVARTIS COLLABORATION

On January 11, 2021, our wholly-owned subsidiary, BeiGene Switzerland GmbH, entered into a Collaboration and License Agreement (the “Novartis Collaboration and License Agreement”) with Novartis, pursuant to which Novartis will have the right to develop, manufacture and commercialize tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan (the “Licensed Territory”). The transaction was closed on February 26, 2021.

Under the Novartis Collaboration and License Agreement, we received an upfront cash payment of US\$650 million from Novartis. Additionally, we are eligible to receive up to US\$1.3 billion upon the achievement of regulatory milestones, US\$250 million upon the achievement of sales milestones, and tiered royalties based on percentages of annual net sales of tislelizumab in the Licensed Territory ranging from the high-teens to high-twenties, with customary reductions in specified circumstances.

Royalties are payable on a country-by-country basis from the time of the first commercial sale until the latest of the expiration of the last valid patent claim, the expiration of regulatory exclusivity, or 10 years after the first commercial sale of tislelizumab in the country of sale.

Under the Novartis Collaboration and License Agreement, we and Novartis have agreed to jointly develop tislelizumab in the Licensed Territory, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals. In addition, both companies may conduct clinical trials to explore potential combinations of tislelizumab with other cancer treatments. We will be responsible for funding the ongoing clinical trials of tislelizumab, and Novartis has agreed to fund any new registrational, bridging, or post-marketing studies in the Licensed Territory. Subject to specified conditions, both parties have agreed to jointly fund other new clinical trials in the Licensed Territory agreed by the parties, provided that each party will be responsible for funding clinical trials evaluating tislelizumab in combination with its own- or third-party cancer treatments. We will initially be responsible for supplying tislelizumab to Novartis, with Novartis having the right to conduct manufacturing for its use in the Licensed Territory after successful transfer of the manufacturing process. In addition, we have an option to co-detail the product in the United States, Canada and Mexico, on an indication-by-indication basis, funded in part by Novartis. Each party retains the worldwide right to commercialize its propriety products in combination with tislelizumab.

The Novartis Collaboration and License Agreement contains customary representations, warranties and covenants by the parties. Unless earlier terminated, the agreement will expire on a country-by-country basis upon expiration of the royalty term in such country and in its entirety upon the expiration of all applicable royalty terms in all countries in the Licensed Territory. We may terminate the agreement in its entirety upon written notice (i) if Novartis challenges the licensed BeiGene patents, or if Novartis files a biologics license application for its anti-PD-1 antibody, spartalizumab, in the Licensed Territory, and we do not elect to include spartalizumab as a licensed product under the agreement or Novartis does not divest the product candidate, in which case Novartis would pay us a specified termination fee. The agreement may be terminated by Novartis upon 120 days’ prior written notice if delivered before first commercial sale or 180 days’ prior written notice if delivered following first commercial sale of tislelizumab in the Licensed Territory, or by either party upon the other party’s bankruptcy or uncured material breach.

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CELGENE LICENSE AND SUPPLY AGREEMENT

On July 5, 2017, we and Celgene Logistics Sàrl, now a wholly-owned subsidiary of BMS, entered into a License and Supply Agreement, which we refer to as the China License Agreement and which became effective on August 31, 2017, pursuant to which we were granted the right to exclusively distribute and promote BMS's approved cancer therapies, REVLIMID®, VIDAZA® and ABRAXANE® in China, excluding Hong Kong, Macau and Taiwan. In addition, if Celgene decides to commercialize a new oncology product through a third party in the licensed territory during the first five years of the term, we have a right of first negotiation to obtain the right to commercialize the product, subject to certain conditions. We subsequently assigned the agreement to our wholly-owned subsidiary, BeiGene Switzerland.

The term of the China License Agreement is 10 years and may be terminated by either party upon written notice in the event of uncured material breach or bankruptcy of the other party, or if the underlying regulatory approvals for the covered products are revoked. BMS also has the right to terminate the agreement with respect to REVLIMID® at any time upon written notice to us under certain circumstances.

The China License Agreement contains customary representations and warranties and confidentiality and mutual indemnification provisions.

INTELLECTUAL PROPERTY

The proprietary nature of, and protection for, our medicines, drug candidates, and their methods of use are an important part of our strategy to develop and commercialize novel medicines, as described in more detail below. We have filed patent applications and obtained patents in the United States and other countries and regions, such as China and Europe, relating to our medicines and certain of our drug candidates, and are pursuing additional patent protection for them and for our other drug candidates and technologies. We rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our manufacturing processes. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and support our development programs.

As of January 31, 2021, we owned 30 issued U.S. patents, 14 issued China patents, a number of pending U.S. and China patent applications, and corresponding patents and patent applications internationally. In addition, we owned pending international patent applications under the Patent Cooperation Treaty ("PCT"), which we plan to file nationally in the United States and other jurisdictions, as well as additional priority PCT applications. With respect to any issued patents in the United States and Europe, we may be entitled to obtain a patent term extension to extend the patent expiration date, provided that we meet the applicable requirements for obtaining such patent term extensions. For example, in the United States, we can apply for a patent term extension of up to five years for one of the patents covering a drug product once the product is approved by the FDA. The exact duration of the extension depends on the time that we spend in clinical studies as well as getting approval from the FDA. In China, the Amended PRC Patent Law, which will become effective on June 1, 2021, provides a patent term extension of up to five years, similar to the United States.

The key patents for our medicines and late-stage clinical drug candidates as of January 31, 2021, are summarized below:

Molecule	Territory	General Subject Matter	Expiration ¹
BRUKINSA® (Zanubrutinib)	U.S.	Compound and composition	2034
	U.S.	Use for the treatment of autoimmune diseases	2034
	U.S.	Use for the treatment of B-cell proliferative disorder	2034
	China	Compound and composition	2034
Tislelizumab	U.S.	Antibodies	2033
	U.S.	Use for the treatment of cancer	2033
	U.S.	Antibodies and use for the treatment of cancer	2033
	U.S.	Antibodies	2033
	China	Antibodies	2033
	China	Antibodies	2033
	China	Antibodies	2033
	China	Antibodies	2033
Pamiparib	U.S.	Compound and composition	2031
	U.S.	Compound and composition	2031
	U.S.	Use for the treatment of cancer	2031
	U.S.	Compositions	2031
	U.S.	Crystalline forms	2036
	U.S.	Crystalline forms	2038
	China	Compound and composition	2031
	China	Use for the treatment of cancer	2031

(1) The expected expiration does not include any additional term for patent term extensions.

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We have three in-licensed medicines in China from Bristol Myers Squibb company (“BMS”). The key patents for them as of January 31, 2021 are summarized below:

Product	Territory	General Subject Matter	Expiration
REVLIMID® (lenalidomide)	China	Use for the treatment of multiple myeloma	2023
	China	Use for the treatment of multiple myeloma	2023
	China	Use for the treatment of multiple myeloma	2023
	China	Use for the treatment of multiple myeloma	2023
VIDAZA® (azacitidine)	China	No patent	N/A
ABRAXANE® (a nanoparticle albumin-bound paclitaxel)	China	Use for the treatment of cancer	2026
	China	Use for the treatment of cancer	2031

Under our collaboration with Amgen, we have the right to commercialize in China two medicines and, upon approval in China, one late-stage product candidate. The key patents necessary for these products in China are summarized below:

Product	Territory	General Subject Matter	Expiration
XGEVA® (denosumab)	China	Antibodies	2022
BLINCYTO® (blinatumomab)	China	No patent	N/A
KYPROLIS® (carfilzomib)	China	Compound and Composition	2025

Although various extensions may be available, the life of a patent and the protection it affords, is limited. REVLIMID®, VIDAZA® and ABRAXANE® face competition from generic medications, and we may face similar competition for our medicines and any approved drug candidates even if we successfully obtain patent protection. The scope, validity or enforceability of our or our collaborators’ patents may be challenged in court or other authorities, and we or they may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. For example, the China patents for KYPROLIS® (carfilzomib) are currently in an invalidation proceeding brought by another company. Additionally, in China, the NMPA may approve a generic version of a brand-name medicine that still has patent protection, such as has occurred with REVLIMID®. Under our license agreements with BMS and Amgen, they retain the responsibility for, but are not obligated, to prosecute, defend and enforce the patents for these in-licensed products. As such, any issued patents may not protect us from generic or biosimilar competition for these medicines.

The term of individual patents may vary based on the countries in which they are obtained. In most countries in which we file, including the United States and China, the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the United States Patent and Trademark Office (the "USPTO"), in excess of a patent applicant's own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost in obtaining FDA regulatory approval. However, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. In China, the Amended PRC Patent Law, which will become effective on June 1, 2021, provides both patent term adjustment and patent term extension, similar to the United States.

In certain foreign jurisdictions similar extensions as compensation for regulatory delays are also available. The actual protection afforded by a patent varies on a claim by claim and country by country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

We may rely, in some circumstances, on trade secrets and unpatented know-how to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with employees, consultants, scientific advisors and contractors and invention assignment agreements with our employees. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Additionally, we currently own a number of registered trademarks and pending trademark applications. We currently have registered trademarks for BeiGene, our corporate logo and product names and logos in the United States, China, the EU and other jurisdictions, and we are seeking further trademark protection for BeiGene, our corporate logo, product names and logos, and other marks in jurisdictions where available and appropriate.

RISK FACTORS

The following section includes the most significant factors that we believe may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Annual Report, including our financial statements and the related notes and the “Management Discussion and Analysis” section of this annual report before deciding to invest in our ADSs or ordinary shares. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our ADSs and ordinary shares could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Commercialization of Our Medicines and Drug Candidates

Our medicines may fail to achieve and maintain the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

Our medicines may fail to achieve and maintain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current cancer treatments like chemotherapy and radiation therapy are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our medicines. In addition, physicians, patients and third-party payors may prefer other novel or generic products to ours. If our medicines do not achieve and maintain an adequate level of acceptance, the sales of our medicines may be limited and we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our medicines will depend on a number of factors, including:

- the clinical indications for which our medicines are approved;
- physicians, hospitals, cancer treatment centers, and patients considering our medicines as safe and effective treatments;
- government agencies, professional societies, practice management groups, insurance carriers, physicians’ groups, private health and science foundations, and organizations publishing guidelines and recommendations recommending our medicines and reimbursement;
- the potential and perceived advantages of our medicines over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities;
- limitations or warnings contained in the labeling approved by regulatory authorities;

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- the timing of market introduction of our medicines as well as competitive medicines;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities; and
- the effectiveness of our sales and marketing efforts.

If any medicines that we commercialize fail to achieve and maintain market acceptance among physicians, patients, hospitals, third-party payors, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our medicines achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our medicines, are more cost effective or render our medicines obsolete.

We have limited experience in launching and marketing our internally developed and in-licensed medicines. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our medicines, we may not be able to generate substantial product sales revenue.

We first became a commercial-stage company in 2017, when we entered into a license and supply agreement with Celgene Logistics Sàrl, now a Bristol Myers Squibb company (“BMS”), to commercialize BMS’s approved cancer therapies, REVLIMID®, VIDAZA® and ABRAXANE® in the People’s Republic of China (“PRC” or “China”), excluding Hong Kong, Macau and Taiwan, and acquired BMS’s commercial operations in China, excluding certain functions.

In October 2019, we entered into a strategic collaboration with Amgen for its commercial-stage oncology products XGEVA®, BLINCYTO®, KYPROLIS®, and a portfolio of clinical- and late-preclinical-stage oncology pipeline products, which became effective on January 2, 2020. XGEVA® was approved in China in July 2020, while BLINCYTO® was approved in China in December 2020.

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We received the first new drug approval for one of our internally developed medicines in November 2019, for our BTK inhibitor BRUKINSA[®] (zanubrutinib), in the United States for the treatment of certain patients with mantle cell lymphoma (“MCL”). We have since received approvals for BRUKINSA[®] in China for the treatment of certain patients with MCL, chronic lymphocytic leukemia (“CLL”) or small lymphocytic lymphoma (“SLL”) (June 2020); and for tislelizumab in China for the treatment of certain patients with classical Hodgkin’s Lymphoma (“cHL”) (December 2019), urothelial carcinoma (“UC”), a form of bladder cancer (April 2020), and squamous non-small cell lung cancer (“NSCLC”) (January 2021).

We continue to build our salesforce in the United States and China to commercialize our internally developed and in-licensed medicines and any additional medicines or drug candidates that we may develop or in-license, which will require significant capital expenditures, management resources and time.

We have limited experience in commercializing our internally developed and in-licensed medicines. We have limited experience in building and managing a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, or managing distributors and a sales force for our medicines. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. As a result, our ability to successfully commercialize our medicines may involve more inherent risk, take longer, and cost more than it would if we were a company with substantial experience in launching medicines.

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

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

RISK FACTORS

The market opportunities for our medicines may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

In markets with approved therapies, we have and expect to initially seek approval of our drug candidates as a later stage therapy for patients who have failed other approved treatments. Subsequently, for those medicines that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first-line therapy, but there is no guarantee that our medicines and drug candidates, even if approved, would be approved for second-line or first-line therapy.

Our projections of both the number of people who have the diseases we are targeting, as well as the subset of people with these diseases in a position to receive later stage therapy and who have the potential to benefit from treatment with our medicines and drug candidates, are based on our beliefs and estimates and may prove to be inaccurate or based on imprecise data. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our medicines and drug candidates may be limited or may not be amenable to treatment with our medicines and drug candidates. Even if we obtain significant market share for our medicines and drug candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first- or second- line therapy.

We face substantial competition, which may result in others discovering, developing, or commercializing competing medicines before or more successfully than we do.

The development and commercialization of new medicines is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of medicines for the treatment of cancer for which we are commercializing our medicines or developing our drug candidates. For example, both BRUKINSA® and tislelizumab face substantial competition, and some of our products face or are expected to face competition from generic therapies. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize medicines that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than our medicines. Our competitors also may obtain approval from the FDA, NMPA, European Medicines Agency (“EMA”) or other comparable regulatory authorities for their medicines more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and or slow our regulatory approval.

RISK FACTORS

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

If we are not able to continue to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our medicines and drug candidates, and our ability to generate revenue will be materially impaired.

Before obtaining regulatory approvals for the commercial sale of any drug candidate for a target indication, we must demonstrate in preclinical studies and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA, that the drug candidate is safe and effective, or the biologic drug candidate is safe, pure, and potent, for use for that target indication and that the manufacturing facilities, processes and controls are adequate. In addition to preclinical and clinical data, the new drug application (“NDA”) or biologics license application (“BLA”) must include significant information regarding the chemistry, manufacturing and controls (“CMC”) for the drug candidate. Obtaining approval of an NDA or BLA is a lengthy, expensive and uncertain process, and approval may not be obtained. If we submit an NDA or BLA to the FDA, the FDA decides whether to accept or reject the submission for filing. We cannot be certain that a submission will be accepted for filing and review by the FDA.

We have limited experience in obtaining regulatory approval for our drug candidates. For example, we have limited experience in preparing the required materials for regulatory submission and navigating the regulatory approval process. As a result, our ability to successfully submit an NDA or BLA and obtain regulatory approval for our drug candidates may involve more inherent risk, take longer, and cost more than it would if we were a company with substantial experience in obtaining regulatory approvals.

Regulatory authorities outside of the United States, such as the NMPA and EMA, also have requirements for approval of medicines for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our drug candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals outside of the United States could require additional nonclinical studies or clinical trials, which could be costly and time consuming. The regulatory approval process outside of the United States may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain regulatory approvals on a timely basis, if at all.

RISK FACTORS

The process to develop, obtain regulatory approval for and commercialize drug candidates is long, complex and costly in the United States, China, Europe and other regions, and approval is never guaranteed. Even if our drug candidates were to successfully obtain approval from regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical trials or surveillance as conditions of approval. Following any approval for commercial sale of our drug candidates, certain changes to the medicine, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by regulatory authorities. Also, regulatory approval for any of our drug candidates may be withdrawn. If we are unable to obtain regulatory approval for our drug candidates in one or more jurisdictions, or any approval contains significant limitations, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed.

We have limited manufacturing capability and must rely on third-party manufacturers to manufacture our commercial products and clinical supplies, and if they fail to meet their obligations, the development and commercialization of our medicines and drug candidates could be adversely affected.

We have limited manufacturing capabilities and experience. Our medicines and drug candidates are composed of multiple components and require specialized formulations for which scale-up and manufacturing can be difficult. We have limited experience in such scale-up and manufacturing, requiring us to depend on a limited number of third parties, who may not be able to deliver in a timely manner, or at all. In order to develop medicines and drug candidates, apply for regulatory approvals, and commercialize our medicines and drug candidates, we will need to develop, contract for, or otherwise arrange for the necessary manufacturing capabilities. There are risks inherent in pharmaceutical manufacturing that could affect the ability of our contract manufacturers to meet our delivery time requirements or provide adequate amounts of material to meet our needs.

We currently rely on third-party manufacturers to produce commercial quantities of the internally developed and in-licensed medicines we are marketing. In addition, if any of our other drug candidates or in-licensed medicines or drug candidates becomes approved for commercial sale, we will need to expand our internal capacity or establish additional third-party manufacturing capacity. Manufacturing partner requirements may require us to fund capital improvements, perhaps on behalf of third parties, to support the scale-up of manufacturing and related activities. We may not be able to establish scaled manufacturing capacity for an approved medicine in a timely or economic manner, if at all. If we or our third-party manufacturers are unable to provide commercial quantities of such an approved medicine, we will have to successfully transfer manufacturing technology to a different manufacturer. Engaging a new manufacturer or modifying manufacturing processes and procedures for such an approved medicine could require us to conduct comparative studies or utilize other means to determine bioequivalence of the new and prior manufacturers' products or of products manufactured by the old and new processes and procedures, which could delay or prevent our ability to commercialize such an approved medicine. If we or any of these manufacturers is unable or unwilling to increase its manufacturing capacity or if we are unable to establish alternative arrangements on a timely basis or on acceptable terms, the development and commercialization of such an approved medicine may be delayed or there may be a shortage in supply. Any inability to manufacture our medicines, drug candidates, in-licensed medicines and drug candidates or future approved medicines in sufficient quantities when needed could seriously harm our business and our financial results.

RISK FACTORS

Manufacturers of our medicines must comply with good manufacturing practice (“GMP”) requirements enforced by the FDA, NMPA, EMA and other comparable foreign health authorities through facilities inspection programs. These requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our approved medicines may be unable to comply with these GMP requirements and with other FDA, NMPA, EMA, state, and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to a manufacturer’s failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our medicines, which would seriously harm our business. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension was based on inspection findings at BMS’s contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of ABRAXANE® in China. As a result, there has been a disruption in ABRAXANE® supply in China and we are working with BMS to restore supply as soon as possible, including through BMS’s remediation efforts at its current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE® from the volume-based procurement list due to the NMPA’s decision to suspend the importation, sales and use of ABRAXANE®. We do not know when the NMPA suspension of ABRAXANE® will be lifted and we will be able to re-commence sales of ABRAXANE®. As such, we do not expect revenue from ABRAXANE® until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE® and qualified medicine is manufactured and available for sale in China.

If we or any third parties with which we may collaborate to market and sell our medicines are unable to achieve and maintain coverage and adequate level of reimbursement, our commercial success and business operations could be adversely affected.

Our ability or the ability of any third parties with which we collaborate to commercialize our medicines successfully will depend in part on the extent to which reimbursement for these medicines is available on adequate terms, or at all, from government health administration authorities, private health insurers and other organizations. In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Sales of our drugs will depend substantially, both domestically and abroad, on the extent to which the costs of our medicines will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Without third-party payor reimbursement, patients may not be able to obtain or afford prescribed medications. Third-party payors also are seeking to encourage the use of generic or biosimilar products or entering into sole source contracts with healthcare providers, which could effectively limit the coverage and level of reimbursement for our medicines and have an adverse impact on the market access or acceptance of our medicines. In addition, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians’ willingness and ability to prescribe our products.

RISK FACTORS

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

In the United States, no uniform policy of coverage and reimbursement for drugs exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a drug from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our medicines on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare and Medicaid Services (the "CMS"). They decide whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is: a covered benefit under its health plan; safe, effective and medically necessary; appropriate for the specific patient; cost-effective; and neither experimental nor investigational.

Coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable regulatory authorities in other countries. Even if we obtain coverage for a given medicine, the resulting reimbursement rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our drugs. Patients are unlikely to use our medicines unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of the drug. Because some of our medicines and drug candidates have a higher cost of goods than conventional therapies and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price ("ASP") and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

RISK FACTORS

In China, drug prices are typically lower than in the United States and Europe, and until recently, the market has been dominated by generic drugs. Government authorities regularly review the inclusion or removal of drugs from China's National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance, or the National Reimbursement Drug List (the "NRDL"), or provincial or local medical insurance catalogues for the National Medical Insurance Program, and the tier under which a drug will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those drugs. There can be no assurance that our medicines and any approved drug candidates will be included in the NRDL or provincial reimbursements lists, or if they are, that they will be included at a price that allows us to be commercially successful. Products included in the NRDL have typically been generic and essential drugs. Innovative drugs similar to our medicines and drug candidates have historically been more limited on their inclusion in the NRDL due to the affordability of the government's Basic Medical Insurance, although this has been changing in recent years. For example, BRUKINSA[®], tislelizumab and XGEVA[®] were included in the NRDL, effective March 1, 2021. While we expect that the demand for these medicines will increase with inclusion in the NDRL, there can be no assurance that demand will increase or, to the extent that demand increases, that such increases will be sufficient to offset the reduction in the prices and our margins, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

RISK FACTORS

We intend to seek approval to market our medicines and drug candidates in the United States, China, Europe and in other jurisdictions. In some countries, such as those in the EU, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Market acceptance and sales of our medicines will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our medicines and may be affected by existing and future health care reform measures.

We may be subject to anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations in the United States and other jurisdictions, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished sales.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. Our operations are subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act (“FCA”), and physician payment sunshine laws and regulations. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we are subject to patient privacy regulation by both the federal government and the states in which we conduct our business.

Additionally, we are subject to state equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply to healthcare services reimbursed by any third-party payor, not just governmental payors, but also private insurers. These laws are enforced by various state agencies and through private actions. Some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or other voluntary industry codes of conduct that restrict the payments made to healthcare providers and other potential referral sources. Several states and local laws also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state, require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and require the registration of pharmaceutical sales representatives. State laws also govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

RISK FACTORS

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal FCA as well as under the false claims laws of several states. Neither the U.S. government nor the U.S. courts have provided definitive guidance on the applicability of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, individual imprisonment, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws.

In addition, the approval, commercialization, and other activities for our medicines and drug candidates outside the United States subjects us to non-U.S. equivalents of the healthcare laws such as those mentioned above, among other non-U.S. laws. As with the state equivalents mentioned above, some of these non-U.S. laws may be broader in scope. Data privacy and security laws and regulations in non-U.S. jurisdictions may also be more stringent than those in the United States, such as the General Data Protection Regulation, or GDPR.

If any of the physicians or other providers or entities with whom we do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may adversely affect our business.

RISK FACTORS

We have operations in the United States, China, Europe and Australia and plan to expand in these and new markets on our own or with collaborators, which exposes us to risks of conducting business in international markets.

We are currently developing and commercializing or plan to commercialize our products in international markets, including China, Europe and other markets outside of the United States, either on our own or with third party collaborators or distributors. Our international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into collaboration or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the acquisition or development of drug candidates;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potential third-party patent rights or potentially reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements, including the loss of normal trade status between China and the United States;
- economic weakness, including inflation;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- currency fluctuations, which could result in increased operating expenses and reduced revenue;
- workforce uncertainty and labor unrest;
- failure of our employees and contracted third parties to comply with Office of Foreign Asset Control rules and regulations and the Foreign Corrupt Practices Act and other anti-bribery and corruption laws; and
- business interruptions resulting from geo-political actions, including trade disputes, war and terrorism, disease or public health pandemics, such as COVID-19, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

RISK FACTORS

These and other risks may materially adversely affect our ability to attain or sustain revenue in international markets.

The illegal distribution and sale by third parties of counterfeit versions of our medicines or stolen products could have a negative impact on our reputation and business.

Third parties might illegally distribute and sell counterfeit or unfit versions of our drugs, which do not meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit drug may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit drugs sold under our or our collaborators' brand name(s). In addition, thefts of inventory at warehouses, plants or while in- transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

Risks Related to Clinical Development and Regulatory Approval of Our Medicines and Drug Candidates

We depend substantially on the success of the clinical development of our medicines and drug candidates. If we are unable to successfully complete clinical development, obtain regulatory approvals and commercialize our medicines and drug candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business depends on the successful development, regulatory approval and commercialization of our medicines and other drug candidates we may develop. We have invested a significant portion of our efforts and financial resources in the development of our medicines and drug candidates. The success of our medicines and drug candidates depends on several factors, including:

- successful enrollment in, and completion of, clinical trials, as well as completion of preclinical studies;
- favorable safety and efficacy data from our clinical trials and other studies;
- receipt of regulatory approvals;
- the performance by contract research organizations ("CROs") or other third parties we may retain of their duties to us in a manner that complies with our protocols and applicable laws and that protects the integrity of the resulting data;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity;

RISK FACTORS

- ensuring that we do not infringe, misappropriate or otherwise violate the valid patent, trade secret or other intellectual property rights of third parties;
- successfully launching our medicines and drug candidates, if and when approved;
- obtaining favorable reimbursement from third-party payors for our medicines and drug candidates, if and when approved;
- competition with other products;
- continued acceptable safety profile following regulatory approval; and
- manufacturing or obtaining sufficient supplies of our medicines, drug candidates and any competitor drug products that may be necessary for use in clinical trials for evaluation of our drug candidates and commercialization of our medicines.

If we do not achieve and maintain one or more of these factors in a timely manner or at all, we could experience significant delays in our ability or be unable to obtain additional regulatory approvals for and/or to successfully commercialize our medicines and drug candidates, which would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials, and initial or interim results of a trial may not be predictive of the final results. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same drug candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, including genetic differences, patient adherence to the dosing regimen and other trial protocol elements and the rate of dropout among clinical trial participants. In the case of any trials we conduct, results may differ from earlier trials due to the larger number of clinical trial sites and additional countries involved in such trials. A number of companies in our industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be favorable.

RISK FACTORS

Even if our future clinical trial results show favorable efficacy and durability of anti-tumor responses, not all patients may benefit. For certain drugs, including checkpoint inhibitors, and in certain indications, it is likely that the majority of patients may not respond to the agents at all, some responders may relapse after a period of response, and certain tumor types may appear particularly resistant.

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

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including but not limited to: regulators, institutional review boards (“IRBs”), or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; our inability to reach agreements on acceptable terms with CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly; manufacturing issues, including problems with manufacturing, supply quality, compliance with GMP, or obtaining sufficient quantities of a drug candidate for use in a clinical trial or for commercialization; clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs; the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate; our third-party contractors, including clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks; regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including noncompliance with regulatory requirements; the cost of clinical trials of our drug candidates may be greater than we anticipate; and the supply or quality of our medicines and drug candidates, companion diagnostics or other materials necessary to conduct clinical trials of our drug candidates or commercialization of our medicines may be insufficient or inadequate.

RISK FACTORS

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

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

Significant clinical trial, manufacturing or regulatory delays may also increase our development costs and could shorten any periods during which we have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do. This could impair our ability to commercialize our drug candidates and may harm our business and results of operations.

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

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We have and may continue to experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including the size and nature of the patient population and the patient eligibility criteria defined in the protocol, competition from competing companies, and natural disasters or public health epidemics, such as the COVID-19 pandemic.

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

RISK FACTORS

Risks Related to Extensive Government Regulation

All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated, and we may face difficulties in complying with or be unable to comply with such regulations, which could have a material adverse effect on our business.

All jurisdictions in which we conduct or intend to conduct our pharmaceutical-industry activities regulate these activities in great depth and detail. We are currently focusing our activities in the major markets of the United States, China, Europe, and other select countries. These geopolitical areas all strictly regulate the pharmaceutical industry, and in doing so they employ broadly similar regulatory strategies, including regulation of product development and approval, manufacturing, and marketing, sales and distribution of products. However, there are differences in the regulatory regimes—some minor, some significant—that make for a more complex and costly regulatory compliance burden for a company like ours that plans to operate in each of these regions.

The process of obtaining regulatory approvals and compliance with appropriate laws and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the product development process, approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. The failure to comply with these regulations could have a material adverse effect on our business. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE[®] in China supplied to us by BMS. This suspension was based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of ABRAXANE[®] in China. As a result, there has been a disruption in ABRAXANE[®] supply in China and we are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE[®] from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE[®]. Additionally, although we have obtained regulatory approvals of our medicines, regulatory authorities could suspend or withdraw these approvals. In order to market approved products in any given jurisdiction, we must comply with numerous and varying regulatory requirements of such jurisdiction regarding safety, efficacy and quality. In any event, the receipt of regulatory approval does not assure the success of our commercialization efforts for our medicines.

RISK FACTORS

The approval processes of regulatory authorities in the United States, China, Europe and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA, the NMPA, the EMA, and other comparable regulatory authorities is unpredictable and typically takes many years following the commencement of preclinical studies and clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities.

Our drug candidates could be delayed or fail to receive regulatory approval for many reasons, including:

- failure to begin or complete clinical trials due to disagreements with regulatory authorities;
- failure to demonstrate that a drug candidate is safe and effective or that a biologic candidate is safe, pure, and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval;
- reporting or data integrity issues related to our clinical trials;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- changes in approval policies or regulations that render our preclinical and clinical data insufficient for approval or require us to amend our clinical trial protocols;
- regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, or questions regarding interpretations of data and results and the emergence of new information regarding our drug candidates or other products;
- failure to satisfy regulatory conditions regarding endpoints, patient population, available therapies and other requirements for our clinical trials in order to support marketing approval on an accelerated basis or at all;
- our failure to conduct a clinical trial in accordance with regulatory requirements or our clinical trial protocols; and
- clinical sites, investigators or other participants in our clinical trials deviating from a trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial.

The FDA, NMPA, EMA or a comparable regulatory authority may require more information, including additional preclinical, CMC, and/or clinical data, to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program.

RISK FACTORS

Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

If we experience delays in the completion of, or the termination of, a clinical trial of any of our drug candidates, the commercial prospects of that drug candidate will be harmed, and our ability to generate product revenues from that drug candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug development and approval process, and jeopardize our ability to commence product sales and generate revenues for that candidate. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

Our development activities and regulatory filings also could be harmed or delayed by a shutdown of the U.S. government, including the FDA, or other governments and regulatory authorities. As of June 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. In July 2020, FDA noted that it is continuing to expedite oncology product development with its staff teleworking full-time. However, FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

Our medicines and any future approved drug candidates will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our medicines and drug candidates.

Our medicines and any additional drug candidates that are approved will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-marketing information, including both federal and state requirements in the United States and requirements of comparable regulatory authorities in China, Europe and other regions. As such, we and our collaborators will be subject to ongoing review and periodic inspections to assess compliance with applicable post-approval regulations. Additionally, to the extent we want to make certain changes to the approved medicines, product labeling, or manufacturing processes, we will need to submit new applications or supplements to regulatory authorities for approval.

RISK FACTORS

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, NMPA, EMA and comparable regulatory authority requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to GMP regulations. As such, we and our contract manufacturers are and will be subject to continual review and inspections to assess compliance with GMP and adherence to commitments made in any NDA or BLA, other marketing application, and previous responses to any inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The failure to comply with these requirements could have a material adverse effect on our business. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE® in China. As a result, there has been a disruption in ABRAXANE® supply in China and we are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply.

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

The FDA, NMPA, EMA or comparable regulatory authorities may seek to impose a consent decree or withdraw marketing approval if compliance with regulatory requirements is not maintained or if problems occur after the drug reaches the market. Later discovery of previously unknown problems with our medicines or drug candidates or with our drug's manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our medicines, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, untitled or warning letters, or holds on clinical trials;
- refusal by the FDA, NMPA, EMA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals or withdrawal of approvals;

RISK FACTORS

- product seizure or detention, or refusal to permit the import or export of our medicines and drug candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA, NMPA, EMA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for their approved indications and for use in accordance with the provisions of the approved label. The FDA, NMPA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. The policies of the FDA, NMPA, EMA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, particularly in China, where the regulatory environment is constantly evolving. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any regulatory approval that we may have obtained and we may not achieve or sustain profitability.

In addition, if we obtain accelerated approval or conditional approval of any of our drug candidates, as we have done with the initial approval of BRUKINSA® in the United States and China and certain approvals of tislelizumab in China, we will be required to conduct a confirmatory study to verify the predicted clinical benefit and may also be required to conduct post-marketing safety studies. Other comparable regulatory authorities may have similar requirements. The results from the confirmatory study may not support the clinical benefit, which could result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval.

Even if we are able to commercialize our medicines and any approved drug candidates, the medicines may become subject to unfavorable pricing regulations or third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower. The EU provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

RISK FACTORS

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact our revenues and results of operations.

Our ability to commercialize our medicines successfully also will depend in part on the extent to which reimbursement for these medicines and related treatments will be available on adequate terms, or at all, from government health administration authorities, private health insurers and other organizations. See “— Risks Related to Commercialization of Our Medicines and Drug Candidates — If we or any third parties with which we may collaborate to market and sell our medicines or drugs candidates are unable to achieve and maintain coverage and adequate level of reimbursement for medicines drug and drug candidate our commercial success and business operations could be adversely affected.”

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any medicine that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price (“ASP”) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Furthermore, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries, proposed bills or announced plans intended to, among other things, bring more transparency to drug pricing, set patient spending caps, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer’s patient programs, reform government program reimbursement methodologies for drug products, allow import of lower-priced drugs from other countries, and set prices based on international reference pricing in other countries. While some proposed measures may require additional authorization to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. We cannot be sure whether additional changes will be enacted, or whether existing regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be.

RISK FACTORS

In China, the government launched a national program for volume-based, centralized drug procurement with minimum quantity commitments in an attempt to negotiate lower prices from drug manufacturers and reduce the price of drugs. Under the program, one of the key determining factors for a successful bid is the price. The government will award a contract to the lowest bidders who are able to satisfy the quality and quantity requirements. The successful bidders will be guaranteed a sale volume for at least a year. A volume guarantee gives the winner an opportunity to gain or increase market share. The volume guarantee is intended to make manufacturers more willing to cut their prices to win a bid. It may also enable manufacturers to lower their distribution and commercial costs. Many types of drugs are covered under the program, including drugs made by international pharmaceutical companies and generics made by domestic Chinese manufacturers. For example, in January 2020, ABRAXANE® and its generic forms were included in the program. We won the bid and became one of the three companies who were awarded a government contract, with a price for sales of ABRAXANE® under the government contract that would have been significantly lower than the price that we had been charging. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE® from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE®, which has adversely impacted our business and results of operations. In August 2020, VIDAZA® and its generic forms were included for bidding in the program. We did not win the bid for VIDAZA®, which has resulted in the drug being restricted from use in public hospitals, which account for a large portion of the market, and a decline in sales revenue. Moreover, the program may change how generic drugs are priced and procured in China and is likely to accelerate the replacement of originator drugs with generics. We cannot be sure whether there will be any changes to the program in the future. The implementation of the program may negatively impact our existing commercial operations in China as well as our strategies on how to commercialize our drugs in China, which could have a material adverse effect on our business, financial condition and results of operations.

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

We intend to seek approval to market our drug candidates in the United States, China, Europe and in other jurisdictions. In some non-U.S. countries, for example those in the EU, the pricing of drugs and biologics is subject to governmental control, which can take considerable time even after obtaining regulatory approval. Market acceptance and sales of our medicines will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for drugs and may be affected by existing and future health care reform measures.

RISK FACTORS

Although China recently adopted changes to its patent law to include patent term extension and an early resolution mechanism for pharmaceutical patent disputes starting in June 2021, key provisions of the law remain unclear and/or subject to implementing regulations. The absence of effective regulatory exclusivity for pharmaceutical products in China could further increase the risk of early generic or biosimilar competition with our medicines in China.

In the United States, a law commonly referred to as “Hatch-Waxman” provides the opportunity for patent-term restoration of up to five years to reflect patent term lost during certain portions of product development and the FDA regulatory review process. The Hatch-Waxman law also provides for patent linkage, pursuant to which FDA will stay approval of certain follow-on new drug applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, for a period of up to 30 months. Finally, the Hatch-Waxman law provides for regulatory exclusivity that can prevent submission or approval of certain follow-on marketing applications. For example, U.S. law provides a five-year period of exclusivity to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical trials to obtain approval for the modification. Similarly, the Orphan Drug Act provides seven years of market exclusivity for certain drugs to treat rare diseases. These provisions, which are designed to promote innovation, can prevent competing products from entering the market for a certain period of time after marketing approval for the innovative product.

In China, however, laws on patent term extension, patent linkage, and data exclusivity (referred to as regulatory data protection) are still developing. Therefore, a lower-cost generic drug can emerge onto the market much more quickly. Chinese regulators have set forth a framework for integrating patent linkage and data exclusivity into the Chinese regulatory regime, as well as for establishing a pilot program for patent term extension. The Economic and Trade Agreement Between the United States of America and the People’s Republic of China announced in January 2020 also provides for a mechanism for early resolution of patent disputes and patent term extension systems. To be implemented, this framework will require adoption of legislation and regulations. In October 2020, China adopted amendments to its Patent Law (the “Amended PRC Patent Law”), which will become effective on June 1, 2021. The Amended PRC Patent Law contains both patent term extension and a mechanism for early resolution of patent disputes, which may be comparable to patent linkage in the United States. However, the provisions for patent term extension and an early resolution mechanism are unclear and/or remain subject to the approval of implementing regulations that are still in draft form or have not yet been proposed, leading to uncertainty about their scope and implementation.

Until the relevant implementing regulations for patent term extension and an early resolution mechanism in the Amended PRC Patent Law are implemented, and until data exclusivity is adopted and implemented, we may be subject to earlier generic or biosimilar competition in China than in the United States and other jurisdictions with stronger regulatory data protection for pharmaceutical products.

RISK FACTORS

The manufacturing facilities for our medicines and drug candidates are subject to rigorous regulations and failure to obtain or maintain regulatory approvals or operate in line with established GMPs and international best practices could delay or impair our ability to commercialize our medicines or drug candidates.

We and the third-party manufacturers of our medicines and drug candidates are subject to applicable GMPs prescribed by the FDA and other rules and regulations prescribed by the NMPA, EMA and other regulatory authorities. To obtain FDA, NMPA and EMA approval for our drug candidates in the United States, China and Europe, we need to undergo strict pre-approval inspections of our or our third-party manufacturing facilities located in China and elsewhere. Historically, some manufacturing facilities in China have had difficulty meeting the FDA's, NMPA's or EMA's standards. When inspecting our or our contractors' manufacturing facilities, the FDA, NMPA or EMA might cite GMP deficiencies, both minor and significant, which we may not be required to disclose. Remediating deficiencies can be laborious and costly and consume significant periods of time. Moreover, if the FDA, NMPA or EMA notes deficiencies as a result of its inspection, it will generally reinspect the facility to determine if the deficiency has been remediated to its satisfaction. The FDA, NMPA or EMA may note further deficiencies as a result of its reinspection, either related to the previously identified deficiency or otherwise. If we or the manufacturers of our drug candidates cannot satisfy the FDA, NMPA and EMA as to compliance with GMP in a timely basis, marketing approval for our drug candidates could be seriously delayed, which in turn would delay commercialization of our drug candidates.

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

Undesirable adverse events ("AEs") caused by our medicines and drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval, or could result in limitations or withdrawal following approvals. If the conduct or results of our trials or patient experience following approval reveal a high and unacceptable severity or prevalence of AEs, our trials could be suspended or terminated and regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates or require us to cease commercialization following approval.

As is typical in the development of pharmaceutical products, drug-related AEs and serious AEs ("SAEs") have been reported in our clinical trials. Some of these events have led to patient deaths. Drug-related AEs or SAEs could affect patient recruitment or the ability of enrolled subjects to complete the trial and could result in product liability claims. Any of these occurrences may harm our reputation, business, financial condition and prospects significantly. In our periodic and current reports filed with the SEC and our press releases and scientific and medical presentations released from time to time we disclose clinical results for our drug candidates, including the occurrence of AEs and SAEs. Each such disclosure speaks only as of the date of the data cutoff used in such report, and we undertake no duty to update such information unless required by applicable law. Also, a number of immune-related adverse events ("IRAEs") have been associated with treatment with checkpoint inhibitors such as tislelizumab, including immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies, nephritis and renal dysfunction, skin adverse reactions, and encephalitis. These IRAEs may be more common in certain patient populations (potentially including elderly patients) and may be exacerbated when checkpoint inhibitors are combined with other therapies.

RISK FACTORS

Additionally, undesirable side effects caused by our medicines and drug candidates, or caused by our medicines and drug candidates when used in combination with other drugs, could potentially cause significant negative consequences, including:

- regulatory authorities could delay or halt pending clinical trials;
- we may suspend, delay or alter development of the drug candidate or marketing of the drug;
- regulatory authorities may withdraw approvals or revoke licenses of the drug, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label;
- we may be required to implement a Risk Evaluation Mitigation Strategy (“REMS”) for the drug, as is the case with REVLIMID®, or, if a REMS is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a regulatory authority;
- we may be required to conduct post-marketing studies; and
- we could be sued and held liable for harm caused to subjects or patients.

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

If safety, efficacy, or other issues arise with any medical product that is used in combination with our medicines, we may be unable to market such medicine or may experience significant regulatory delays or supply shortages, and our business could be materially harmed.

We plan to develop certain of our medicines and drug candidates for use as a combination therapy. If a regulatory authority revokes its approval of the other therapeutic that we use in combination with our medicines or drug candidates, we will not be able to market our medicines or drug candidates in combination with such revoked therapeutic. If safety or efficacy issues arise with these or other therapeutics that we seek to combine with our medicines and drug candidates in the future, we may experience significant regulatory delays, and we may be required to redesign or terminate the applicable clinical trials. In addition, if manufacturing or other issues result in a supply shortage of any component of our combination medicines or drug candidates, we may not be able to complete clinical development of our drug candidates on our current timeline or at all, or we may experience disruptions in the commercialization of our approved medicines. For example, we have in-licensed drug candidates from third parties to conduct clinical trials in combination with our drug candidates. We may rely on those third parties to manufacture the in-licensed drug candidates and may not have control over their manufacturing process. If these third parties encounter any manufacturing difficulties, disruptions or delays and are not able to supply sufficient quantities of drug candidates, our drug combination study program may be delayed.

RISK FACTORS

Recently enacted and future legislation may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our medicines and drug candidates and affect the prices we may obtain.

In the United States, China, the EU and some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding healthcare that could prevent or delay regulatory approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our medicines and any drug candidates for which we obtain regulatory approval. We expect that healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved medicine. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our medicines and drug candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether any regulations, guidance or interpretations will be changed, or what the impact of such changes on the regulatory approvals of our medicines and drug candidates may be.

For example, in the United States, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act (the “ACA”), and we expect there will be additional challenges and amendments to the ACA in the future. The United States Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 (“Tax Act”) includes a provision that decreased the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, commonly referred to as the “individual mandate,” to nil, effective January 1, 2019. On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. Pending a decision, the ACA remains in effect, but it is unclear at this time what effect these developments will have on the status of the ACA.

RISK FACTORS

Further, on January 20, 2017, former President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, former President Trump signed another Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. The former Trump administration concluded that cost-sharing reduction (“CSR”) payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than US\$12 billion in ACA risk corridor payments to third-party payors who argued the payments were owed to them. On April 27, 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit’s decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is unclear what impact these rulings will have on our business, especially given the new administration.

In addition, CMS published a final rule that would give states greater flexibility as of 2020 in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may not become profitable.

Investment in pharmaceutical drug development is highly capital-intensive and speculative. It entails substantial upfront capital expenditures and significant risk that a drug candidate will fail to gain regulatory approval or become commercially viable. We continue to incur significant expenses related to our ongoing operations. As a result, we have incurred losses in each period since our inception, except in the third quarter of 2017, when we were profitable due to revenue recognized from an up-front license fee from Celgene. As of December 31, 2020, we had an accumulated deficit of US\$3.6 billion. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from selling, general and administrative expenses associated with our operations.

RISK FACTORS

We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase in the near term as we continue and expand our development of, and seek regulatory approvals for, our drug candidates, and our manufacturing facilities, commercialize our medicines and launch new medicines, if approved, maintain and expand regulatory approvals, contribute up to US\$1.25 billion to the global development of a portfolio of Amgen pipeline assets under our collaboration agreement, and commercialize the medicines that we have licensed from Amgen, BMS and other parties and any other medicines that we may successfully develop or license. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. In addition, we will continue to incur costs associated with operating as a public company. We will also incur costs in support of our growth as a commercial-stage global biotechnology company. The size of our future net losses will depend, in part, on the number and scope of our drug development programs and the associated costs of those programs, the cost of our manufacturing activities, the cost of commercializing our approved products, our ability to generate revenues and the timing and amount of milestones and other payments we make or receive with arrangements with third parties. If we fail to achieve market acceptance for our medicines or any of our drug candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research, development, manufacturing and commercialization efforts, expand our business or continue our operations.

We have limited experience in obtaining regulatory approvals and commercializing pharmaceutical products, which may make it difficult to evaluate our current business and predict our future performance.

We have limited experience in completing large-scale, pivotal or registrational clinical trials and obtaining, maintaining or expanding regulatory approvals for our medicines and drug candidates. Additionally, we have limited experience in manufacturing, sales, marketing or distribution of pharmaceutical products. We became a commercial-stage company in 2017, with the in-license of medicines in China from BMS, and received the first approvals for our internally developed drug candidates in late 2019 in the United States and in 2020 in China. Our limited experience operating as a commercial-stage company may make it difficult to evaluate our current business and reliably predict our future performance. We may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If we do not address these risks and difficulties successfully, our business will suffer.

RISK FACTORS

We may need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development of our drug candidates or achieve profitability.

Our portfolio of drug candidates will require the completion of clinical development, regulatory review, scale up and availability of manufacturing resources, significant marketing efforts and substantial investment before they can provide us with product sales revenue. Additionally, we are investing in the manufacturing and commercialization of our approved medicines. Our operations have consumed substantial amounts of cash since inception. Our operating activities used US\$1.3 billion and US\$750.3 million of net cash during the years ended December 31, 2020 and 2019, respectively. We recorded negative net cash flows from operating activities in 2020 and 2019 primarily due to our net losses of US\$1.6 billion and US\$950.6 million, respectively. Although we recorded positive net cash flows from operating activities in 2017, primarily due to the upfront fees received from the BMS collaboration, we cannot assure you that we will be able to generate positive cash flows from operating activities in the future. In January 2020, we received approximately US\$2.8 billion from the sale of our shares to Amgen, and in July 2020, we received approximately US\$2.1 billion from the sale of our shares to eight existing investors, including entities associated with Hillhouse Capital and Baker Bros. Advisors LP, as well as Amgen.

Our liquidity and financial condition may be materially and adversely affected by the negative net cash flows, and we cannot assure you that we will have sufficient cash from other sources to fund our operations. If we resort to other financing activities to generate additional cash, we will incur financing costs and we cannot guarantee that we will be able to obtain the financing on terms acceptable to us, or at all, and if we raise financing by issuing further equity securities your interest in our company may be diluted. If we have negative operating cash flows in the future, our liquidity and financial condition may be materially and adversely affected.

We expect to continue to spend substantial amounts on drug discovery, advancing the clinical development of our drug candidates, contributing to the global development of a portfolio of Amgen pipeline assets, developing our manufacturing capabilities and securing drug supply, and launching and commercializing our and our collaborators' medicines and any additional drug candidates for which we receive regulatory approval, including building and maintaining a commercial organization to address markets in China, the United States and other countries.

RISK FACTORS

Since September 2017, we have generated revenues from the sale of medicines in China licensed from BMS, and since the fourth quarter of 2019, we have generated revenues from our internally developed medicines. These revenues are not sufficient to support our operations. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we believe that we have sufficient cash, cash equivalents and short-term investments to meet our projected operating requirements for at least the next 12 months. However, we believe that our existing cash, cash equivalents and short-term investments may not be sufficient to enable us to complete all global development or launch all of our current medicines and drug candidates for the currently anticipated indications and to invest in additional programs. Accordingly, we may require further funding through public or private offerings, debt financing, collaboration and licensing arrangements or other sources. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- our ability to successfully market our approved medicines;
- the progress, timing, scope and costs of our clinical trials, including the ability to timely enroll patients in our planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals of our drug candidates;
- the number and characteristics of medicines and drug candidates that we may in-license and develop;
- the amount and timing of the development, milestone and royalty payments we receive from our collaborators;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- selling and marketing costs associated with our medicines and any future drug candidates that may be approved, including the cost and timing of expanding our marketing and sales capabilities;
- the terms and timing of any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions, licensing and/or the development of other medicines and drug candidates;
- the cost and timing of development and completion of commercial-scale internal or outsourced manufacturing activities; and
- our headcount growth and associated costs.

RISK FACTORS

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or commercialization efforts. Our inability to obtain additional funding when we need it could seriously harm our business.

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

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our shares. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our shares to decline. In the event that we enter into collaborations or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to technologies or drug candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Fluctuations in exchange rates could result in foreign currency exchange losses and could materially reduce the value of your investment.

We incur portions of our expenses, and derive revenues, in currencies other than the U.S. dollar or Hong Kong dollar, in particular, the RMB, the Euro, and Australian dollar. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. We do not regularly engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in countries in which we operate could have a negative impact on our results of operations. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations, and cash flows.

The value of the RMB against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions and the foreign exchange policy proposed or adopted by the PRC, Australia and other governments. It is difficult to predict how market forces or PRC, Australia, other governments outside the U.S. and U.S. government policies may impact the exchange rate of RMB and the U.S. dollar or any other currencies in the future. There remains significant international pressure on the China to adopt a more flexible currency policy, including from the U.S. government, which has threatened to label China as a “currency manipulator,” which could result in greater fluctuation of the RMB against the U.S. dollar.

RISK FACTORS

Substantially all of our revenues are denominated in U.S. dollars and RMB, our costs are denominated in U.S. dollars, Australian dollars and RMB, and a large portion of our financial assets and a significant portion of our debt is denominated in U.S. dollars and RMB. To the extent that we need to convert U.S. dollars into RMB for our operations, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends or for other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount we would receive.

In addition, there are limited instruments available for us to reduce our foreign currency risk exposure at reasonable costs. Furthermore, we are also currently required to obtain the Chinese government approval before converting significant sums of foreign currencies into RMB. All of these factors could materially and adversely affect our business, financial condition, results of operations, and prospects, and could reduce the value of, and any dividends payable on, our shares in foreign currency terms.

Our business, profitability and liquidity may be adversely affected by deterioration in the credit quality of, or defaults by, our distributors and customers, and an impairment in the carrying value of our short-term investments could negatively affect our consolidated results of operations.

We are exposed to the risk that our distributors and customers may default on their obligations to us as a result of bankruptcy, lack of liquidity, operational failure or other reasons. As we continue to expand our business, the amount and duration of our credit exposure will be expected to increase, as will the breadth of the entities to which we have credit exposure. Although we regularly review our credit exposure to specific distributors and customers that we believe may present credit concerns, default risks may arise from events or circumstances that are difficult to detect or foresee.

Also, the carrying amounts of cash and cash equivalents, restricted cash and short-term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of US\$1,382.0 million, restricted cash of US\$8.1 million and short-term investments of US\$3,268.7 million at December 31, 2020, most of which are deposited in financial institutions outside of China. Although our cash and cash equivalents in China are deposited with various major reputable financial institutions, the deposits placed with these financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, we may be unlikely to claim our deposits back in full. As of December 31, 2020, our short-term investments consisted of U.S. Treasury securities.

Although we believe that the U.S. Treasury securities are of high credit quality and continually monitor the credit worthiness of these institutions, concerns about, or a default by, one institution in the U.S. market, could lead to significant liquidity problems, losses or defaults by other institutions, which in turn could adversely affect us.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our medicines and drug candidates through intellectual property rights, or if the scope of such intellectual property rights is not sufficiently broad, third parties may compete against us.

Our success depends in large part on our ability to protect our medicines, drug candidates and proprietary technology from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect the medicines, drug candidates and technology that we consider commercially important by filing patent applications in the United States, the PRC, the EU and other territories, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and/or patent applications at a reasonable cost or in a timely manner. As a result, we may not be able to prevent competitors from developing and commercializing competitive drugs in all such fields and territories.

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

In addition, under the PRC Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model accomplished in China is required to report to the National Intellectual Property Administration, or NIPA, for security examination. Otherwise, if an application is later filed in China, the patent right will not be granted.

RISK FACTORS

The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States, PRC and other countries. We may be subject to a third-party preissuance submission of prior art to the USPTO or become involved in opposition, derivation, revocation, re-examination, post-grant and *inter partes* review, or interference proceedings or similar proceedings in foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our medicines or drug candidates and compete directly with us without payment to us, or result in our inability to manufacture or commercialize medicines or drug candidates without infringing, misappropriating or otherwise violating third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge the priority of our invention or other features of patentability of our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology, drugs, and drug candidates. Such proceedings also may result in substantial costs and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Consequently, we do not know whether any of our medicines or drug candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Furthermore, although various extensions may be available, the life of a patent and the protection it affords, is limited. For example, the approved cancer therapies we have licensed from BMS in China face competition from generic medications, and we may face similar competition for our approved medicines even if we successfully obtain patent protection. Manufacturers of generic drugs may challenge the scope, validity or enforceability of our patents, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. The issued patents and pending patent applications, if issued, for our medicines and drug candidates are expected to expire on various dates as described in “Business-Intellectual Property” of our Annual Report. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

RISK FACTORS

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

We may not be able to protect our intellectual property rights throughout the world. If we fail to adequately protect our intellectual property rights, our competitive position could be impaired and our business could be materially harmed.

Filing, prosecuting, maintaining and defending patents on drugs or drug candidates in all countries throughout the world could be prohibitively expensive for us, and our intellectual property rights in some countries can have a different scope and strength than in the United States. In addition, the laws of certain countries do not protect intellectual property rights to the same extent as U.S. laws do. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing drugs made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and further, may export otherwise infringing drugs to non-U.S. jurisdictions where we have patent protection, but where enforcement rights are not as strong as those in the United States. These drugs may compete with our medicines and drug candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing. In addition, we may not be able to enforce patents that we in-license from third parties, who may delay or decline to enforce patents in the licensed territory.

We currently hold issued trademark registrations and have trademark applications pending, any of which may be the subject of a governmental or third-party objection, which could prevent the maintenance or issuance of the same. If we are unsuccessful in obtaining trademark protection for our primary brands, we may be required to change our brand names, which could materially adversely affect our business. Moreover, as our products mature, our reliance on our trademarks to differentiate us from our competitors will increase, and as a result, if we are unable to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, our business could be materially adversely affected.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, including China. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights.

RISK FACTORS

We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our medicines and drug candidates could be found invalid or unenforceable if challenged in court or before government patent authority.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us challenging the validity or enforceability of our patents or alleging that we infringe their intellectual property rights.

Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include *ex parte* re-examination, *inter partes* review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our drugs or drug candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our medicines or drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

RISK FACTORS

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our medicines or drug candidates.

Our commercial success depends in part on our avoiding infringement of the valid patents and other intellectual property rights of third parties. We are aware of numerous issued patents and pending patent applications belonging to third parties that exist in fields of our medicines and drug candidates. There may also be third-party patents or patent applications of which we are currently unaware, and given the dynamic area in which we operate, additional patents are likely to issue that relate to aspects of our business. There is a substantial amount of litigation and other claims and proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our medicines and drug candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are using technology in violation of their patent or other proprietary rights. Defense of these claims, regardless of their merit, could involve substantial litigation expense and divert our technical personnel, management personnel, or both from their normal responsibilities. Even in the absence of litigation, we may seek to obtain licenses from third parties to avoid the risks of litigation, and if a license is available, it could impose costly royalty and other fees and expenses on us.

If third parties bring successful claims against us for infringement of their intellectual property rights, we may be subject to injunctive or other equitable relief, which could prevent us from developing and commercializing one or more of our medicines and drug candidates. In the event of a successful claim against us of infringement or misappropriation, or a settlement by us of any such claims, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, pay royalties or redesign our infringing medicines and drug candidates, which may be impossible or require substantial time and cost. In the event of an adverse result in any such litigation, or even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our medicines or drug candidates. Any such license might not be available on reasonable terms or at all. In the event that we are unable to obtain such a license, we would be unable to further develop and commercialize one or more of our medicines and drug candidates, which could harm our business significantly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could significantly harm our business.

RISK FACTORS

We are aware of patents in the U.S. and some other jurisdictions with claims covering certain antibodies that are relevant to tislelizumab for which patents are expected to expire in 2023 or 2024; complexes of irreversible BTK inhibitors that are relevant to BRUKINSA® for which the patent is expected to expire in 2027; and the use of PARP inhibitors to treat certain cancers that are relevant to pamiparib for which patents are expected to expire between 2027 and 2031. We are also aware of issued patents in Europe and China relevant to pamiparib. Although we believe that the relevant claims of these patents would likely be held invalid, we can provide no assurance that a court or an administrative agency would agree with our assessment. If the validity of the relevant claims of one or more of these patents were to be upheld upon a validity challenge, and our related medicine was approved for sale in the United States before the expiration of the relevant patents, we would need a license to commercialize the medicine in the United States before the expiration of the relevant patents. In addition, depending upon the circumstances, we may need licenses for jurisdictions outside of the United States where we wish to commercialize a particular medicine before the expiration of corresponding patents covering that medicine. In such cases, we can provide no assurance that we would be able to obtain a license or licenses on commercially reasonable terms or at all, which could materially and adversely affect our business.

Even if litigation or other proceedings are resolved in our favor, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other patent agencies in several stages over the lifetime of the patent. The USPTO and other patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

RISK FACTORS

If we do not obtain patent term extension and regulatory exclusivity for our medicines, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our medicines and drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman law. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, although China has amended its patent law, effective on June 1, 2021, to include patent term extension, the patent term extension provision of the law is unclear and/or remains subject to the approval of implementing regulations that are still in draft form or have not yet been proposed, leading to uncertainty about its scope and implementation. As a result, the patents we have in the PRC are not yet eligible to be extended for patent term lost during clinical trials and the regulatory review process. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our medicines or drug candidates.

The laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. There could be changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

In addition to our issued patent and pending patent applications, we rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position and to protect our medicines and drug candidates. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, any of these parties may breach such agreements and disclose our proprietary information, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us and our competitive position would be harmed.

RISK FACTORS

Furthermore, many of our employees, including our senior management, were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and in some cases non-competition agreements in connection with their previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and scientific personnel.

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

We have entered into license agreements with third parties providing us with rights under various third-party patents and patent applications. These license agreements impose diligence, development or commercialization timelines and milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under our current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any drug or drug candidate that is covered by the licenses provided for under these agreements or we may face claims for monetary damages or other penalties under these agreements. Such an occurrence could diminish the value of these products and our company. Termination of the licenses provided for under these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements.

RISK FACTORS

Risks Related to Our Reliance on Third Parties

If we fail to maintain an effective distribution channel for our medicines, our business and sales could be adversely affected.

We rely on third-party distributors to distribute our approved medicines. For example, we rely on sole third-party distributors to distribute Amgen's and BMS's approved cancer therapies in China and multiple third-party distributors for the distribution of our internally developed medicines. We also expect to rely on third-party distributors to distribute our other internally developed and in-licensed drug products, if approved. Our ability to maintain and grow our business will depend on our ability to maintain an effective distribution channel that ensures the timely delivery of our medicines. However, we have relatively limited control over our distributors, who may fail to distribute our drugs in the manner we contemplate. For example, while we have long-standing business relationship with our sole distributor for the in-licensed products from BMS, the agreement we entered into with our sole distributor can be terminated by either party upon six months' written notice. If price controls or other factors substantially reduce the margins our distributors can obtain through the resale of our medicines to hospitals, medical institutions and sub-distributors, they may terminate their relationship with us. While we believe alternative distributors are readily available, there is a risk that, if the distribution of our medicines is interrupted, our sales volumes and business prospects could be adversely affected.

We rely on third parties to manufacture some of our commercial and clinical drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

Although we currently have manufacturing facilities that may be used for clinical-scale manufacturing and processing and are building a biologics manufacturing facility in China, we rely on outside vendors to manufacture supplies and process our medicines and drug candidates. For example, we have entered into a commercial supply agreement for tislelizumab with Boehringer Ingelheim Biopharmaceuticals (China) Ltd. ("Boehringer Ingelheim") and entered into a commercial supply agreement for BRUKINSA® with Catalent Pharma Solutions, LLC ("Catalent"). In addition, we rely on BMS and its third-party manufacturers for supply of REVLIMID®, VIDAZA® and ABRAXANE® in China. We rely on Amgen for the supply of XGEVA® and BLINCYTO® and will be dependent on Amgen for the supply of other drugs that we plan to develop and commercialize in China under the collaboration with Amgen. We have limited experience in manufacturing or processing our medicines and drug candidates on a commercial scale. Additionally, we have limited experience in managing the manufacturing process, and our process may be more difficult or expensive than the approaches currently in use.

RISK FACTORS

Although we intend to use our own manufacturing facilities, we also intend to use third parties as part of our manufacturing process and for the clinical and commercial supply of our medicines and drug candidates. Our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and regulatory authorities must evaluate and/or approve any manufacturers as part of their regulatory oversight of our medicines and drug candidates. This evaluation would require new testing and GMP- compliance inspections by regulatory authorities;
- our manufacturers may have little or no experience with manufacturing our medicines and drug candidates, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our medicines and drug candidates;
- our third-party manufacturers might be unable to timely manufacture our medicines and drug candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any. For example, we encountered supply disruptions of ABRAXANE® in 2019, and in 2020 the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS, as further described below;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the United States to ensure strict compliance with GMPs and other government regulations and by other comparable regulatory authorities for corresponding non-U.S. requirements. We do not have control over third-party manufacturers' compliance with these regulations and requirements. For example, in 2020, based on inspection findings at BMS's contract manufacturing facility in the United States, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS, as further described below;
- we may not own, or may have to share, the intellectual property rights to some of the technology used and improvements made by our third-party manufacturers in the manufacturing process for our medicines and drug candidates;
- raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects; and
- our contract manufacturers and drug component suppliers may be subject to disruptions in their business, including unexpected demand for or shortage of raw materials or components, cyber-attacks on supplier systems, labor disputes or shortage and inclement weather, as well as natural or man-made disasters or pandemics.

RISK FACTORS

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our drug candidates, result in higher costs or adversely impact development of our drug candidates or commercialization of our medicines. In addition, we will rely on third parties to perform certain specification tests on our medicines and drug candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE® in China. There has been a disruption in ABRAXANE® supply in China and we are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE® from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE®. Additionally, there are risks that our supplemental import drug application for ABRAXANE®, which was accepted by the NMPA in May 2019, as well as our clinical study evaluating tislelizumab in combination with ABRAXANE®, may be adversely affected. Until the corrective actions are implemented and accepted by the NMPA or the approval of an alternative manufacturing site is granted, the NMPA may refuse to grant approval of applications for ABRAXANE® and/or refuse to grant import certificates for ABRAXANE®. We do not know when the NMPA suspension of ABRAXANE® will be lifted and we will be able to re-commence sales of ABRAXANE®. As such, we do not expect revenue from ABRAXANE® until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE® and qualified drug is manufactured and available for sale in China.

RISK FACTORS

Currently, the raw materials for our manufacturing activities are supplied by multiple source suppliers, although portions of our supply chain may rely on sole source suppliers. We have agreements for the supply of drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business. Two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials and/or commercial medicines, which could lead to delays in these trials and/or issues with our commercial supply. Throughout the COVID-19 outbreak, there has been public concern over the availability and accessibility of critical medical products, and the CARES Act enhances FDA's existing authority with respect to drug shortage measures. Under the CARES Act, we must have in place a risk management plan that identifies and evaluates the risks to the supply of approved drugs for certain serious diseases or conditions for each establishment where the drug or API is manufactured. The risk management plan will be subject to FDA review during an inspection. If we experience shortages in the supply of our marketed products, our business and results of operations could be materially impacted. If we or our third party manufacturers experience a shortage in supply of active ingredients or other raw materials, we may not be able to continue to supply adequate levels of our medicines to our customers, which would have a negative impact on our business and results of operations.

Manufacturers of drug and biological products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and non-U.S. regulations. Furthermore, if contaminants are discovered in the supply of our medicines and drug candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our medicines and drug candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our medicines for commercial sale and our drug candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely.

RISK FACTORS

If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition could be adversely affected.

Before a third party can begin commercial manufacture of our medicines, they are subject to regulatory inspections of their manufacturing facilities, processes and quality systems. Due to the complexity of the processes used to manufacture drug and biological products, any potential third-party manufacturer may be unable to initially pass regulatory inspections in a timely or cost-effective manner in order for us to obtain regulatory approval. If contract manufacturers do not pass their inspections by the relevant regulatory authorities, our commercial supply of drug product or substance will be significantly delayed and may result in significant additional costs, including the delay or denial of any marketing application for our drug candidates or disruption in sales. In addition, drug and biological manufacturing facilities are continuously subject to inspection by regulatory authorities, before and after drug approval, and must comply with GMPs. Our or our collaborators' contract manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. In addition, contract manufacturers' failure to achieve and maintain high manufacturing standards in accordance with applicable regulatory requirements, or the incidence of manufacturing errors, could result in patient injury, product liability claims, product shortages, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. If a third-party manufacturer with whom we or our collaborators' contract is unable to comply with manufacturing regulations, we may also be subject to fines, unanticipated compliance expenses, recall or seizure of our drugs, product liability claims, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution. These possible sanctions could materially adversely affect our financial results and financial condition. For example, on March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE[®] in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE[®] in China. As a result, there has been a disruption in ABRAXANE[®] supply in China and we are working with BMS to restore supply as soon as possible, including through BMS's remediation efforts at the current manufacturing site and application to qualify an alternative manufacturing site for China supply. On March 25, 2020, the China National Healthcare Security Administration removed ABRAXANE[®] from the volume-based procurement list due to the NMPA's decision to suspend the importation, sales and use of ABRAXANE[®]. In addition to any possible sanctions, we do not expect to recognize revenue from sales of ABRAXANE[®] in China until the suspension on the importation, sales and use of ABRAXANE[®] in China is lifted by the NMPA and qualified drug is manufactured and available for sale in China, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

RISK FACTORS

Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third-party manufacturer, could require prior review by regulatory authorities and/or approval of the manufacturing process and procedures in accordance with applicable requirements. This review may be costly and time consuming and could delay or prevent the launch of a product or impact commercialization or continuous supply of approved drugs. The new facility will also be subject to pre-approval inspection. In addition, we have to demonstrate that the product made at the new facility is equivalent to the product made at the former facility by physical and chemical methods, which are costly and time consuming. It is also possible that regulatory authorities may require clinical testing as a way to prove equivalency, which would result in additional costs and delay. For example, we are working with BMS to restore supply of ABRAXANE® as soon as possible, including through BMS's application to qualify an alternative manufacturing site for China supply, which requires prior review and approval by the NMPA and is subject to various requirements described above.

We have entered into licensing and collaboration arrangements and may enter into additional collaborations, licensing arrangements, or strategic alliances in the future, and we may not realize the benefits of such arrangements.

We have entered into licensing and collaboration agreements and may enter into additional collaboration, licensing arrangements, or strategic alliances with third parties that we believe will complement or augment our research, development and commercialization efforts. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business.

In August 2017, we acquired Celgene's commercial operations in China and an exclusive license to Celgene's (now BMS's) commercial cancer portfolio in China, REVLIMID®, VIDAZA® and ABRAXANE® (the "BMS China License"). In 2019, we entered into a strategic collaboration with Amgen with respect to its commercial-stage oncology products XGEVA®, BLINCYTO® and KYPROLIS® and a portfolio of clinical- and late-preclinical-stage oncology pipeline products. In January 2021, we entered into a collaboration and license agreement with Novartis Pharma AG ("Novartis") to develop, manufacture and commercialize our anti-PD-1 antibody tislelizumab in the North America, Japan, EU, and six other European countries, which was closed on February 26, 2021.

RISK FACTORS

Our strategic collaborations with Amgen, Novartis and BMS involve numerous risks. For our collaboration with Amgen, we cannot be certain that we will achieve the financial and other benefits that led us to enter into the collaboration. Moreover, we may not achieve the revenue and cost synergies expected from our collaborations with Amgen or BMS for their commercial products in China, and our management's attention may be diverted from our drug discovery and development business. For our collaboration with Novartis, we cannot be certain that we will achieve potential benefits that led us to enter into the collaboration. These synergies are inherently uncertain, and are subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. If we achieve the expected benefits, they may not be achieved within the anticipated time frame. Lastly, strategic collaborations can be terminated for various reasons. For example, our strategic collaboration with Celgene for the development and commercialization of tislelizumab, which we entered into in connection with the BMS China License in 2017, was terminated in June 2019 in advance of the acquisition of Celgene by BMS, and we received a US\$150.0 million payment and regained global rights to tislelizumab. The termination of the collaboration agreement for tislelizumab did not impact the BMS China License, which remains in effect.

Additionally, from time to time, we may enter into joint ventures with other companies. Establishment of a joint venture involves significant risks and uncertainties, including (i) our ability to cooperate with our strategic partner, (ii) our strategic partner having economic, business, or legal interests or goals that are inconsistent with ours, and (iii) the potential that our strategic partner may be unable to meet its economic or other obligations, which may require us to fulfill those obligations alone.

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

RISK FACTORS

Collaborations involving our medicines and drug candidates are subject to numerous risks, which may include the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our drug candidates and medicines or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive drugs, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a drug candidate, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our medicines or drug candidates;
- a collaborator with marketing and distribution rights to one or more medicines may not commit sufficient resources to their marketing and distribution or may set prices that reduce the profitability of the medicines;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; for example, the China patents for KYPROLIS® (carfilzomib) are in an invalidation proceeding brought by another company and if such patents are not successfully defended we could face generic competition in China sooner than expected, which would have a material adverse effect on any potential sales of KYPROLIS® in China, once approved;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our medicines and drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable medicines and drug candidates; and
- collaborators may own or co-own intellectual property covering our medicines and drug candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

RISK FACTORS

As a result, we may not be able to realize the benefit of current or future collaborations, licensing arrangements or strategic alliances for our medicines and drug candidates if we are unable to successfully integrate such products with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will be able to fulfill all of our contractual obligations in a timely manner or achieve the revenue, specific net income or other goals that justify such transaction. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our medicines and drug candidates or bring them to market and generate product revenue, which would harm our business prospects, financial condition and results of operations.

If we are not able to successfully develop and/or commercialize Amgen's oncology products, the expected benefits of the collaboration will not materialize.

We have a collaboration agreement with Amgen pursuant to which we and Amgen have agreed to collaborate on the commercialization of Amgen's oncology products XGEVA[®], BLINCYTO[®] and KYPROLIS[®] in China, and the global development and commercialization in China of a portfolio of Amgen's clinical- and late-preclinical-stage pipeline products. Amgen has paused or stopped development of some of the pipeline assets due to portfolio prioritization, and the parties expect that the development plan for the pipeline assets will continue to evolve over time. Additionally, Amgen has advised us that its applications to the Human Genetic Resources Administration of China ("HGRAC") to obtain approval to conduct clinical studies in China for the pipeline assets, including its application for sotorasib (AMG 510), a first-in-class investigational KRAS G12C inhibitor, are currently delayed. Approval from the HGRAC is required for the initiation of clinical trials involving the collection of human genetic materials in China. We do not expect this to affect the conduct of the clinical trials in China for our drug candidates, other than assets that are part of the collaboration. The Amgen collaboration involves numerous risks, including unanticipated costs and diversion of our management's attention from our other drug discovery and development business. There can be no assurance that we will be able to successfully develop and commercialize Amgen's oncology products in China, which could disrupt our business and harm our financial results.

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

RISK FACTORS

We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our medicines and drug candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We, our CROs for our clinical programs and our clinical investigators are required to comply with GCPs, which are regulations and guidelines enforced by regulatory authorities for all of our drug candidates in clinical development. If we or any of our CROs or clinical investigators fail to comply with applicable GCPs and other regulatory requirements, the clinical data generated in our clinical trials may be deemed unreliable and regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our pivotal clinical trials must be conducted with drug product produced under GMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We could also be subject to government investigations and enforcement actions.

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

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

RISK FACTORS

Risks Related to Our Industry, Business and Operations

We have significantly increased and expect to continue to increase our research, development, manufacturing, and commercial capabilities, and we may experience difficulties in managing our growth.

At the beginning of 2020, we had approximately 3,400 employees, and we ended the year with approximately 5,100 employees, an increase of 50%, and we expect to continue our growth. Most of our employees are full-time. As our research, development, manufacturing and commercialization plans and strategies evolve, we must add a significant number of additional managerial, operational, drug development, clinical, regulatory affairs, manufacturing, sales, marketing, financial and other personnel in the United States, China, Europe and other regions. Our recent growth and any anticipated future growth will impose significant added responsibilities on members of management, including:

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

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

We currently rely, and for the foreseeable future will continue to rely, on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all.

If we are not able to effectively manage our growth and further expand our organization by hiring new employees and expanding our groups of consultants and contractors as needed, we may not be able to successfully implement the tasks necessary to further develop, manufacture and commercialize our medicines and drug candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals.

RISK FACTORS

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Xiaodong Wang, Ph.D., our Co-Founder, Chairman of our scientific advisory board, and director; John V. Oyler, our Co-Founder, Chief Executive Officer and Chairman of the board of directors; Xiaobin Wu, Ph.D., our President, Chief Operating Officer and General Manager of China; and the other principal members of our management and scientific teams. Although we have employment agreements or offer letters with each of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided share option, restricted share unit and restricted share grants that vest over time or based on performance conditions. The value to employees of these equity grants that may be significantly affected by movements in our share price that are beyond our control and may be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements or offer letters with our key employees, any of our employees could leave our employment at any time, with or without notice.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating and executing our discovery, clinical development, manufacturing and commercialization strategy. The loss of the services of our executive officers or other key employees and consultants could impede the achievement of our research, development, manufacturing and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executives, key employees or consultants may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel or consultants on acceptable terms, given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

RISK FACTORS

Our business is subject to complex and evolving industry-specific laws and regulations regarding the collection and transfer of personal data. These laws and regulations can be complex and stringent, and many are subject to change and uncertain interpretation, which could result in claims, changes to our data and other business practices, significant penalties, increased cost of operations, or otherwise adversely impact our business.

Regulatory authorities around the world have implemented industry-specific laws and regulations that affect the collection and transfer of personal data. For example, in China, the Regulation on the Administration of Human Genetic Resources promulgated by the State Council (the “HGR Regulation”), which became effective in 2019, applies to activities that involve sampling, biobanking, use of HGR materials and associated data, in China, and provision of such to foreign parties. The HGR Regulation prohibits both onshore or offshore entities established or actually controlled by foreign entities and individuals from sampling or biobanking any China HGR in China and require approval for the sampling of certain HGR and biobanking of all HGR by Chinese parties. Approval for any export or cross-border transfer of the HGR material is required, and transfer of China HGR data by Chinese parties to foreign parties or entities established or actually controlled by them also requires the Chinese parties to file, before the transfer, a copy of the data to the HGR administration for record. The HGR Regulation also requires that foreign parties ensure the full participation of Chinese parties in international collaborations and all records and data must be shared with the Chinese parties. For information about applications under the HGR Regulation for clinical studies in China that are part of the Amgen- BeiGene Collaboration, see the risk factor entitled “*If we are not able to successfully develop and commercialize Amgen’s oncology products in China, the expected benefits of the collaboration will not materialize.*”

If the Chinese parties fail to comply with data protection laws, regulations and practice standards, and our research data is obtained by unauthorized persons, used or disclosed inappropriately or destroyed, it could result in a loss of our confidential information and subject us to litigation and government enforcement actions. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our or our collaborators’ practices, potentially resulting in suspension of relevant ongoing clinical trials or the initiation of new trials, confiscation of HGR samples and associated data and administrative fines, disgorgement of illegal gains, or temporary or permanent debarment of our or our collaborators’ entities and responsible persons from further HGR projects and, consequently, a de-facto ban on the debarred entities from initiating new clinical trials in China. So far, the HGR administration has disclosed a number of HGR violation cases. In one case, the sanctioned party was the Chinese subsidiary of a multinational pharmaceutical company that was found to have illegally transferred certain HGR materials to CROs for conducting certain unapproved research. In addition to a written warning and confiscation of relevant HGR materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGR administration to take rectification measures and at the same time banned from submitting any HGR applications until the HGR administration was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in China until the ban was lifted. In another case, a public hospital was found to have illegally transferred certain HGR data to a university in Europe, and that hospital was eventually subject to the same ban.

RISK FACTORS

To further tighten the control of China HGR, the government adopted amendments to the criminal code in December 2020, which became effective on March 1, 2021, which criminalize the illegal collection of China HGR, the illegal transfer of China HGR materials outside of China, and the transfer of China HGR data to foreign parties or entities established or actually controlled by them without going through security review and assessment. An individual who is convicted of any of these violations may be subject to public surveillance, criminal detention, a fixed-term imprisonment of up to 7 years, and/or a criminal fine. In October 2020, the government adopted the Biosecurity Law, which became effective on April 15, 2021. The Biosecurity Law establishes an integrated system to regulate biosecurity-related activities in China, including the security regulation of HGR and biological resources. The Biosecurity Law for the first time expressly declares that China has sovereignty over its HGR and further endorsed the HGR Regulation by recognizing the fundamental regulatory principles and systems established by it over the utilization of Chinese HGR by foreign entities in China. Although the Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by China's highest legislative authority, it gives China's major regulatory authority of HGR, i.e., the Ministry of Science and Technology, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for Chinese HGR will evolve and become even more rigorous. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

We expect that these areas will receive greater and continued attention and scrutiny from regulators and the public going forward, which could increase our compliance costs and subject us to heightened risks and challenges associated with data security and protection. If we are unable to manage these risks, we could become subject to significant penalties, including fines, suspension of business and revocation of required licenses, and our reputation and results of operations could be materially and adversely affected.

We manufacture some of our medicines and intend to manufacture some of our drug candidates, if approved. Delays in completing and receiving regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.

We currently have manufacturing facilities in Beijing, Guangzhou, and Suzhou, China. These facilities may encounter unanticipated delays and expenses due to a number of factors, including regulatory requirements. If construction or expansion, regulatory evaluation and/or approval of our facilities are delayed, we may not be able to manufacture sufficient quantities of our medicines and drug candidates, which would limit our development and commercialization activities and our opportunities for growth. Cost overruns associated with constructing or maintaining our facilities could require us to raise additional funds from other sources.

RISK FACTORS

In addition to the similar manufacturing risks described in “Risks Related to Our Reliance on Third Parties”, our manufacturing facilities are subject to inspection in connection with clinical development and new drug approvals and ongoing, periodic inspection by the FDA, NMPA, EMA or other comparable regulatory agencies to ensure compliance with GMP and other regulatory requirements. Our failure to follow and document our adherence to such GMP regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of marketing applications for our drug candidates or the commercialization of our medicines. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet FDA, NMPA, EMA or other comparable regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with GMP regulations and other requirements of the FDA, NMPA, EMA or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our drug candidates, delays, suspension or withdrawal of approvals, supply disruptions, license revocation, seizures or recalls of drug candidates or medicines, operating restrictions and criminal prosecutions, any of which could harm our business.

Developing advanced manufacturing techniques and process controls is required to fully utilize our facilities. Advances in manufacturing techniques may render our facilities and equipment inadequate or obsolete.

To supply commercial quantities for our marketed products, produce our drugs in the quantities that we believe will be required to meet anticipated market demand, and to supply clinical drug material to support the continued growth of our clinical programs, we will need to increase, or “scale up,” the production process by a significant factor over the initial level of production, which will require substantial additional expenditures and various regulatory approvals and permits. If we are unable to do so, are delayed, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our drugs in a sufficient quantity to meet future demand.

RISK FACTORS

In addition to the similar manufacturing risks described in “Risks Related to Our Reliance on Third Parties”, if our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. In the event of a temporary or protracted loss of the facilities or equipment, we might not be able to transfer manufacturing to a third party. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements and we would need regulatory agency approval before selling any drugs manufactured at that facility. Such an event could delay our clinical trials or reduce our product sales. Any interruption in manufacturing operations at our manufacturing facilities could result in our inability to satisfy the demands of our clinical trials or commercialization. Any disruption that impedes our ability to manufacture our drug candidates or drugs in a timely manner could materially harm our business, financial condition and operating results.

Currently, we maintain insurance coverage against damage to our property, plant and equipment in amounts we believe are reasonable. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our drug candidates and medicines if there were a catastrophic event or interruption or failure of our manufacturing facilities or processes.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance requirements, including establishing and maintaining internal controls over financial reporting. We may be exposed to potential risks if we are unable to comply with these requirements.

As a public company in the United States and Hong Kong, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the listing rules of the Nasdaq Stock Market (“Nasdaq”) and The Stock Exchange of Hong Kong Limited (the “HKEx”), and incur significant legal, accounting and other expenses to comply with applicable requirements. These rules impose various requirements on public companies, including requiring certain corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly.

For example, the Sarbanes-Oxley Act of 2002 (the “Sarbanes-Oxley Act”) requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluations and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Such compliance may require that we incur substantial accounting expenses and expend significant management efforts. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. In the event we identify significant deficiencies or material weaknesses in our internal controls that we cannot remediate in a timely manner, the market price of our shares could decline if investors and others lose confidence in the reliability of our financial statements, we could be subject to sanctions or investigations by the SEC, HKEx or other applicable regulatory authorities, and our business could be harmed.

RISK FACTORS

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

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

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

In addition, if we undertake acquisitions or strategic collaborations, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. For example, in connection with the Amgen transaction, we issued to Amgen a total of 206,635,013 ordinary shares in the form of ADSs, representing 20.5% of the issued share capital of the Company after giving effect to the share issuance, which resulted in Amgen becoming our largest shareholder and the ownership of our existing shareholders being diluted.

RISK FACTORS

PRC regulations and rules concerning mergers and acquisitions, including the Regulations on Mergers and Acquisitions of Domestic Companies by Foreign Investors (the “M&A Rules”), and other recently adopted regulations and rules with respect to mergers and acquisitions established additional procedures and requirements that could make merger and acquisition activities by foreign investors more time consuming and complex. For example, the M&A Rules require that the Ministry of Commerce of the PRC (the “MOFCOM”) be notified in advance of any change-of-control transaction in which a foreign investor takes control of a PRC domestic enterprise, if (i) any important industry is concerned, (ii) such transaction involves factors that have or may have impact on the national economic security, or (iii) such transaction will lead to a change in control of a domestic enterprise which holds a famous trademark or PRC time-honored brand. Moreover, according to the Anti-Monopoly Law of the PRC and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings (the “Prior Notification Rules”) issued by the State Council, the concentration of business undertakings by way of mergers, acquisitions or contractual arrangements that allow one market player to take control of or to exert decisive impact on another market player must also be notified in advance to the State Administration of Market Regulation (the “SAMR”) when the threshold is crossed and such concentration shall not be implemented without the clearance of prior notification. In addition, the Measures for Security Review of Foreign Investment jointly issued by the National Development and Reform Commission and MOFCOM and the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (the “Security Review Rules”) issued by the MOFCOM specify that mergers and acquisitions by foreign investors that raise “national defense and security” concerns and mergers and acquisitions through which foreign investors may acquire the de facto control over domestic enterprises that raise “national security” concerns are subject to strict review by the MOFCOM, and the rules prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements.

We may also be subject to similar review and regulations in other jurisdictions, such as the laws and regulations on foreign investment in the United States under the jurisdiction of the Committee on Foreign Investment in the United States (the “CFIUS”) and other agencies, including the Foreign Investment Risk Review Modernization Act (the “FIRRMA”), which became effective in February 2020.

In the future, we may grow our business by acquiring complementary businesses. Complying with the requirements of the above-mentioned regulations and other relevant rules to complete such transactions could be time consuming, and any required approval processes, including obtaining approval from CFIUS, the SAMR, the MOFCOM or other agencies may delay or inhibit our ability to complete such transactions. It is unclear whether those complementary businesses we may acquire in the future would be deemed to be in an industry that raises “national defense and security” or “national security” concerns.

However, CFIUS, MOFCOM or other government agencies may publish explanations in the future determining that certain of the complementary business is in an industry subject to the security review, in which case our future acquisitions in the United States and the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

RISK FACTORS

If we fail to comply with the U.S. Foreign Corrupt Practices Act or other anti-bribery and corruption laws, our reputation may be harmed and we could be subject to penalties and significant expenses that have a material adverse effect on our business, financial condition and results of operations.

We are subject to the Foreign Corrupt Practices Act (the “FCPA”). The FCPA generally prohibits us from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. We are also subject to the anti-bribery and corruption laws of other jurisdictions, particularly China. The anti-bribery laws in China generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. As our business has expanded, the applicability of the FCPA and other anti-bribery and corruption laws to our operations has increased.

We do not fully control the interactions our employees, distributors and third-party promoters have with hospitals, medical institutions and doctors, and they may try to increase sales volumes of our products through means that constitute violations of United States, PRC or other countries’ anti-corruption and related laws. If our employees, distributors or third-party promoters engage in corrupt or other improper conduct that results in violation of applicable anti-corruption laws, our reputation could be harmed. Furthermore, we could be held liable for actions taken by our employees, distributors or third-party promoters, which could expose us to regulatory investigations and penalties.

Although we have policies and procedures designed to ensure that we, our employees and our agents comply with anti-bribery laws, there is no assurance that such policies or procedures will prevent our agents, employees and intermediaries from engaging in bribery activities. Our procedures and controls to monitor anti-bribery and corruption compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery and corruption laws, our reputation could be harmed and we could incur criminal or civil penalties, including but not limited to imprisonment, criminal and civil fines, suspension of our ability to do business with the government, denial of government reimbursement for our products and/or exclusion from participation in government healthcare programs, other sanctions and/or significant expenses, which could have a material adverse effect on our business.

RISK FACTORS

If we or our CROs or contract manufacturing organizations (“CMOs”) fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We and third parties, such as our CROs or CMOs, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and waste. In addition, our construction projects can only be put into operation after certain regulatory procedures with the relevant administrative authorities in charge of environmental protection, health and safety have been completed. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and waste. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our insurance coverage. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers’ compensation insurance to cover us for costs and expenses that we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

In addition, we may be required to incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development, manufacturing or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

RISK FACTORS

Our information technology systems, or those used by our contractors or collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development and commercialization efforts.

Despite the implementation of security measures, our information technology systems and those of our contractors and collaborators, are vulnerable to damage from internal or external events, such as computer viruses, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures, which can compromise the confidentiality, integrity and availability of the systems. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our research, development, manufacturing, regulatory and commercialization efforts and our business operations.

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business-critical information, including research and development information, commercial information and business and financial information. Because information systems, networks and other technologies are critical to many of our operating activities, shutdowns or service disruptions at our company or vendors that provide information systems, networks, or other services to us pose increasing risks. Such disruptions may be caused by events such as computer hacking, phishing attacks, ransomware, dissemination of computer viruses, worms and other destructive or disruptive software, denial of service attacks and other malicious activity, as well as power outages, natural disasters (including extreme weather), terrorist attacks or other similar events. Such events could cause loss of data, damage to systems and data and leave us unable to utilize key business systems or access important data needed to operate our business. Our contractors and collaborators have and in the future may face similar risks, and service disruptions or security breaches of their systems could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information or expose our confidential data. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues. In addition, we may not have adequate insurance coverage to compensate for any losses associated with such events.

RISK FACTORS

We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. Like other companies, we and our third-party vendors have on occasion experienced, and will continue to experience, threats to our or their data and systems, including malicious codes and viruses, phishing, business email compromise attacks, ransomware, or other cyber-attacks. The number and complexity of these threats continue to increase over time. If a material breach of our information technology systems or those of our vendors occurs, we could be required to expend significant amounts of money and other resources to respond to these threats or breaches and to repair or replace information systems or networks and could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have processes to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud-based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our contractors and collaborators, as well as our and their efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruptions, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, ransomware, industrial espionage attack or insider threat attack that could adversely affect our business and operations and/or result in the loss or exposure of critical, proprietary, private, confidential or otherwise sensitive data, which could result in financial, legal, business or reputational harm to us.

RISK FACTORS

Our failure to comply with data protection laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection.

In the United States, we are subject to laws and regulations that address privacy, personal information protection and data security at both the federal and state levels. Numerous laws and regulations, including security breach notification laws, health information privacy laws, and consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by regulators or courts in their interpretation.

Regulatory authorities in Europe have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the General Data Protection Regulation (EU) 2016/679 (“GDPR”), which became effective in 2018, imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including requirements relating to having legal bases for processing personal information, including personal health data, relating to identifiable individuals and transferring such information outside the European Economic Area, providing information to those individuals regarding the data processing of their personal information, implementing safeguards to keep personal information secure and confidential, having data processing agreements with third parties who process personal information, responding to individuals’ requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, and recordkeeping. The GDPR imposes strict rules on the transfer of personal data to countries outside the European Economic Area, and also imposes restrictions on cross-border data transfers. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10 million or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20 million or up to 4% of our total worldwide annual turnover for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. We face uncertainty as to the interpretation of these requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the law. Despite our best efforts to comply, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. National laws of member states of the EU are in the process of being adapted to the requirements under the GDPR. Because the GDPR specifically gives member states flexibility with respect to certain matters, national laws may partially deviate from the GDPR and impose different obligations from country to country, leading to additional complexity and uncertainty. Further, the United Kingdom’s decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

RISK FACTORS

China has implemented rules and is considering a number of additional proposals concerning data protection. The Cyber Security Law of the PRC (the “Cyber Security Law”), which became effective in 2017, created China’s first national-level data protection for “network operators,” which may include all organizations in China that provide services over the internet or another information network. Numerous related laws, regulations, guidelines and other measures are expected to be adopted, such as draft Data Security Law and draft Personal Information Protection Law, which may, upon enactment, require security review before transferring human health-related data out of China. Additionally, the Measures for the Management of Scientific Data (the “Scientific Data Measures”) provides a broad definition of scientific data and relevant rules for the management of scientific data in China and requires that enterprises in China must seek regulatory approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Any researcher conducting research funded at least in part by the Chinese government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal.

We expect that these data protection and transfer laws and regulations will receive greater attention and focus from regulators going forward, and we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under European, Chinese and other data protection, privacy and security laws will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant administrative, civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information or scientific data (such as the results of our preclinical studies or clinical trials conducted within China), result in the suspension of research and development of drug candidates, ongoing clinical trials or ban on initiation of new trials, require us to change our business practices, increase our costs, or materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law. In addition, a data breach affecting personal information, including health information, or a failure to comply with applicable requirements could result in significant management resources, legal and financial exposure and reputational damage that could potentially have a material adverse effect on our business, results of operations, and financial condition.

RISK FACTORS

If we or parties on whom we rely fail to maintain the necessary licenses for the development, manufacture, sale and distribution of our products, our ability to conduct our business could be materially impaired.

We are required to obtain, maintain and renew various permits, licenses and certificates to develop, manufacture, promote and sell our products. Third parties, such as distributors, third-party promoters and third-party manufacturers, on whom we may rely to develop, manufacture, promote, sell and distribute our products may be subject to similar requirements. We and third parties on whom we rely may be also subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome of such inspections, examinations, inquiries or audits may result in the loss or non-renewal of the relevant permits, licenses and certificates. Moreover, the criteria used in reviewing applications for, or renewals of permits, licenses and certificates may change from time to time, and there can be no assurance that we or the parties on whom we rely will be able to meet new criteria that may be imposed to obtain or renew the necessary permits, licenses and certificates. Many of such permits, licenses and certificates are material to the operation of our business, and if we or parties on whom we rely fail to maintain or renew material permits, licenses and certificates, our ability to conduct our business could be materially impaired. Furthermore, if the interpretation or implementation of existing laws and regulations change, or new regulations come into effect, requiring us or parties on whom we rely to obtain any additional permits, licenses or certificates that were previously not required to operate our business, there can be no assurance that we or parties on whom we rely will successfully obtain such permits, licenses or certificates.

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

Our operations and those of our third-party contractors and collaborators could be subject natural or man-made disasters, public health epidemics or other business interruptions, for which we are predominantly self-insured. In addition, we partially rely on our third-party research institution collaborators for conducting research and development of our drug candidates, and they may be affected by such business interruptions, government shutdowns or withdrawn funding. The occurrence of any of these business interruptions could seriously harm our operations and financial condition and increase our costs and expenses. We partially rely on third-party manufacturers to produce and process our medicines and drug candidates. Our ability to obtain supplies of our medicines and drug candidates could be disrupted if the operations of these suppliers are affected by man-made or natural disasters, public health epidemics or other business interruptions. Damage or extended periods of interruption to our or our vendors' corporate, development, research or manufacturing facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry, public health epidemics or other events could cause us to delay or cease development or commercialization of some or all of our medicines and drug candidates. Although we maintain insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. For example, the COVID-19 outbreak has impacted and could continue to negatively impact our business and our financial performance. Our clinical development and commercial efforts could be delayed or otherwise negatively impacted, as patients may be reluctant to go to the hospitals to receive treatment, or our regulatory filings and approvals could be delayed. We have already experienced delays in clinical trial recruitment. Additionally, the commercial or clinical supply of our medicines and drug candidates could be negatively impacted due to reduced operations or a shutdown of our or our third-party manufacturing facilities, distribution channels and transportation systems, or shortages of raw materials and drug product.

RISK FACTORS

Our business and results of operations could be adversely affected by public health crises and natural catastrophes or other disasters outside of our control in the locations in which we and our contractors and collaborators operate.

Our global operations expose us to risks associated with public health crises, such as epidemics and pandemics, natural catastrophes, such as earthquakes, hurricanes, typhoons, or floods, or other disasters such as fires, explosions and terrorist activity or wars that are outside of our control, including government reactions due to such events. Our business operations and those of our contractors and collaborators may potentially suffer interruptions caused by any of these events.

In December 2019, the COVID-19 outbreak began to impact the population in China and since January 2020, the COVID-19 outbreak has spread around the world. The continued spread of COVID-19 has negatively impacted our business and results of operations, including commercial sales, regulatory interactions, inspections, and filings, and clinical trial recruitment, participation and data read outs. In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring many employees to work remotely. We have suspended or limited non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism or employee turnover, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our business, results of operations, and financial condition.

The extent to which the COVID-19 pandemic may continue to impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the United States, China, Europe and other geographies where we or our third-party contractors and collaborators operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions and any new wave of COVID-19 cases could have a widespread impact on our business and results of operations depending on where infection rates are the highest. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, results of operations, and financial condition.

RISK FACTORS

Product liability claims or lawsuits could cause us to incur substantial liabilities.

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

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our medicines and drug candidates. Although we currently hold product liability coverage which we believe to be sufficient in light of our current products and clinical programs, the amount of such insurance coverage may not be adequate, and we may be unable to maintain such insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

RISK FACTORS

We are subject to the risks and challenges of doing business globally, which may adversely affect our business operations.

Because we operate in China, Europe and other regions outside of the United States, our business is subject to risks and challenges associated with doing business globally. Accordingly, our business and financial results could be adversely affected due to a variety of factors, including: changes in a specific country's or region's political and cultural climate or economic condition; unexpected changes in laws and regulatory requirements in local jurisdictions; challenges in replicating or adapting our company policies and procedures to operating environments different from that of the United States; difficulty of effective enforcement of contractual provisions in local jurisdictions; inadequate intellectual property protection in certain countries; enforcement of anti-corruption and anti-bribery laws, such as the FCPA; trade-protection measures or disputes, import or export licensing requirements, and fines, penalties or suspension or revocation of export privileges; laws and regulations on foreign investment in the United States under the jurisdiction of the CFIUS and other agencies; the effects of applicable local tax regimes and potentially adverse tax consequences; the impact of public health epidemics on employees, our operations and the global economy; restrictions on international travel and commerce; and significant adverse changes in local currency exchange rates. For example, the withdrawal of the United Kingdom from the EU effective on January 31, 2020, commonly referred to as "Brexit," may cause increased economic volatility, affecting our operations and business. In addition, in 2017 the United Kingdom Financial Conduct Authority, which regulates the London Interbank Offered Rate ("LIBOR"), announced that it will no longer require banks to submit rates for the calculation of LIBOR to the LIBOR administrator after 2021, and it is anticipated that LIBOR will be phased out and replaced by 2022. While various replacement reference rates have been proposed, an alternative reference rate to LIBOR has not yet been widely adopted. As such, the replacement of LIBOR could have an adverse effect on the market for, or value of, LIBOR-linked financial instruments. Failure to manage these risks and challenges could negatively affect our ability to expand our businesses and operations as well as materially and adversely affect our business, financial condition and results of operations.

RISK FACTORS

Future operating results could be negatively affected by changes in tax rates, the adoption of new tax legislation in the jurisdictions in which we operate, or exposure to additional tax liabilities.

The nature of our international operations subjects us to local, state, regional and national tax laws in jurisdictions around the world. Our future tax expense could be affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities or changes in tax laws or their interpretation. Additionally, tax rules governing cross-border activities are continually subject to modification as a result of both coordinated actions by governments and unilateral measures designed by individual countries, both intended to address concerns over base erosion and profit shifting (BEPS) and perceived international tax avoidance techniques. For example, the Cayman Islands has enacted the International Tax Co-operation (Economic Substance) Law (2020 Revision) (the “Economic Substance Law”), which originally took effect on January 1, 2019, and which is accompanied by Guidance on Economic Substance for Geographically Mobile Activities (Version 2.0; April 30, 2019) published by the Cayman Islands Tax Information Authority. The Economic Substance Law embraces a global initiative to combat BEPS and demonstrates the continued commitment of the Cayman Islands to international best practice. The Economic Substance Law provides that relevant entities that existed before January 1, 2019 and that had been conducting relevant activities by that date must comply with the economic substance requirements from July 1, 2019, and relevant entities that are established from January 1, 2019 onwards must comply with the requirements from the date they commence the relevant activity. Although we believe that we currently are not obliged to meet the economic substance requirements under the Economic Substance Law, we cannot predict any changes to the legislation or its interpretation in the future. If we are obliged to meet certain economic substance requirements in the future, our business and results of operations could be negatively impacted if we are required to make changes to our business in order to gain compliance or if we fail to comply.

We have received tax rulings from various governments that have jurisdictional authority over our operations. If we are unable to meet the requirements of such agreements, or if they expire or are renewed on less favorable terms, the result could negatively impact our future earnings. Additionally, the European Commission has opened formal investigations into specific tax rulings granted by several countries to specific taxpayers. While we believe that our rulings are consistent with accepted tax ruling practices, the ultimate resolution of such activities cannot be predicted and could also have an adverse impact on future operating results.

RISK FACTORS

Risks Related to Our Doing Business in the PRC

Changes in the political and economic policies of the PRC government or in relations between China and the United States or other governments may materially and adversely affect our business, financial condition, and results of operations and may result in our inability to sustain our growth and expansion strategies.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in the PRC or changes in government relations between China and the United States or other governments. There is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While China's economy has experienced significant growth over the past four decades, growth has been uneven across different regions and among various economic sectors. The government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall Chinese economy, but may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the Chinese government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United States or other governments deteriorate, our business in China and United States may also be adversely affected.

The audit report included in our Annual Report on Form 10-K filed with the SEC is prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board (the "PCAOB"), and as such, investors are deprived of the benefits of such inspection.

Our auditor, Ernst & Young Hua Ming LLP, is required to undergo regular inspections by the PCAOB as an auditor of companies that are publicly traded in the United States and a firm registered with the PCAOB. However, because we have substantial operations within the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese government authorities, our auditor and its audit work that is carried out in the PRC is not currently able to be inspected independently and fully by the PCAOB.

Inspections of other auditors conducted by the PCAOB outside the PRC have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The lack of PCAOB inspections of audit work undertaken in the PRC prevents the PCAOB from regularly evaluating our auditor's audits and its quality control procedures. As a result, investors may be deprived of the benefits of PCAOB inspections and may lose confidence in our reported financial information and procedures and the quality of our financial statements.

RISK FACTORS

As part of a continued regulatory focus in the United States on access to audit and other information currently protected by national law, in particular China's, in June 2019, a bipartisan group of U.S. lawmakers introduced bills that would require the SEC to maintain a list of issuers for which the PCAOB is not able to inspect or investigate the audit work performed by a foreign public accounting firm completely. The proposed Ensuring Quality Information and Transparency for Abroad-Based Listings on our Exchanges ("EQUITABLE") Act prescribes increased disclosure requirements for these issuers and, beginning in 2025, the delisting from U.S. national securities exchanges of issuers included on the SEC's list for three consecutive years. It is unclear if this proposed legislation will be enacted. Furthermore, the U.S. government has considered limiting or restricting China-based companies from accessing U.S. capital markets. In addition, the Holding Foreign Companies Accountable Act (the "HFCA Act") became law in December 2020. The HFCA Act includes requirements for the SEC to identify issuers whose audit work is performed by auditors that the PCAOB is unable to inspect or investigate completely because of a restriction imposed by a non-U.S. authority in the auditor's local jurisdiction. The HFCA Act also requires that, to the extent that the PCAOB has been unable to inspect an issuer's auditor for three consecutive years since 2021, the SEC shall prohibit its securities registered in the United States from being traded on any national securities exchange or over-the-counter markets in the United States.

As a result, our securities may be prohibited from trading on Nasdaq or another U.S. stock exchange if our auditor is not inspected by the PCAOB for three consecutive years as specified in the HFCA Act, and this ultimately could result in our ADSs being delisted. While there has been dialogue among the China Securities Regulatory Commission (the "CSRC"), the SEC and the PCAOB regarding the inspection of PCAOB-registered accounting firms in China, there can be no assurance that our auditor or us will be able to comply with requirements imposed by U.S. regulators. Delisting of our ADSs would force holders of our ADSs to sell their ADSs or convert them into our ordinary shares, which are listed for trading on the Hong Kong Stock Exchange. Although our ordinary shares are listed in Hong Kong, investors may face difficulties in converting their ADSs into ordinary shares and migrating the ordinary shares to Hong Kong, or may have to incur increased costs or suffer losses in order to do so. The market price of our ADSs could be adversely affected as a result of anticipated negative impacts of these actions upon, as well as negative investor sentiment towards, companies with significant operations in China that are listed in the United States, regardless of whether these actions are implemented and regardless of our actual operating performance.

As our global business has expanded, we have built substantial organizational capabilities outside of China. We are evaluating, designing, and implementing additional business processes and control changes to meet the requirements of the HFCA Act, which we believe will enable us to engage an independent registered public accounting firm that satisfies the PCAOB inspection requirements for the audit of our consolidated financial statements, subject to compliance with SEC and other requirements. However, these efforts may not be sufficient, or may take time for us to implement and ultimately may not be successful. We may also be subject to enforcement under the HFCA Act, the rules implementing the act that may be adopted by the SEC, and any other similar legislation that may be enacted into law or executive orders that may be adopted in the future. Although we are committed to complying with the rules and regulations applicable to listed companies in the United States, we are currently unable to predict the potential impact on our listed status by the rules that may be adopted by the SEC under the HFCA Act. If we failed to comply with those rules, it is possible that our ADSs will be delisted. Failure to adopt effective contingency plans may have a material adverse impact on our business and the price of our ADSs and ordinary shares.

RISK FACTORS

Proceedings instituted by the SEC against five PRC-based accounting firms, including our independent registered public accounting firm, could result in our inability to find a registered public accounting firm to audit and issue an opinion on our financial statements, which could result in us not being in compliance with the requirements of the Exchange Act.

In 2012, the SEC brought administrative proceedings against five accounting firms in China, including our independent registered public accounting firm, alleging that they had refused to produce audit work papers and other documents related to certain other PRC-based companies under investigation by the SEC. In 2014, an initial administrative law decision was issued, censuring these accounting firms and suspending four of these firms from practicing before the SEC for a period of six months. In 2015, each of the four PRC-based accounting firms agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC. These firms' ability to continue to serve their clients was not affected by the settlement. The settlement required these firms to follow detailed procedures to seek to provide the SEC with access to Chinese firms' audit documents via the China Securities Regulatory Commission (the "CSRC"). If these firms do not follow these procedures, the SEC could impose penalties such as suspensions, or it could restart the administrative proceedings. Our audit committee is aware of the policy restriction and communicates with our independent registered public accounting firm to ensure compliance. If additional remedial measures are imposed on the China-based accounting firms, including our independent registered public accounting firm, in administrative proceedings brought by the SEC alleging the firms' failure to meet specific criteria set by the SEC with respect to requests for the production of documents, we could be unable to timely file future financial statements in compliance with the requirements of the Exchange Act. The settlement did not require these firms to admit to any violation of law and preserves these firms' legal defenses in the event the administrative proceeding is restarted. In the event that the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the United States with major PRC operations may find it difficult or impossible to retain auditors in respect of their operations in the PRC, which could result in financial statements being determined to not be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding PRC-based, U.S.-listed companies and the market price of the ADSs and/or ordinary shares may be adversely affected.

If our independent registered public accounting firm is denied, even temporarily, the ability to practice before the SEC and we are unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined to be not in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to deregistration from the SEC, which would substantially reduce or effectively terminate the trading of our ADSs in the United States. Moreover, any negative news about the proceedings against these audit firms may adversely affect investor confidence in companies with substantial mainland China-based operations listed in the United States. All these would materially and adversely affect the market price of the ADSs and substantially reduce or effectively terminate the trading of our ADSs in the United States, and the market price of our ordinary shares may be adversely affected.

RISK FACTORS

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

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

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

China's Foreign Investment Law and its implementing rule came into force in January 2020. The Foreign Investment Law and implementing rules embody an expected regulatory trend to rationalize China's foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the legal requirements for both foreign and domestic investments. There are still uncertainties with respect to the interpretation and implementation of the Foreign Investment Law and the implementing rules. For example, the Foreign Investment Law and its implementing rules provide that foreign invested entities established according to the previous laws regulating foreign investment prior to the implementation of the new law may maintain their structure and corporate governance for a five-year transition period. It is uncertain whether governmental authorities may require us to adjust the structure and corporate governance of certain of our Chinese subsidiaries in such transition period. Failure to take timely and appropriate measures to meet any of these or similar regulatory requirements could materially affect our current corporate governance practices and business operations and our compliance costs may increase significantly. In addition, The Measures for the Security Review of Foreign Investment (the "New Measures"), effective from January 18, 2021, embody China's continued efforts to provide a legal regime for national security review comparable to similar procedures in other jurisdictions, such as CFIUS review in the United States. There are still uncertainties with respect to the interpretation, implementation and enforcement of the New Measures. For example, national security remains undefined and there is no clear guidance on whether the biotechnology industry requires security review and what factors the regulatory authority may consider in determining whether there are security concerns. It is difficult to evaluate the impact of the New Measures on our existing investments or potential investments in China.

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

RISK FACTORS

It may be difficult for overseas regulators to conduct investigations or collect evidence within China. In China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigations initiated outside China. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the United States may not be efficient in the absence of a mutual and practical cooperation mechanism. According to Article 177 of the PRC Securities Law, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the PRC territory. While detailed interpretation of or implementation rules under Article 177 have yet to be promulgated, the inability for an overseas securities regulator to directly conduct investigations or evidence collection activities within China may further increase the difficulties you face in protecting your interests. For risks associated with investing in us as a Cayman Islands company, see also “—Risks Related to Our American Depositary Shares and Ordinary Shares—We are a Cayman Islands company. Because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than under Hong Kong law or U.S. law, our shareholders may have fewer shareholder rights than they would have under Hong Kong law or U.S. law and may face difficulties in protecting their interests.”

In addition, any administrative and court proceedings in China may be protracted, resulting in substantial costs and diversion of resources and management attention. Since administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy than in more developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered and could materially and adversely affect our business, financial condition and results of operations.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries to fund any cash and financing requirements we may have, and any limitation on the ability of our PRC subsidiaries to make payments to us could have a material and adverse effect on our ability to conduct our business.

We are a holding company incorporated in the Cayman Islands, and we may rely on dividends and other distributions on equity paid by our PRC subsidiaries for our cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders or to service any debt we may incur. If any of our PRC subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other distributions to us. Under PRC laws and regulations, our PRC subsidiaries may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, a wholly foreign-owned enterprise is required to set aside at least 10% of its accumulated after-tax profits each year, if any, to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Such reserve funds cannot be distributed to us as dividends. At its discretion, a wholly foreign-owned enterprise may allocate a portion of its after-tax profits based on PRC accounting standards to an enterprise expansion fund, or a staff welfare and bonus fund. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in the PRC, up to the amount of net assets held in each operating subsidiary. As of December 31, 2020, these restricted assets totaled US\$119.8 million.

RISK FACTORS

Our PRC subsidiaries generate primarily all of their revenue in RMB, which is not freely convertible into other currencies. As a result, any restriction on currency exchange may limit the ability of our PRC subsidiaries to use their RMB revenues to pay dividends to us.

In response to the persistent capital outflow in the PRC and RMB's depreciation against the U.S. dollar in the fourth quarter of 2016, China's People's Bank of China ("PBOC") and the SAFE promulgated a series of capital control measures, including stricter vetting procedures for domestic companies to remit foreign currency for overseas investments, dividends payments and shareholder loan repayments.

The PRC government may continue to strengthen its capital controls, and more restrictions and substantial vetting process may be put forward by the SAFE for cross-border transactions falling under both the current account and the capital account. Any limitation on the ability of our PRC subsidiaries to pay dividends or make other kinds of payments to us could materially and adversely limit our ability to grow, make investments or acquisitions that could be beneficial to our business, pay dividends, or otherwise fund and conduct our business.

The Enterprise Income Tax Law (the "EIT Law") and its implementation rules provide that China-sourced income of foreign enterprises, such as dividends paid by a PRC subsidiary to its equity holders that are non-PRC resident enterprises, will normally be subject to PRC withholding tax at a rate of 10%, unless any such foreign investor's jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. As a result, dividends paid to us by our PRC subsidiaries may be subject to PRC withholding tax at a rate of 10%.

Pursuant to an arrangement between Mainland China and the Hong Kong Special Administrative Region (the "Hong Kong Tax Treaty"), BeiGene HK, the shareholder of some of our PRC subsidiaries, may be subject to a withholding tax at a rate of 5% on dividends received from our PRC operating subsidiaries as a Hong Kong tax resident. Pursuant to the Hong Kong Tax Treaty, subject to certain conditions, this reduced withholding tax rate will be available for dividends from PRC entities provided that the recipient can demonstrate it is a Hong Kong tax resident and it is the beneficial owner of the dividends. The government adopted regulations in 2018 which stipulate that in determining whether a non-resident enterprise has the status as a beneficial owner, comprehensive analysis shall be conducted based on the factors listed therein and the actual circumstances of the specific case shall be taken into consideration. Specifically, it expressly excludes an agent or a designated payee from being considered as a "beneficial owner." BeiGene HK currently does not hold a Hong Kong tax resident certificate from the Inland Revenue Department of Hong Kong, and there is no assurance that the reduced withholding tax rate will be available.

RISK FACTORS

We may be treated as a resident enterprise for PRC tax purposes under the EIT Law and we may therefore be subject to PRC income tax on our worldwide taxable income. Dividends payable to foreign investors and gains on the sale of our ADSs or ordinary shares by our foreign investors may become subject to PRC tax.

Under the PRC Enterprise Income Tax (“EIT”) Law, an enterprise established outside the PRC with “de facto management bodies” within the PRC is considered a “resident enterprise,” meaning that it is treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. The implementing rules of the EIT Law define “de facto management bodies” as “management bodies that exercise substantial and overall management and control over the production and operations, personnel, accounting, and properties” of the enterprise. In addition, PRC regulations specify that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have PRC enterprises or enterprise groups as their primary controlling shareholders, will be classified as resident enterprises if all of the following are located or resident in China: (i) senior management personnel and departments that are responsible for daily production, operation and management; (ii) financial and personnel decision-making bodies; (iii) key properties, accounting books, company seal, and minutes of board meetings and shareholders’ meetings; and (iv) half or more of senior management or directors having voting rights.

Although BeiGene, Ltd. does not have a PRC enterprise or enterprise group as its primary controlling shareholder and is therefore not a Chinese-controlled offshore incorporated enterprise within the meaning of these regulations, in the absence of guidance specifically applicable to us, we have applied the guidance set forth in the regulations to evaluate the tax residence status of BeiGene, Ltd. and its subsidiaries organized outside of the PRC.

We are not aware of any offshore holding company with a corporate structure similar to ours that has been deemed a PRC “resident enterprise” by the PRC tax authorities. Accordingly, we do not believe that our company or any of our overseas subsidiaries should be treated as a PRC resident enterprise. However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities and uncertainties remain with respect to the interpretation of the term “de facto management body.” If the PRC tax authorities determine that our Cayman Islands holding company is a resident enterprise for PRC enterprise income tax purposes, a number of unfavorable PRC tax consequences could follow and we may be subject to enterprise income tax at a rate of 25% on our worldwide taxable income, as well as to PRC enterprise income tax reporting obligations. If we are deemed a PRC resident enterprise, dividends paid on our shares and any gain realized from the transfer of our ordinary shares may be treated as income derived from sources within the PRC. As a result, dividends paid to non-PRC resident enterprise ADS holders or shareholders may be subject to PRC withholding tax at a rate of 10% (or 20% in the case of non-PRC individual ADS holders or shareholders) and gains realized by non-PRC resident enterprises ADS holders or shareholders from the transfer of our ordinary shares or ADSs may be subject to PRC tax at a rate of 10% (or 20% in the case of non-PRC individual ADS holders or shareholders).

RISK FACTORS

We and our shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company, or other assets attributable to a PRC establishment of a non-PRC company.

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

There are uncertainties as to the application of these regulations, which may be determined by the tax authorities to be applicable to sale of the shares of our offshore subsidiaries or investments where PRC taxable assets are involved. The transferors and transferees may be subject to the tax filing and withholding or tax payment obligation, while our PRC subsidiaries may be requested to assist in the filing. Furthermore, we, our non-resident enterprises and PRC subsidiaries may be required to spend valuable resources to comply with these regulations or to establish that we and our non-resident enterprises should not be taxed under these regulations, for our previous and future restructuring or disposal of shares of our offshore subsidiaries, which may have a material adverse effect on our financial condition and results of operations.

The PRC tax authorities have the discretion to make adjustments to the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities make adjustments to the taxable income of the transactions under these regulations, our income tax costs associated with such potential acquisitions or disposals will increase, which may have an adverse effect on our financial condition and results of operations.

RISK FACTORS

Restrictions on currency exchange may limit our ability to utilize our revenue effectively.

The PRC government imposes controls on the conversion of RMB into foreign currencies and, in certain cases, the remittance of currency out of the PRC. A portion of our revenue is denominated in RMB. Shortages in availability of foreign currency may restrict the ability of our PRC subsidiaries to remit sufficient foreign currency to our offshore entities for our offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign currency denominated obligations. The RMB is currently convertible under the “current account,” which includes dividends, trade and service-related foreign exchange transactions, but not under the “capital account,” which includes foreign direct investment and loans, including loans we may secure from our onshore subsidiaries. Currently, our PRC subsidiaries may purchase foreign currency for settlement of “current account transactions,” including payment of dividends to us, without the approval of SAFE by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our revenue is denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our ordinary shares and the ADSs. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities or designated banks. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Our business benefits from certain financial incentives and discretionary policies granted by local governments. Expiration of, or changes to, these incentives or policies would have an adverse effect on our results of operations.

Local governments in the PRC have granted certain financial incentives from time to time to our PRC subsidiaries as part of their efforts to encourage the development of local businesses. The timing, amount and criteria of government financial incentives are determined within the sole discretion of the local government authorities and cannot be predicted with certainty before we actually receive any financial incentive. We generally do not have the ability to influence local governments in making these decisions. Local governments may decide to reduce or eliminate incentives at any time. In addition, some of the government financial incentives are granted on a project basis and subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific project therein. We cannot guarantee that we will satisfy all relevant conditions, and if we do so we may be deprived of the relevant incentives. We cannot assure you of the continued availability of the government incentives currently enjoyed by us. Any reduction or elimination of incentives would have an adverse effect on our results of operations.

RISK FACTORS

Any failure to comply with PRC regulations regarding our employee equity plans and investments in offshore companies by PRC residents may subject the PRC plan participants and PRC-resident beneficial owners or us to fines and other legal or administrative sanctions.

We and our directors, executive officers and other employees who are PRC residents have participated in our employee equity plans. We are an overseas listed company, and therefore, we and our directors, executive officers and other employees who are PRC citizens or who have resided in the PRC for a continuous period of not less than one year and who have been granted restricted share units, restricted shares, options or other forms of equity incentives or rights to acquire equity are subject to the PRC regulations, according to which, employees, directors, supervisors and other management members participating in any share incentive plan of an overseas publicly listed company who are PRC citizens or who are non-PRC citizens residing in the PRC for a continuous period of not less than one year, subject to limited exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain other procedures. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our directors and employees under PRC law. Moreover, failure to comply with the various foreign exchange registration requirements could result in liability under PRC law for circumventing applicable foreign exchange restrictions.

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

A large portion of our business is conducted in China. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. In recent years, the regulatory framework in China for pharmaceutical companies has undergone significant changes, which we expect will continue. While we believe our strategies regarding research, development, manufacturing and commercialization in China are aligned with the Chinese government's policies, they may in the future diverge, requiring a change in our strategies. Any such change may result in increased compliance costs on our business or cause delays in or prevent the successful research, development, manufacturing or commercialization of our drug candidates or medicines in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China.

Chinese authorities have become increasingly vigilant in enforcing laws affecting the pharmaceutical industry. Any failure by us or our partners to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our business activities in China. Reports of what have come to be viewed as significant quality-control failures by Chinese vaccine manufacturers have led to enforcement actions against officials responsible for implementing national reforms favorable to innovative drugs (such as ours). While not directly affecting us, this macro-industry event could cause state or private resources to be diverted away from fostering innovation and be redirected toward regulatory enforcement, which could adversely affect our research, development, manufacturing and commercialization activities and increase our compliance costs.

RISK FACTORS

Risks Related to Our American Depositary Shares and Ordinary Shares

The trading prices of our ordinary shares and/or ADSs can be volatile, which could result in substantial losses to you.

The trading price of our ordinary shares and/or ADSs can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with significant business operations in China that have listed their securities in Hong Kong or the United States may affect the volatility in the price of and trading volumes for our ordinary shares and/or ADSs. Some of these companies have experienced significant volatility. The trading performances of these companies' securities may affect the overall investor sentiment towards other companies with significant operations in China that are listed in Hong Kong or the United States and consequently may impact the trading performance of our ordinary shares and/or ADSs.

In addition to market and industry factors, the price and trading volume for our ordinary shares and/or ADSs may be highly volatile for various reasons, including: announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for its use, or changes or delays in the regulatory review process; announcements of therapeutic innovations, new products, acquisitions, strategic relationships, joint ventures or capital commitments by us or our competitors; adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities; any adverse changes to our relationship with manufacturers or suppliers; the results of our testing and clinical trials; the results of our efforts to acquire or license additional medicines or drug candidates; variations in the level of expenses related to our existing medicines and drug candidates or preclinical, clinical development and commercialization programs; any intellectual property infringement actions in which we may become involved; announcements concerning our competitors or the pharmaceutical industry in general; fluctuations in product revenue, sales and marketing expenses and profitability; manufacture, supply or distribution shortages; variations in our results of operations; announcements about our results of operations that are not in line with analyst expectations, the risk of which is enhanced because it is our policy not to give guidance on results of operations; publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts; changes in financial estimates by securities research analysts; media reports, whether or not true, about our business, our competitors or our industry; additions to or departures of our management; fluctuations of exchange rates between the RMB, the U.S. dollar and Hong Kong dollar; release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares or ADSs; sales or perceived potential sales of additional ordinary shares or ADSs by us, our executive officers and directors or our shareholders; general economic and market conditions and overall fluctuations in the United States or Hong Kong equity markets; changes in accounting principles; trade disputes or U.S.-China government relations; and changes or developments in the United States, PRC, EU or global regulatory environment.

RISK FACTORS

In addition, the stock market, in general, and pharmaceutical and biotechnology companies, in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our ordinary shares and/or ADSs, regardless of our actual operating performance. Further, the current volatility in the financial markets and related factors beyond our control may cause the ordinary share and/or ADS price to decline rapidly and unexpectedly.

The characteristics of the U.S. capital markets and the Hong Kong capital markets are different.

The Nasdaq and the HKEx have different trading hours, trading characteristics (including trading volume and liquidity), trading and listing rules, and investor bases (including different levels of retail and institutional participation). As a result of these differences, the trading prices of our ordinary shares and the ADSs representing them might not be the same, even allowing for currency differences. Fluctuations in the price of our ADSs due to circumstances peculiar to its home capital market could materially and adversely affect the price of the ordinary shares, and vice versa. Because of the different characteristics of the U.S. and Hong Kong equity markets, the historic market prices of our ADSs and ordinary shares may not be indicative of the performance of our securities going forward.

We may be subject to securities litigation, which is expensive and could divert management attention.

Companies that have experienced volatility in the volume and market price of their shares have been subject to an increased incidence of securities class action litigation, particularly in our industry in recent years. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, and, if adversely determined, could have a material adverse effect on our business, financial condition and results of operations.

Future sales of our ordinary shares and/or ADSs in the public market could cause the ordinary shares and/or ADS price to fall.

The price of our ordinary shares and/or ADSs could decline as a result of sales of a large number of the ordinary shares and/or ADSs or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

As of February 12, 2021, 1,190,821,941 ordinary shares, par value US\$0.0001 per share, were outstanding, of which 963,301,885 ordinary shares were held in the form of 74,100,145 ADSs, each representing 13 ordinary shares.

RISK FACTORS

We filed a registration statement on Form S-3 with the SEC on behalf of certain shareholders on May 11, 2020, registering 300,197,772 ordinary shares, including 224,861,338 ordinary shares in the form of 17,297,026 ADSs to be resold by the selling shareholders identified therein and in any related prospectus supplement from time to time. Furthermore, we have registered or plan to register the offer and sale of all securities that we have issued and may issue in the future under our equity compensation plans, including upon the exercise of share options and vesting of restricted share units and under our employee share purchase plan. If these additional securities are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares and/or ADSs could decline. Amgen also has specified registration rights upon expiration of a lock-up period.

In addition, in the future, we may issue additional ordinary shares, ADSs or other equity or debt securities convertible into ordinary shares or ADSs in connection with a financing, acquisition, license, litigation settlement, employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing shareholders and could cause the ordinary share and/or ADS price to decline.

We have filed to conduct a public offering and to list our shares on the Science and Technology Innovation Board (the “STAR Market”), which if completed, will result in increased regulatory scrutiny and compliance costs and may increase fluctuations in the prices of our ADSs listed on the Nasdaq and ordinary shares listed on the HKEx.

In January 2021 we filed an initial listing application for a proposed public offering and listing of our ordinary shares on the STAR Market of the Shanghai Stock Exchange (the “SSE”). The proposed offering and listing of our ordinary shares, which will be denominated in RMB (the “RMB shares”), is currently expected to be completed in 2021, subject to, among other things, market conditions, approval of our shareholders, and necessary regulatory approvals, including approvals or decisions made by relevant regulatory authorities and governmental departments of the PRC, Hong Kong and other applicable jurisdictions. There is no assurance as to when the proposed offering and listing on the STAR Market will be completed, if at all. If we complete a public offering and listing on the STAR Market, we will become subject to the applicable laws, rules and regulations governing public companies listed on the STAR Market in addition to the various laws, rules and regulations that we are subject to in the United States and Hong Kong. The listing and trading of our equity securities in multiple jurisdictions and multiple markets will lead to increased compliance obligations and costs for us, and we may face the risk of significant intervention by regulatory authorities in these jurisdictions and markets. In addition, if we complete a public offering and listing on the STAR Market, we may be subject to securities litigations filed with the courts in China by the investors with respect to the RMB Shares traded on the STAR Market in the future.

RISK FACTORS

In addition, under current PRC laws and regulations, our ADSs and ordinary shares will not be interchangeable or fungible with our RMB-denominated ordinary shares traded on the STAR Market, and there is no trading or settlement between either the Nasdaq or the HKEx and the SSE. Furthermore, the Nasdaq, HKEx and SSE have different trading characteristics and investor bases, including different levels of retail and institutional participation. As a result of these differences, the trading prices of our ADSs and ordinary shares, accounting for the ADS to ordinary share ratio, may not be the same as the trading prices of equity securities we may decide to offer and/or list on the STAR Market. The fluctuations in the trading price of our RMB-denominated ordinary shares may also lead to increased volatility in, and may otherwise materially decrease, the prices of our ADSs listed on the Nasdaq and ordinary shares listed on the HKEx.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ordinary shares and/or ADSs for return on your investment.

We intend to retain most, if not all, of our available funds and earnings to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future. Therefore, you should not rely on an investment in the ordinary shares and/or ADSs as a source for any future dividend income.

Our board of directors has significant discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiaries, our financial condition, contractual and regulatory restrictions and other factors deemed relevant by our board of directors. Accordingly, the return on your investment in the ordinary shares and/or ADSs will likely depend entirely upon any future price appreciation of the ordinary shares and/or ADSs. There is no guarantee that the ordinary shares and/or ADSs will appreciate in value or even maintain the price at which you purchased the ordinary shares and/or ADSs. You may not realize a return on your investment in the ordinary shares and/or ADSs and you may even lose your entire investment in the ordinary shares and/or ADSs.

If securities or industry analysts do not continue to publish research or publish inaccurate or unfavorable research about our business, the market price for the ordinary shares and/or ADSs and trading volume could decline.

The trading market for the ordinary shares and ADSs relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. If research analysts do not maintain adequate research coverage or if one or more of the analysts who covers us downgrades the ordinary shares and/or ADSs or publishes inaccurate or unfavorable research about our business, the market price for the ordinary shares and/or ADSs would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which, in turn, could cause the market price or trading volume for the ordinary shares and/or ADSs to decline significantly.

RISK FACTORS

We are a Cayman Islands company. Because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than under Hong Kong law or U.S. law, our shareholders may have fewer shareholder rights than they would have under Hong Kong law or U.S. law and may face difficulties in protecting their interests.

We are an exempted company with limited liability incorporated in the Cayman Islands. Our corporate affairs are governed by our amended and restated memorandum and articles of association (as may be further amended from time to time), the Companies Law (as amended) of the Cayman Islands, and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors are to a large extent governed by the common law of the Cayman Islands. This common law is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, which has persuasive, but not binding, authority on courts in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in Hong Kong and the United States. In particular, the Cayman Islands has a less developed body of securities law than Hong Kong or the United States. In addition, some states in the United States, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands.

In addition, as a Cayman Islands exempted company, our shareholders have no general rights under Cayman Islands law to inspect corporate records and accounts or to obtain copies of lists of shareholders, with the exception that shareholders may request a copy of the current amended and restated memorandum and articles of association. Our directors have discretion under our amended and restated articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for shareholders to obtain the information needed to establish facts necessary for a shareholder action or to solicit proxies from other shareholders in connection with a proxy contest. As a Cayman Islands company, we may not have standing to initiate a derivative action in a Hong Kong or U.S. federal court. As a result, shareholders may be limited in their ability to protect their interests if they are harmed in a manner that would otherwise enable them to sue in a United States federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in Hong Kong or U.S. federal courts.

Some of our directors and executive officers reside outside of Hong Kong and the United States and a substantial portion of their assets are located outside of Hong Kong and the United States. As a result, it may be difficult or impossible for shareholders to bring an action against us or against these individuals in Hong Kong or in the United States in the event that shareholders believe that their rights have been infringed under the securities laws of Hong Kong, the United States or otherwise. To the extent our directors and executive officers reside outside of China or their assets are located outside of China, it may not be possible for investors to effect service of process upon us or our management inside China. Even if shareholders are successful in bringing an action, the laws of the Cayman Islands and China may render them unable to enforce a judgment against our assets or the assets of our directors and officers. There is no statutory recognition in the Cayman Islands of judgments obtained in the United States, Hong Kong or China, although the courts of the Cayman Islands will generally recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

RISK FACTORS

As a result of the above, shareholders may have more difficulty protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as shareholders of a Hong Kong company or a U.S. company.

Voting rights of our ADS holders are limited by the terms of the deposit agreement. The depositary for the ADSs will give us a discretionary proxy to vote our ordinary shares underlying our ADS holders ADSs if they do not vote at shareholders' meetings, except in limited circumstances, which could adversely affect their interests.

Holders of our ADSs may exercise their voting rights with respect to the ordinary shares underlying their ADSs only in accordance with the provisions of the deposit agreement. Upon receipt of voting instructions from ADS holders in the manner set forth in the deposit agreement, the depositary for the ADSs will endeavor to vote the holder's underlying ordinary shares in accordance with these instructions. Under our articles of association, the minimum notice period required for convening an annual general meeting is 21 calendar days and the minimum notice period required for convening an extraordinary general meeting is 14 calendar days. When a general meeting is convened, ADS holders may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their ordinary shares to allow them to cast your vote with respect to any specific matter at the meeting. In addition, the depositary and its agents may not be able to send voting instructions to ADS holders or carry out their voting instructions in a timely manner. We will make reasonable efforts to cause the depositary to extend voting rights to our ADS holders in a timely manner, but they may not receive the voting materials in time to ensure that they can instruct the depositary to vote your shares.

Furthermore, the depositary and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, ADS holders may not be able to exercise their right to vote and they may lack recourse if the ordinary shares underlying their ADSs are not voted as they requested.

Under the deposit agreement for the ADSs, the depositary will give us a discretionary proxy to vote the ordinary shares underlying ADS holders ADSs at shareholders' meetings if such holders do not give voting instructions to the depositary, unless:

- we have failed to timely provide the depositary with our notice of meeting and related voting materials;
- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting; or
- a matter to be voted on at the meeting would have a material adverse impact on shareholders.

The effect of this discretionary proxy is that, if ADS holders fail to give voting instructions to the depositary, they cannot prevent the ordinary shares underlying their ADSs from being voted, absent the situations described above, and it may make it more difficult for such ADS holders to influence our management. Holders of our ordinary shares are not subject to this discretionary proxy.

RISK FACTORS

Anti-takeover provisions in our constitutional documents may discourage our acquisition by a third party, which could limit our shareholders' opportunity to sell their shares at a premium.

Our amended and restated memorandum and articles of association include provisions that could limit the ability of others to acquire control of our company, could modify our structure or could cause us to engage in change-of-control transactions. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares, at a premium over prevailing market prices by discouraging third parties from seeking to obtain control in a tender offer or similar transaction.

For example, our board of directors has the authority, without further action by our shareholders, to issue preferred shares in one or more series and to fix the powers and rights of these shares, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights associated with our ordinary shares. Preferred shares could thus be issued quickly with terms calculated to delay or prevent a change in control or make removal of management more difficult. In addition, if our board of directors authorizes the issuance of preferred shares, the market price of the ordinary shares and/or ADSs may fall and the voting and other rights of the holders of our ordinary shares and/or ADSs may be materially and adversely affected.

Furthermore, our amended and restated articles of association permit our directors to vary all or any of the rights attaching to any class of shares in issue without the consent of shareholders but only if such variation is considered by the directors not to have a material adverse effect upon such holders. The amended and restated articles of association provide that the holders must consent to any such material adverse changes in the manner set out therein.

Because our directors are divided into three classes with staggered terms of three years each, shareholders can only elect or remove a limited number of our directors in any given year. The length of these terms could present an obstacle to certain actions, such as a merger or other change of control, which could be in the interest of our shareholders.

RISK FACTORS

Our amended and restated memorandum and articles of association designate specific courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our amended and restated memorandum and articles of association provide that, unless we consent in writing to the selection of an alternative forum, the courts of Cayman Islands will be the sole and exclusive forum for any derivative action or proceeding brought on behalf of us, any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of us to us or our shareholders, any action asserting a claim arising pursuant to any provision of the Companies Law of the Cayman Islands as amended from time to time, or the amended and restated memorandum and articles of association, or any action asserting a claim governed by the internal affairs doctrine (as such concept is recognized under the U.S. laws). In connection with our proposed offering and listing on the STAR Market, and subject to shareholder approval, we plan to adopt a further amended and restated memorandum and articles of association, which will provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (the "Securities Act"). In addition, the further amended and restated memorandum and articles of association will provide that any person or entity purchasing or otherwise acquiring any interest in any of our shares is deemed to have notice of and consented to these provisions; provided, however, that shareholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and rules and regulations thereunder.

These provisions may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits. Alternatively, if a court were to find these provisions of our amended and restated memorandum and articles of association inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions.

Our amended and restated memorandum and articles of association provide that any shareholder bringing an unsuccessful action against us may be obligated to reimburse us for any costs we have incurred in connection with such unsuccessful action.

Our amended and restated memorandum and articles of association provide that under certain circumstances the fees, costs, and expenses that we incur in connection with actions or proceedings brought by any person or entity, which we refer to as claiming parties, may be shifted to such person or entity. If a claiming party asserts any claim; initiates any proceeding; or joins, offers substantial assistance to, or has a direct financial interest in any claim or proceeding against us, and such claiming party or the third party that received substantial assistance from the claiming party or in whole claim the claiming party had a direct financial interest is unsuccessful in obtaining a judgment on the merits in which the claiming party prevails, then such claiming party shall (to the fullest extent permitted by law) be obligated to reimburse us for all fees, costs, and expenses, including but not limited to all reasonable attorneys' fees and other litigation expenses, that we may incur in connection with such claim or proceeding.

RISK FACTORS

Fee-shifting articles are relatively new and untested in the Cayman Islands, the United States and Hong Kong. The case law and potential legislative action on fee-shifting articles are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such articles. The application of our fee-shifting article in connection with claims under the Cayman Islands, the United States or Hong Kong securities laws, if any, will depend in part on future developments of the law. We cannot assure you that we will or will not invoke our fee-shifting article in any particular dispute. Consistent with our directors' fiduciary duties to act in the best interests of the Company, the directors may in their sole discretion from time to time decide whether or not to enforce this article. In addition, given the unsettled state of the law related to fee-shifting articles, such as ours, we may incur significant additional costs associated with resolving disputes with respect to such articles, which could adversely affect our business and financial condition.

If a shareholder that brings any such claim or proceeding is unable to obtain the judgment sought, the attorneys' fees and other litigation expenses that might be shifted to a claiming party may be significant. This fee-shifting article, therefore, may dissuade or discourage current or former shareholders (and their attorneys) from initiating lawsuits or claims against us. In addition, it may impact the fees, contingency or otherwise, required by potential plaintiffs' attorneys to represent our shareholders or otherwise discourage plaintiffs' attorneys from representing our shareholders at all. As a result, this article may limit the ability of shareholders to affect the management and direction of our company, particularly through litigation or the threat of litigation.

Holders of ADSs may be subject to limitations on transfer of their ADSs.

ADSs are transferable only on the books of the depository. However, the depository may close its books at any time or from time to time when it deems expedient in connection with the performance of its duties. The depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository think it is advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, as amended, or for any other reason, subject to ADS holders' right to cancel their ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of ADSs and withdrawal of the underlying ordinary shares may arise because the depository has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting or we are paying a dividend on our ordinary shares.

In addition, holders of ADSs may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

RISK FACTORS

The depository for the ADSs is entitled to charge holders fees for various services, including annual service fees.

The depository for the ADSs is entitled to charge holders fees for various services, including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs, and annual service fees. In the case of ADSs issued by the depository into The Depository Trust Company (“DTC”), the fees will be charged by the DTC participant to the account of the applicable beneficial owner in accordance with the procedures and practices of the DTC participant as in effect at the time.

Dealings in ordinary shares registered in our Hong Kong register of members will be subject to Hong Kong stamp duty. There is uncertainty as to whether Hong Kong stamp duty will apply to the trading or conversion of the ADSs.

In connection with our Hong Kong public offering in 2018, we established a branch register of members in Hong Kong (the “Hong Kong share register”). Our ordinary shares that are traded on the HKEx, including those that may be converted from ADSs, are registered on the Hong Kong share register, and the trading of these ordinary shares on the HKEx are subject to Hong Kong stamp duty. To facilitate ADS to ordinary share conversion and trading between the Nasdaq and the HKEx, we moved a portion of our issued ordinary shares from our Cayman share register to our Hong Kong share register.

Under the Hong Kong Stamp Duty Ordinance, any person who effects a sale or purchase of Hong Kong stock, defined as stock the transfer of which is required to be registered in Hong Kong, is required to pay Hong Kong stamp duty. The stamp duty is currently set at a total rate of 0.2% of the greater of the consideration for, or the value of, shares transferred, with 0.1% payable by each of the buyer and the seller.

To the best of our knowledge, Hong Kong stamp duty has not been levied in practice on the trading or conversion of ADSs of companies that are listed in both the United States and Hong Kong and that have maintained all or a portion of their ordinary shares, including ordinary shares underlying ADSs, in their Hong Kong share registers. However, it is unclear whether, as a matter of Hong Kong law, the trading or conversion of ADSs of these dual-listed companies constitutes a sale or purchase of the underlying Hong Kong registered ordinary shares that is subject to Hong Kong stamp duty. We advise investors to consult their own tax advisors on this matter. If Hong Kong stamp duty is determined by the competent authority to apply to the trading or conversion of the ADSs, the trading price and the value of your investment in our ADSs or ordinary shares may be affected.

RISK FACTORS

Holders of ADSs may not receive distributions on our ordinary shares or any value for them if it is illegal or impractical to make them available.

The depositary of the ADSs has agreed to ADS holders the cash dividends or other distributions it or the custodian for the ADSs receives on our ordinary shares or other deposited securities after deducting its fees and expenses. ADS holders will receive these distributions in proportion to the number of our ordinary shares that their ADSs represent. However, the depositary is not responsible for making such payments or distributions if it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed pursuant to an applicable exemption from registration. The depositary is not responsible for making a distribution available to any holders of ADSs if any government approval or registration required for such distribution cannot be obtained after reasonable efforts made by the depositary. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that holders of ADSs may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to such holders. These restrictions may materially reduce the value of our ADSs.

Holders of ADSs may not be able to participate in rights offerings and may experience dilution of their holdings.

From time to time, we may distribute rights to our shareholders, including rights to acquire securities. Under the deposit agreement, the depositary will not distribute rights to holders of ADSs unless the distribution and sale of rights and the securities to which these rights relate are either exempt from registration under the Securities Act with respect to all holders of ADSs or are registered under the Securities Act. The depositary may, but is not required to, attempt to sell these undistributed rights to third parties and may allow the rights to lapse. We may be unable to establish an exemption from registration under the Securities Act, and we are under no obligation to file a registration statement with respect to these rights or underlying securities or to try to have a registration statement declared effective. Accordingly, holders of ADSs may be unable to participate in our rights offerings and may experience dilution of their holdings as a result.

Our corporate actions are substantially controlled by our directors, executive officers and other principal shareholders, who can exert significant influence over important corporate matters, which may reduce the price of our ordinary shares and/or ADSs and deprive shareholders of an opportunity to receive a premium for their ordinary shares and/or ADSs.

Our directors, executive officers and principal shareholders beneficially owned approximately 66% of our outstanding ordinary shares as of February 12, 2021. These shareholders, if acting together, could exert substantial influence over matters such as electing directors and approving material mergers, acquisitions or other business combination transactions. This concentration of ownership may also discourage, delay or prevent a change in control of our company, which could have the dual effect of depriving our shareholders of an opportunity to receive a premium for their shares as part of a sale of our company and reducing the price of our ordinary shares and/or ADSs. These actions may be taken even if they are opposed by our other shareholders. In addition, these persons could divert business opportunities away from us to themselves or others.

RISK FACTORS

We may be a passive foreign investment company in future taxable years, which may have adverse U.S. federal income tax consequences for U.S. shareholders.

A non-U.S. corporation will be classified as a “passive foreign investment company” (“PFIC”) for any taxable year if either (1) 75% or more of its gross income consists of certain types of passive income or (2) 50% or more of the average quarterly value of its assets during such year produce or are held for the production of passive income. Based upon the current and expected composition of our income and assets (taking into account the proceeds from the registered direct offering completed in July 2020), we do not presently expect to be a PFIC for the current taxable year. Nevertheless, because our PFIC status must be determined annually with respect to each taxable year and will depend on the composition and character of our assets and income, including our use of proceeds from any equity offerings, and the value of our assets (which may be determined, in part, by reference to the market value of our ADSs and ordinary shares, which may be volatile) over the course of such taxable year, we may be a PFIC in any taxable year. The determination of whether we will be or become a PFIC may also depend, in part, on how, and how quickly, we use our liquid assets and the cash raised in equity offerings. If we determine not to deploy significant amounts of cash for active purposes, our risk of being a PFIC may substantially increase. Because there are uncertainties in the application of the relevant rules and PFIC status is a factual determination made annually after the close of each taxable year, there can be no assurance that we will not be a PFIC for the current taxable year or any future taxable year. In addition, it is possible that the Internal Revenue Service may challenge our classification of certain income and assets as non-passive, which may result in our being or becoming a PFIC in the current or subsequent years. We believe that we were not a PFIC for the taxable year ended December 31, 2020.

If we are a PFIC for any taxable year during a U.S. shareholder’s holding period of the ordinary shares or ADSs, then such U.S. shareholder may incur significantly increased United States income tax on gain recognized on the sale or other disposition of the ordinary shares or ADSs and on the receipt of distributions on the ordinary shares or ADSs to the extent such distribution is treated as an “excess distribution” under the United States federal income tax rules. In addition, such holders may be subject to burdensome reporting requirements.

Further, if we are classified as a PFIC for any year during which a U.S. shareholder holds our ordinary shares or ADSs, we generally will continue to be treated as a PFIC for all succeeding years during which such U.S. shareholder holds such ordinary shares or ADSs. Each U.S. shareholder should consult its tax advisor regarding the PFIC rules and the U.S. federal income tax consequences of the acquisition, ownership and disposition of the ordinary shares and ADSs.

RISK FACTORS

If you are a “Ten Percent Shareholder,” you may be subject to adverse U.S. federal income tax consequences if we are classified as a Controlled Foreign Corporation.

Each “Ten Percent Shareholder” (as defined below) in a non-U.S. corporation that is classified as a “controlled foreign corporation” (“CFC”), for U.S. federal income tax purposes is generally required to include in income for U.S. federal tax purposes such Ten Percent Shareholder’s pro rata share of the CFC’s “Subpart F income” and investment of earnings in U.S. property, even if the CFC has made no distributions to its shareholders. Each Ten Percent Shareholder is also required to include in gross income its “global intangible low-taxed income,” which is determined by reference to the income of CFCs of which such Ten Percent Shareholder is a Ten Percent Shareholder. Ten Percent Shareholders that are corporations may be entitled to a deduction equal to the foreign portion of any dividend when a dividend is paid. A non-U.S. corporation will generally be classified as a CFC for U.S. federal income tax purposes if Ten Percent Shareholders own in the aggregate, directly or indirectly, more than 50% of either the total combined voting power of all classes of stock of such corporation entitled to vote or of the total value of the stock of such corporation. A “Ten Percent Shareholder” is a U.S. person (as defined by the Internal Revenue Code of 1986, as amended), who owns or is considered to own 10% or more of the total combined voting power of all classes of stock entitled to vote of such corporation or 10% of the value of all classes of stock of such corporation. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain.

Although we believe we are not a CFC now, we may become one or own interests in one in the future. Holders are urged to consult their own tax advisors with respect to our potential CFC status and the consequences thereof.

FINANCIAL SUMMARY

	For the year ended December 31,				
	2016	2017	2018	2019	2020
	US\$' 000	US\$' 000	US\$' 000	US\$' 000	US\$' 000
Operating results					
Product revenue, net	–	24,428	130,885	222,596	308,874
Collaboration revenue	1,070	213,959	67,335	205,616	–
Total revenues	1,070	238,387	198,220	428,212	308,874
Gross profit	1,070	233,413	169,515	357,022	238,217
Loss before income tax expense	119,163	91,064	689,829	943,586	1,618,194
Net Loss	119,217	93,299	674,033	950,578	1,600,523
Adjusted net loss ⁽¹⁾	108,592	50,436	586,906	816,424	1,417,042
Net loss attributable to BeiGene, Ltd.	119,217	93,105	673,769	948,628	1,596,906
Profitability					
Gross margin (%)	100%	98%	86%	83%	77%
Net profit margin (%)	-11,142%	-39%	-340%	-222%	-518%
Adjusted net profit margin (%) ⁽¹⁾	-10,149%	-21%	-296%	-191%	-459%

	For the year ended December 31,				
	2016	2017	2018	2019	2020
	US\$' 000	US\$' 000	US\$' 000	US\$' 000	US\$' 000
Financial position					
Cash, cash equivalents, and restricted cash	87,514	239,602	740,713	620,775	1,390,005
Short-term investments	280,660	597,914	1,068,509	364,728	3,268,725
Working capital	339,341	763,509	1,697,390	862,384	3,885,491
Total assets	405,813	1,046,479	2,249,684	1,612,289	5,600,757
Total liabilities	52,906	362,248	496,037	633,934	1,731,514
Noncontrolling interest	–	14,422	14,445	16,150	–
Total equity (deficit)	352,907	684,231	1,753,647	978,355	3,869,243

(1) The share-based compensation expenses were excluded.

(2) Financial results and financial position for the relevant periods are prepared based on Annual Report on Form 10-K, which were filed with SEC.

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

We are a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and expand access for patients worldwide.

Our research organization has delivered ten molecules into the clinic in our first ten years, including our two lead commercial medicines, BRUKINSA[®], a small molecule inhibitor of BTK for the treatment of various blood cancers, and tislelizumab, an anti-PD-1 antibody immunotherapy for the treatment of various solid tumor and blood cancers. We are marketing BRUKINSA[®] in the world's two largest pharmaceutical markets, the United States and China, and tislelizumab in China, with an established, science-based commercial organization. We have built state-of-the-art biologic and small molecule manufacturing facilities in China to support the potential future demand of our products, and we also work with high quality CMOs to manufacture our internally developed clinical and commercial products.

We are a leader in China-inclusive global clinical development, which we believe can facilitate faster and more cost-effective development of innovative medicines. Our internal clinical development capabilities are deep, including a more than 1,600-person global clinical development team that is running more than 60 ongoing or planned clinical trials. This includes more than 25 pivotal or registration-enabling trials for three product candidates that have enrolled more than 12,000 patients and healthy volunteers, of which approximately one-half have been outside of China, as of January 2021. We have over 45 products and product candidates in commercial stage or clinical development, including 7 approved medicines, 5 pending approval, and over 30 in clinical development.

Supported by our development and commercial capabilities, we have entered into collaborations with world-leading biopharmaceutical companies such as Amgen and Novartis to develop, manufacture and commercialize innovative medicines globally. Since our inception in 2010 in Beijing, we have become a fully integrated global organization of over 5,300 employees in 14 countries and regions, including China, the United States, Europe and Australia.

RECENT DEVELOPMENTS

On April 12, 2021, we announced results from a planned interim analysis of the Phase 3 RATIONALE 303 trial of tislelizumab compared to docetaxel as second- or third-line therapy for patients with locally advanced or metastatic NSCLC in an oral presentation at the American Association for Cancer Research ("AACR") Annual Meeting 2021. A sBLA based on these results from the RATIONALE 303 trial was accepted in March 2021 and is currently under regulatory review in China.

On April 11, 2021, we announced that clinical data on tislelizumab, in combination with the investigational spectrum-selective kinase inhibitor sitravatinib being jointly developed with Mirati Therapeutics, Inc., were presented in two oral presentations at the AACR Annual Meeting 2021. Data presented at the meeting were from two cohorts of a Phase 1b trial (NCT03666143), in patients with unresectable or metastatic melanoma who were refractory or resistant to PD-1/L1 inhibitors and in patients with advanced platinum-resistant ovarian cancer (PROC).

MANAGEMENT DISCUSSION AND ANALYSIS

On April 8, 2021, we announced that the Phase 2 trial evaluating BRUKINSA® in patients hospitalized with respiratory symptoms of COVID-19, requiring supplemental oxygen without mechanical ventilation, did not meet the co-primary efficacy endpoints of respiratory failure-free survival or reduction in days on oxygen as compared to placebo. There were no new or additional safety signals for zanubrutinib identified in the trial.

On April 7, 2021, we announced approval from the NMPA for BeiGene to begin manufacturing commercial supply of our approved anti-PD-1 antibody, tislelizumab, at our state-of-the-art biologics facility in Guangzhou, China. At over one million square feet (100,000 square meters) and 8,000 liters of biologics capacity approved for commercial supply, this wholly owned facility will immediately begin production of commercial supply of tislelizumab for the China market. An additional phase of construction currently in progress to bring total capacity to 64,000 liters is expected to be completed by the end of 2022.

On March 30, 2021, we announced that Julia Wang has been appointed as Chief Financial Officer, effective June 30, 2021. Ms. Wang will succeed Howard Liang, Ph.D., who previously announced his intention to retire from BeiGene and will stay on through June 30 to ensure an orderly transition.

On March 10, 2021, we announced that the first patient has been dosed in a Phase 1 clinical trial of BGB-15025, our investigational hematopoietic progenitor kinase 1 (HPK1) inhibitor. BGB-15025 is designed to be a potent and highly selective small molecule oral inhibitor of HPK1, a kinase downstream of the T cell receptor (TCR) signaling pathway that is believed to play a key role in T cell activation.

On March 5, 2021, we announced that a sBLA for anti-PD1 antibody tislelizumab was accepted by the CDE of the NMPA for treatment in the second- or third-line setting of patients with locally advanced or metastatic NSCLC who have progressed on prior platinum-based chemotherapy.

On March 2, 2021, we announced that BRUKINSA® has been approved by Health Canada for the treatment of adult patients with WM.

On February 26, 2021, we announced the closing of the collaboration and license agreement with Novartis, previously announced on January 11, 2021, to develop, manufacture, and commercialize BeiGene's anti-PD-1 antibody tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan. The companies have agreed to jointly develop tislelizumab in these licensed countries, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals. In addition, both companies may conduct clinical trials globally to explore combinations of tislelizumab with other cancer treatments, and BeiGene has an option to co-detail the product in North America, funded in part by Novartis.

On February 17, 2021, we announced that the FDA accepted a sNDA for BRUKINSA® for the treatment of adult patients with WM. The Prescription Drug User Fee Act target action date is October 18, 2021.

MANAGEMENT DISCUSSION AND ANALYSIS

On January 29, 2021, we announced that the SSE had accepted our listing application for a proposed public offering of our ordinary shares and listing of such shares on the Science and Technology Innovation Board (the “STAR Market”) of the SSE (the “STAR Offering”). The consummation of the STAR Offering is subject to, among other things, market conditions, shareholder approval, and applicable regulatory approvals.

On January 13, 2021, we announced that our anti-PD-1 antibody tislelizumab received approval from the NMPA for use in combination with chemotherapy as a first-line treatment for patients with advanced squamous NSCLC. This is the third approval in China for tislelizumab, and its first in a lung cancer indication.

On December 27, 2020, we announced that three of our innovative oncology medicines were included in the updated NRDL by the NHSA, including our internally-developed anti-PD1 antibody tislelizumab, our internally-developed BTK inhibitor BRUKINSA® (zanubrutinib), and XGEVA® (120-mg denosumab) from our strategic collaboration with Amgen.

On December 7, 2020, we announced that the NMPA approved BLINCYTO® for injection for the treatment of adult patients with R/R B-cell precursor ALL. The biologics license application had been submitted by Amgen and received priority review by the CDE of the NMPA. Developed by Amgen and licensed to us in China under a strategic collaboration commenced earlier in 2020, this is the first approval for BLINCYTO® in China and our first product licensed from Amgen to be newly approved. With this approval, BLINCYTO® has become the first bispecific immunotherapy approved in China.

On November 19, 2020, we announced that the NMPA approved XGEVA® for the prevention of SREs in patients with bone metastases from solid tumors and in patients with MM. Developed by Amgen and licensed to BeiGene in China under a strategic collaboration commenced earlier in 2020, XGEVA® is also approved and marketed in China for the treatment of adults and skeletally mature adolescents with GCTB that is unresectable or where surgical resection is likely to result in severe morbidity.

FUTURE AND OUTLOOK

Our mission is to provide access to high-quality, innovative, impactful, and affordable medicines to billions more people globally. We believe that we have built competitive advantages in research, clinical development, manufacturing and commercialization that will drive our business into the future. We intend to continue to develop and expand our competitive advantages and become a global leader by focusing on the following key strategic imperatives:

1. **Research And Innovation Focus.** We have built one of the largest research teams in China with more than 450 people and a robust suite of capabilities that fuel our innovation pipeline. To date, our research organization has advanced more than 10 internally discovered molecules into the clinic and, of those programs, two medicines have been approved for commercial use in multiple indications. Our team has discovered promising new drug candidates, including our investigational TIGIT antibody and BCL-2 inhibitor currently in development. We plan to continue to invest in research and innovation with the aim of discovering additional innovative product candidates for patients.

MANAGEMENT DISCUSSION AND ANALYSIS

2. **World Class Clinical Development.** We believe that leveraging our leadership position in China-inclusive clinical development will enable us to develop products with advantages in speed and cost efficiency, while maintaining quality. We plan to continue to invest to in-source our clinical capabilities to mitigate the challenges associated with relying on third-party CROs, with the intention of becoming one of the best clinical development organizations in the world.
3. **China Commercial Leadership.** We have built a large commercial team in China, with over 2,200 colleagues spread across the country and organized under experienced executive leadership. We believe that we have established BeiGene as a high-quality, science-driven, leading provider of innovative and affordable medicines in China. We aspire to grow our commercial portfolio through both internal discovery efforts and through in-licensing additional products and product candidates, striving to be a partner of choice and creating mutual benefits with our partners wherever possible. We believe that our commercial capabilities in China, coupled with our China-inclusive clinical development capabilities conducted at global-quality standards, enable us to attract favorable in-licensing opportunities. We plan to further invest in our China commercial organization and create advantages in scale, speed, and quality to establish our commercial leadership in China.
4. **Global Leadership, Access, and Reputation.** We have launched BRUKINSA® in the United States and built a targeted commercial team focused on medical thought leaders in blood cancer treatments. This competitive foothold is based on the clinical differentiation of our approved products and product candidates and our deep relationships. We aspire to establish our reputation globally as a leading biotechnology company by delivering highly effective and differentiated medicines in the United States, China, Europe and new markets.
5. **Broad Accessibility.** We believe that our commercial scale in China, potentially lower upfront development costs through China-inclusive clinical development, sizeable portfolio of innovative therapies, and overall commercial expertise in serving large, underserved populations give us a unique advantage and create an opportunity for us to be an early mover in providing innovative medicines at affordable prices to many geographies that are not traditionally the focus for pharmaceutical or biotechnology companies. We plan to focus our long-term strategy on seeking approvals of our portfolio compounds globally and building clinical development and commercial capabilities in these markets, either alone or through our collaborators.

MANAGEMENT DISCUSSION AND ANALYSIS

FINANCIAL REVIEW

Components of Operating Results

Revenue

Product Revenue

We began generating product revenue in September 2017 through our in-license agreement with BMS to distribute the approved cancer therapies REVLIMID[®], VIDAZA[®], and ABRAXANE[®] in China. Following approval from the FDA in November 2019, we launched our first internally developed medicine, BRUKINSA[®], in the United States. We launched our second internally developed medicine, tislelizumab, in China in March 2020 and in June 2020, we launched BRUKINSA[®] in China. In July 2020, we began selling XGEVA[®] under our in-license agreement with Amgen.

Revenues from product sales are recognized when there is a transfer of control from the Company to the customer. The Company determines transfer of control based on when the product is delivered, and title passes to the customer. Revenues from product sales are recognized net of variable consideration resulting from rebates, chargebacks, trade discounts and allowances, sales returns allowances and other incentives. Provisions for estimated reductions to revenue are provided for in the same period the related sales are recorded and are based on contractual terms, historical experience and trend analysis. We expect revenue from our internal product sales to increase during 2021. We received approval for BLINCYTO[®] in China in December 2020 and plan to launch additional in-licensed products from our collaborations in 2021, and continue to expand our efforts to promote our existing commercial products.

Collaboration Revenue

We recognize collaboration revenues for amounts earned under collaborative and out-licensing arrangements. Prior to the third quarter of 2019, we recorded revenue from our 2017 collaboration and license agreement with BMS for tislelizumab, which was terminated in June 2019. Under this agreement, we received an upfront payment related to the license fee, which was recognized upon the delivery of the license right. Additionally, the portion of the upfront payment related to the reimbursement of undelivered research and development services was deferred and recognized over the performance period of the collaboration arrangement. We recognized the remainder of the deferred research and development services revenue balance upon termination of the collaboration agreement. We also received research and development reimbursement revenue for the clinical trials that BMS opted into until the termination of the collaboration agreement. Pursuant to the terms of the termination agreement, we received a one-time payment of US\$150 million in June 2019, which was recognized in full at that time because we had no further performance obligations under the collaboration.

MANAGEMENT DISCUSSION AND ANALYSIS

Expenses

Cost of Sales

Cost of sales includes the cost of products purchased from Amgen and BMS and distributed in China and the costs to manufacture our internally developed commercial products. Also included in cost of sales are amounts paid to Amgen for its share of net sales or gross margin earned on sales of their in-licensed products. Costs to manufacture inventory in preparation for commercial launch of a product incurred prior to regulatory approval are expensed to research and development expense as incurred. Cost of sales for newly launched products will not be recorded until the initial pre-launch inventory is depleted and additional inventory is manufactured.

Research and Development Expenses

Research and development expenses consist of the costs associated with our research and development activities, conducting preclinical studies and clinical trials, and activities related to regulatory filings. Our research and development expenses consist of:

- expenses incurred under agreements with CROs, CMOs, and consultants that conduct and support clinical trials and preclinical studies;
- costs of comparator drugs in certain of our clinical trials;
- manufacturing costs related to pre-commercial activities;
- costs associated with preclinical activities and development activities;
- costs associated with regulatory operations;
- employee-related expenses, including salaries, benefits, travel and share-based compensation expense for research and development personnel;
- in-process research and development costs expensed as part of collaboration agreements entered into; and
- other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies used in research and development activities.

MANAGEMENT DISCUSSION AND ANALYSIS

Our current research and development activities mainly relate to the clinical advancement of our internally developed medicines and drug candidates:

- BRUKINSA® (zanubrutinib), a small molecule inhibitor of BTK;
- tislelizumab, a humanized monoclonal antibody against PD-1;
- pamiparib, an investigational selective small molecule inhibitor of PARP1 and PARP2;
- BGB-A1217, an investigational humanized monoclonal antibody against TIGIT;
- BGB-11417, an investigational small molecular inhibitor of Bcl-2;
- lifirafenib, an investigational novel small molecule inhibitor of both the monomer and dimer forms of BRAF;
- BGB-A333, an investigational humanized monoclonal antibody against PD-L1; and
- BGB-A425, an investigational humanized monoclonal antibody against TIM-3.

Research and development activities also include costs associated with in-licensed drug candidates, including:

- R&D expense related to the co-development of pipeline assets under the Amgen collaboration agreement. Our total cost share obligation to Amgen is split between R&D expense and a reduction to the R&D cost share liability;
- sitravatinib, an investigational, spectrum-selective kinase inhibitor, licensed from Mirati Therapeutics, Inc. (“Mirati”);
- zanidatamab (ZW25) and ZW49, two investigational bispecific antibody-based product candidates targeting HER2, licensed from Zymeworks Inc. (“Zymeworks”);
- BA3071, an investigational CAB-CTLA-4 antibody, licensed from BioAtla, Inc. (“BioAtla”);
- BAT1706, an investigational biosimilar to Avastin® (bevacizumab), licensed from Bio-Thera Solutions, Ltd. (“Bio-Thera”); and
- DXP-593 and DXP-604, investigational anti-COVID-19 antibodies, licensed from Singlomics (Beijing DanXu) Biopharmaceuticals Co., Ltd. (“Singlomics”).

MANAGEMENT DISCUSSION AND ANALYSIS

We expense research and development costs when we incur them. We record costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information our vendors provide to us. We expense the manufacturing costs of our internally developed products that are used in clinical trials as they are incurred as research and development expense. We do not allocate employee-related costs, depreciation, rental and other indirect costs to specific research and development programs because these costs are deployed across multiple product programs under research and development and, as such, are separately classified as unallocated research and development expenses.

At this time, it is difficult to estimate or know for certain, the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our internally developed medicines and drug candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our medicines and drug candidates, if approved. This is due to the numerous risks and uncertainties associated with developing such medicines and drug candidates, including the uncertainty of:

- successful enrollment in and completion of clinical trials;
- establishing an appropriate safety and efficacy profile;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- receipt of marketing and other required approvals from applicable regulatory authorities;
- successfully launching and commercializing our medicines and drug candidates, if and when approved, whether as monotherapies or in combination with our internally developed medicines and drug candidates or third-party products;
- market acceptance, pricing and reimbursement;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our medicines and drug candidates;
- continued acceptable safety and efficacy profiles of the products following approval;
- sufficient supply of the products following approval;
- competition from competing products; and
- retention of key personnel.

A change in the outcome of any of these variables with respect to the development of any of our medicines and drug candidates would significantly change the costs, timing and viability associated with the commercialization or development of that medicine or drug candidate.

MANAGEMENT DISCUSSION AND ANALYSIS

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, as we continue to support the clinical trials of our medicines and drug candidates as treatments for various cancers and as we move these medicines and drug candidates into additional clinical trials, including potential pivotal trials. There are numerous factors associated with the successful commercialization of any of our medicines and drug candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control may impact our clinical development and commercial programs and plans.

Cautionary Statement required by Rule 18A.08(3) of the HK Listing Rules: We may not be able to ultimately develop and market pamiparib successfully.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of product promotion costs, distribution costs, salaries and related benefit costs, including share-based compensation for selling, general and administrative personnel. Other selling, general and administrative expenses include professional fees for legal, consulting, auditing and tax services as well as other direct and allocated expenses for rent and maintenance of facilities, travel costs, insurance and other supplies used in selling, general and administrative activities. We anticipate that our selling, general and administrative expenses will increase in future periods to support planned increases in commercialization activities with respect to tislelizumab, BRUKINSA[®], XGEVA[®] and BLINCYTO[®] and the preparation for potential launch and commercialization of additional in-licensed products from our collaborations and internally developed products, if approved. We also expect selling, general and administrative expenses to increase in future periods to support our research and development efforts, including the continuation of the clinical trials of our treatments for various cancers and the initiation of clinical trials for potential new indications or drug candidates. These cost increases will likely be due to increased promotional costs, increased headcount, increased share-based compensation expenses, expanded infrastructure and increased costs for insurance. We also incur significant legal, compliance, accounting, insurance and investor and public relations expenses associated with being a public company with our ADSs and ordinary shares listed for trading on The NASDAQ Global Select Market and the HKEx, respectively.

Interest Income (Expense), Net

Interest Income

Interest income consists primarily of interest generated from our cash and short-term investments in money market funds, time deposits, U.S. Treasury securities and U.S. agency securities.

Interest Expense

Interest expense consists primarily of interest on our bank loans and shareholder loan.

MANAGEMENT DISCUSSION AND ANALYSIS

Other Income (Expense), Net

Other income consists primarily of gains recognized related to equity investments, government grants and subsidies received that involve no conditions or continuing performance obligations by us, realized and unrealized gains and losses related to foreign currency exchange rates, unrealized gains and losses on equity securities, and realized gains and losses on the sale of investments.

RESULTS OF OPERATIONS

Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Change	
	2020	2019		%
	(US dollars in thousands)			
Revenues				
Product revenue, net	308,874	222,596	86,278	38.8%
Collaboration revenue	—	205,616	(205,616)	(100.0)%
Total revenues	308,874	428,212	(119,338)	(27.9)%
Expenses				
Cost of sales – product	70,657	71,190	(533)	(0.7)%
Research and development	1,294,877	927,338	367,539	39.6%
Selling, general and administrative	600,176	388,249	211,927	54.6%
Amortization of intangible assets	846	1,326	(480)	(36.2)%
Total expenses	1,966,556	1,388,103	578,453	41.7%
Loss from operations	(1,657,682)	(959,891)	(697,791)	72.7%
Interest income, net	1,998	9,131	(7,133)	(78.1)%
Other income, net	37,490	7,174	30,316	422.6%
Loss before income tax expense	(1,618,194)	(943,586)	(674,608)	71.5%
Income tax (benefit) expense	(17,671)	6,992	(24,663)	(352.7)%
Net loss	(1,600,523)	(950,578)	(649,945)	68.4%
Less: Net loss attributable to noncontrolling interest	(3,617)	(1,950)	(1,667)	85.5%
Net loss attributable to BeiGene, Ltd.	(1,596,906)	(948,628)	(648,278)	68.3%

MANAGEMENT DISCUSSION AND ANALYSIS

Revenue

Total revenue decreased by approximately US\$119.3 million to approximately US\$308.9 million for the year ended December 31, 2020, from approximately US\$428.2 million for the year ended December 31, 2019, primarily due to the cessation of collaboration revenue following the termination of the BMS collaboration agreement in the second quarter of 2019, and the related US\$150.0 million termination fee that was recognized as revenue. The following table summarizes the components of our revenue for the year ended December 31, 2020 and 2019, respectively:

	Year Ended December 31,		Changes	
	2020	2019		%
	(US dollars in thousands)			
Product revenue	308,874	222,596	86,278	38.8%
Collaboration revenue:				
Reimbursement of research and development costs	-	27,634	(27,634)	(100.0)%
Research and development service revenue	-	27,982	(27,982)	(100.0)%
Other	-	150,000	(150,000)	(100.0)%
Total collaboration revenue	-	205,616	(205,616)	(100.0)%
Total	308,874	428,212	(119,338)	(27.9)%

Net product revenue consisted of the following:

	Year Ended December 31,		Changes	
	2020	2019		%
	(US dollars in thousands)			
Tislelizumab	163,358	-	163,358	NM
BRUKINSA®	41,702	1,039	40,663	3,913.7%
REVLIMID®	47,372	78,044	(30,672)	(39.3)%
VIDAZA®	29,975	32,234	(2,259)	(7.0)%
ABRAXANE®	17,770	111,279	(93,509)	(84.0)%
XGEVA®	8,496	-	8,496	NM
Other	201	-	201	NM
Total product revenue	308,874	222,596	86,278	38.8%

MANAGEMENT DISCUSSION AND ANALYSIS

Net product revenue was US\$308.9 million for the year ended December 31, 2020, compared to US\$222.6 million in the prior year, primarily due to increased sales of our internally-developed products, BRUKINSA® and tislelizumab, as well as initial sales of Amgen's XGEVA®, offset by decreased sales of the BMS products in China. Product revenue for tislelizumab reflects sales since its launch in China in March 2020. Product revenue for BRUKINSA® reflects sales in China since its launch in June 2020, as well as sales in the United States since its launch in November 2019. Product revenue for XGEVA® reflects sales in China since July 2020.

In December 2020, we announced the inclusion of tislelizumab, BRUKINSA®, and XGEVA® in the updated NRDL by the NHSA, effective March 2021. The NRDL's inclusion is expected to help expand access to these high-quality oncology treatments across China, but we expect net product revenue in China in the first quarter of 2021 to be impacted as the lower NRDL price is applied to tislelizumab, BRUKINSA® and XGEVA® product in the distribution channel. Overall, we expect our internally-developed products and in-licensed products from Amgen to lead to total product revenue growth in 2021, driven by an increase in sales volumes as our launches mature.

We expect product revenue from the in-licensed products from BMS to continue to be impacted by the NMPA's suspension of the importation, sales and use of ABRAXANE® in China in March 2020 and the subsequent voluntary recall of ABRAXANE® by BMS, as well as increased competition from generic products for REVLIMID® and the loss of VBP status for VIDAZA®. Although the impact of COVID-19 on commercial activities in China lessened in the second half of 2020, there is continued uncertainty regarding the future potential impact of the pandemic both in China and the United States, as well as globally. We do not expect revenue from ABRAXANE® until the NMPA lifts its suspension on the importation, sale and use of ABRAXANE® and qualified drug is manufactured and available for sale in China. We do not know when the NMPA suspension of ABRAXANE® will be lifted and when we will be able to re-commence sales of ABRAXANE®.

We did not have any collaboration revenue during the year ended December 31, 2020. Collaboration revenue totaled US\$205.6 million for the year ended December 31, 2019, comprised primarily of a US\$150.0 million payment received upon termination of the collaboration agreement with BMS for tislelizumab, as well as the revenue recognition of previously deferred amounts. Additionally, we recognized US\$27.6 million for the reimbursement of research and development costs for the clinical trials that BMS had opted into prior to the agreement being terminated.

Cost of Sales

Cost of sales decreased to US\$70.7 million for the year ended December 31, 2020 from US\$71.2 million for the year ended December 31, 2019, primarily due to a change in sales mix from lower margin in-licensed products to higher margin internally-developed products.

MANAGEMENT DISCUSSION AND ANALYSIS

Research and Development Expense

Research and development expense increased by US\$367.5 million, or 39.6%, to US\$1.3 billion for the year ended December 31, 2020, from US\$927.3 million for the year ended December 31, 2019. The following table summarizes the external cost of development programs, upfront license fees, and internal research and development expense for the years ended December 31, 2020 and 2019:

	Year Ended December 31,		Changes	
	2020	2019		%
	(US dollars in thousands)			
External cost of development programs	502,399	483,526	18,873	3.9%
Upfront license fees	109,500	50,000	59,500	119.0%
Amgen co-development expenses ¹	117,005	–	117,005	NM
Internal research and development expenses	<u>565,973</u>	<u>393,812</u>	<u>172,161</u>	43.7%
Total research and development expenses	<u>1,294,877</u>	<u>927,338</u>	<u>367,539</u>	39.6%

1. Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the year ended December 31, 2020 totaled US\$231.0 million, of which US\$117.0 million was recorded as R&D expense. The remaining US\$114.0 million was recorded as a reduction for the R&D cost share liability.

The increase in research and development expenses for the year December 31, 2020 was primarily attributable to:

- an increase of US\$117.0 million related to expense recognized on co-development fees to Amgen;
- an increase of US\$59.5 million related to license fees under collaboration agreements; and
- an increase of US\$18.9 million in external clinical program costs, primarily due to the continued enrollment and expansion of pivotal clinical trials for our tislelizumab program and increases due to the expansion and advancement of and manufacturing costs for our earlier-stage clinical drug candidates.

MANAGEMENT DISCUSSION AND ANALYSIS

Internal research and development expense increased US\$172.2 million, primarily attributable to the expansion of our global development organization including the internalization of previously outsourced activities and the continued development of our clinical and preclinical drug candidates, and included the following:

- US\$67.6 million increase of employee salary and benefits, primarily attributable to hiring more research and development personnel to support our expanding research and development activities;
- US\$60.3 million increase of materials and reagent expenses, primarily in connection with the in-house manufacturing of drug candidates used for clinical purposes;
- US\$16.7 million increase of share-based compensation expense, primarily attributable to our increased headcount, resulting in more awards being expensed related to the growing employee population; and
- US\$30.5 million increase of facilities, depreciation, office expense, rental fees, and other expenses to support the growth of our organization.

These expense increases were partially offset by a US\$2.9 million decrease of consulting fees, which was primarily attributable to decreased travel, meeting and seminar expenses related to scientific, regulatory and development consulting activities.

Selling, General and Administrative Expense

Selling, general and administrative expense increased by US\$211.9 million, or 54.6%, to US\$600.2 million for the year ended December 31, 2020, from US\$388.2 million for the year ended December 31, 2019. The increase was primarily attributable to the following:

- US\$117.5 million increase in employee salary and benefits, which was primarily attributable to the expansion of our commercial organizations in China and the United States and the hiring of more personnel to support our growing business;
- US\$36.2 million increase in external commercial expenses, including selling and marketing, market access studies, meeting and seminar expenses, promotional activities, and sponsorship and grant expenses;
- US\$32.6 million increase in share-based compensation expense, primarily attributable to our increased headcount, resulting in more awards being expensed related to the growing employee population; and
- US\$25.6 million increase in professional fees, consulting, recruiting, information technology, tax, accounting and audit services; and facility expenses, rental fees, office expenses, and other administrative expenses, primarily attributable to the global expansion of our business, including the expansion of our commercial operations in China and the United States.

MANAGEMENT DISCUSSION AND ANALYSIS

Interest Income, Net

Interest income, net decreased to US\$2.0 million for the year ended December 31, 2020, from US\$9.1 million for the year ended December 31, 2019. The decrease in interest income, net, was primarily attributable to higher interest expense related to larger loan balances in 2020 and lower interest earned on our investments.

Other Income, Net

Other income, net increased by US\$30.3 million to US\$37.5 million for the year ended December 31, 2020, from US\$7.2 million for the year ended December 31, 2019. The increase was mainly attributable to the gain recognized in conjunction with the deconsolidation of MapKure, unrealized gains on equity securities, and realized gains on sales of available-for-sale securities, as well as foreign currency exchange gains.

Income Tax (Benefit) Expense

Income tax benefit was US\$17.7 million for the year ended December 31, 2020 compared with income tax expense of US\$7.0 million for the year ended December 31, 2019. The income tax benefit for the year ended December 31, 2020 was primarily attributable to the tax benefit of U.S. share-based compensation deductions in excess of the tax expense on income reported in certain China subsidiaries as adjusted for certain non-deductible expenses.

DISCUSSION OF CERTAIN KEY BALANCE SHEET ITEMS

Cash, cash equivalents, restricted cash and short-term investments

As of December 31, 2020, the Company's cash, cash equivalents, restricted cash and short-term investments primarily comprised (1) US\$4.0 billion denominated in US dollars; (2) approximately RMB4.3 billion (equivalent to approximately US\$659.3 million) denominated in Renminbi; and (3) approximately US\$16.9 million denominated in Australian dollar, Euro and other currencies.

Property, plant and equipment, net

The property, plant and equipment increased by 47.6% from US\$242.4 million as of December 31, 2019 to US\$357.7 million as of December 31, 2020, primarily attributable to our ongoing buildout of the Guangzhou manufacturing facility.

MANAGEMENT DISCUSSION AND ANALYSIS

Accounts receivable

Accounts receivable decreased by 14.8% from US\$70.9 million as of December 31, 2019 to US\$60.4 million as of December 31, 2020, primarily due to the shorter average collection period of accounts receivable for the year ended December 31, 2020, and the suspension of ABRAXANE® in China by the NMPA in March 2020, as compared to the year ended December 31, 2019.

Inventories

The inventories increased by 212.2% from US\$28.6 million as of December 31, 2019 to US\$89.3 million as of December 31, 2020, primarily due to stock preparation for the increased sales of our internally-developed products, BRUKINSA® and tislelizumab, as well as initial sales of Amgen's XGEVA®.

Prepaid expenses and other current assets

Prepaid expenses and other current assets consist of the following as of December 31, 2020 and 2019:

	As of December 31,	
	2020	2019
	(US dollars in thousands)	
Prepaid research and development costs	71,341	65,886
Prepaid taxes	30,392	9,498
Payroll tax receivable	3,580	5,365
Non-trade receivable	4,464	–
Interest receivable	6,619	1,932
Prepaid insurance	1,347	711
Prepaid manufacturing cost	25,996	3,829
Income tax receivable	4,607	–
Other	11,666	3,017
	<u>160,012</u>	<u>90,238</u>
Total	<u>160,012</u>	<u>90,238</u>

Prepaid expenses and other current assets increased by 77.4% from US\$90.2 million as of December 31, 2019 to US\$160.0 million as of December 31, 2020. The increase was primarily due to (i) the increase of prepaid VAT; (ii) the expansion of manufacturing cost of our internally developed products.

Accounts payable

Accounts payable includes amounts due to third parties and totaled US\$232.0 million and US\$122.5 million as of December 31, 2020 and 2019, respectively.

MANAGEMENT DISCUSSION AND ANALYSIS

The following table sets forth an aging analysis of accounts payables as of the dates indicated, which is based on invoice date:

	As of December 31,	
	2020	2019
	(US dollars in thousands)	
Within 3 months	230,638	118,787
3 to 6 months	312	1,889
6 months to 1 year	147	1,272
Over 1 year	<u>860</u>	<u>540</u>
Total	<u>231,957</u>	<u>122,488</u>

Accrued expenses and other payables

Accrued expenses and other payables consist of the following as of December 31, 2020 and 2019:

	As of December 31,	
	2020	2019
	(US dollars in thousands)	
Compensation related	106,765	54,156
External research and development activities related	143,302	62,794
Commercial activities	66,131	25,645
Individual income tax and other taxes	14,373	9,648
Sales rebates and returns related	11,874	3,198
Other	<u>3,699</u>	<u>8,115</u>
Total accrued expenses and other payables	<u>346,144</u>	<u>163,556</u>

Accrued expenses and other payables increased by 111.6% from US\$163.6 million as of December 31, 2019 to US\$346.1 million as of December 31, 2020. The increase was primarily due to (i) hiring of more personnel to support our expanding commercial, research and clinical activities and our growing organization; (ii) expansion of clinical trials for drug candidates, including the initiation or continuation of pivotal trials; and (iii) expansion of our commercial operations and launch of the new products.

MANAGEMENT DISCUSSION AND ANALYSIS

LIQUIDITY AND CAPITAL RESOURCES

The following table represents our cash, short-term investments, and debt balances as of December 31, 2020:

	Year Ended December 31,	
	2020	2019
	(US dollars in thousands)	
Cash, cash equivalents and restricted cash	1,390,005	620,775
Short-term investments	3,268,725	364,728
Total debt	<u>518,652</u>	<u>240,695</u>

We have incurred annual net losses and negative cash flows from operations since inception, resulting from the funding of our research and development programs and selling, general and administrative expenses associated with our operations, as well as to support the commercialization of our products globally. We incurred net losses of approximately US\$1.6 billion and US\$950.6 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of US\$3.6 billion.

To date, we have financed our operations principally through proceeds from public and private offerings of our securities and proceeds from our collaborations, together with product sales since September 2017. Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of December 31, 2020 will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months after the date of this report.

On January 29, 2021, SSE accepted our listing application for a proposed public offering of our ordinary shares and listing of such shares on the STAR Market of the SSE. The STAR Offering will be conducted within the PRC, and such shares will be issued to and subscribed for by investors in Renminbi (“RMB”) in the PRC and listed and traded on the STAR Market in RMB (the “RMB Shares”). The number of RMB Shares (including the over-allotment option) to be issued will not exceed 132,313,549 ordinary shares, representing no more than 10% of the sum of the total number of our issued ordinary shares as of January 7, 2021 and the total number of RMB Shares to be issued in the STAR Offering. The STAR Offering is subject to, among other things, market conditions, the approval of our shareholders, and applicable regulatory approvals.

On January 11, 2021, we entered into a collaboration and license agreement with Novartis to develop, manufacture and commercialize tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan. The transaction was closed on February 26, 2021. Under the agreement, we received an upfront cash payment of US\$650 million from Novartis, which is not included in our cash balance as of December 31, 2020, upon closing of the transaction.

MANAGEMENT DISCUSSION AND ANALYSIS

The following table provides information regarding our cash flows for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
	(US dollars in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	620,775	740,713
Net cash used in operating activities	(1,283,461)	(750,269)
Net cash (used in) provided by investing activities	(3,168,366)	554,163
Net cash provided by financing activities	5,202,826	85,680
Net effect of foreign exchange rate changes	<u>18,231</u>	<u>(9,512)</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>769,230</u>	<u>(119,938)</u>
Cash, cash equivalents and restricted cash at end of period	<u><u>1,390,005</u></u>	<u><u>620,775</u></u>

Operating Activities

Cash flows from operating activities is net income adjusted for certain non-cash items and changes in assets and liabilities.

Operating activities used US\$1.3 billion of cash for the year ended December 31, 2020, which resulted principally from our net loss of approximately US\$1.6 billion, partially offset by non-cash charges of US\$166.5 million and a decrease in our net operating assets and liabilities of US\$150.6 million. The non-cash charges were primarily driven by share-based compensation expense, offset by amortization of the research and development cost share liability. The decrease in working capital were driven largely by increases in accounts payable, accrued expenses and other liabilities, offset by increases in inventory and prepaid expenses.

Operating activities used US\$750.3 million of cash for the year ended December 31, 2019, which resulted principally from our net loss of US\$950.6 million and an increase in our net operating assets and liabilities of US\$10.8 million, partially offset by non-cash charges of US\$211.1 million. The increase in working capital was driven primarily by increases in accounts receivable and other non-current assets, as well as a decrease in deferred revenue, offset by increases in accounts payable and accrued expenses.

MANAGEMENT DISCUSSION AND ANALYSIS

Investing Activities

Cash flows from investing activities consist primarily of capital expenditures, investment purchases, sales, maturities, and disposals, and upfront payments related to our collaboration agreements.

Investing activities used US\$3.2 billion of cash for the year ended December 31, 2020, consisting of US\$5.7 billion in purchases of investment securities, US\$117.5 million of capital expenditures, and US\$109.5 million upfront collaboration payments, all of which were offset by sales and maturities of investment securities of US\$2.8 billion.

Investing activities provided US\$554.2 million of cash for the year ended December 31, 2019, which was primarily due to cash proceeds from the sale and maturities of investment securities of US\$1.9 billion, partially offset by purchases of investment securities of US\$1.2 billion, US\$69.0 million of upfront payments related to our license agreements and the termination of our collaboration agreement with Merck KGaA, Darmstadt Germany, and capital expenditures of US\$89.6 million.

Financing Activities

Cash flows from financing activities consist primarily of sale of ordinary shares and ADSs through equity offerings, issuance and repayment of short-term and long-term debt, and proceeds from the sale of ordinary shares and ADSs through employee equity compensation plans.

Financing activities provided US\$5.2 billion of cash for the year ended December 31, 2020. This consisted primarily of US\$2.8 billion received from our collaboration with Amgen and US\$2.1 billion from a registered direct offering of ordinary shares to certain existing investors. Other inflows included US\$93.1 million from the exercise of employee share options and proceeds from the issuance of shares through our employee share purchase plan, and US\$433.9 million from loan proceeds. These inflows were partially offset by US\$144.3 million of repayment of principal under the Shareholder Loan with GET and US\$28.7 million of cash consideration paid for the acquisition of the remaining 5% minority interest in our subsidiary BeiGene Biologics Co., Ltd. (“BeiGene Biologics”).

Financing activities provided US\$85.7 million of cash for the year ended December 31, 2019. This consisted primarily of US\$67.5 million from bank loans to fund our Guangzhou manufacturing facility and working capital requirements and US\$47.0 million from the exercise of employee share options. These inflows were partially offset by US\$32.8 million for repayments of our Suzhou manufacturing facility and working capital bank loans.

MANAGEMENT DISCUSSION AND ANALYSIS

Effects of Exchange Rates on Cash

We have substantial operations in the PRC, which generate a significant amount of RMB-denominated cash from product sales and require a significant amount of RMB-denominated cash to pay our obligations. Since the reporting currency of the Company is the U.S. dollar, periods of volatility in exchange rates may have a significant impact on our consolidated cash balances.

Operating Capital Requirements

We expect to continue to incur losses for the foreseeable future and expect these losses to increase in the near term, as we continue to develop and seek regulatory approvals for our product candidates, expand our research and manufacturing facilities and activities, and commercialize both our internally developed and in-licensed products. The size of our future net losses will depend, in part, on the number and scope of our development programs and the associated costs of those programs, our ability to generate product revenue, and the timing and amount of payments we make or receive from arrangements with third parties. If any of our products and product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

Our future capital requirements will depend on many factors, including:

- our ability to successfully commercialize our internally developed and in-licensed medicines and drug candidates, if approved;
- the costs, timing and outcome of regulatory reviews and approvals;
- the ability of our drug candidates to progress through clinical development successfully;
- the initiation, progress, timing, costs and results of nonclinical studies and clinical trials for our other programs and potential drug candidates;
- the number and characteristics of the medicines and drug candidates we pursue;
- the costs of establishing or expanding commercial manufacturing capabilities or securing necessary supplies from third-party manufacturers;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs of establishing and expanding our commercial operations and the success of those operations;
- the extent to which we acquire or in-license other products and technologies; and
- our ability to establish and maintain collaboration arrangements on favorable terms, if at all.

MANAGEMENT DISCUSSION AND ANALYSIS

Until such time, if ever, as we can generate substantial product revenue, we may be required to finance our cash needs through a combination of equity offerings, debt financings, collaboration agreements, strategic alliances, licensing arrangements, government grants, and other available sources. Under the rules of the SEC, we currently qualify as a “well-known seasoned issuer,” which allows us to file shelf registration statements to register an unspecified amount of securities that are effective upon filing. On May 11, 2020, we filed such a shelf registration statement with the SEC for the issuance of an unspecified amount of ordinary shares (including in the form of ADSs), preferred shares, various series of debt securities and/or warrants to purchase any of such securities, either individually or in units, from time to time at prices and on terms to be determined at the time of any such offering. This registration statement was effective upon filing and will remain in effect for up to three years from filing, prior to which time we may file another shelf registration statement that will be effective for up to three years from filing.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of ADSs or ordinary shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends, and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through collaboration agreements, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our products or drug candidates, future revenue streams or research programs, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings, collaborations or other sources when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market products or drug candidates that we would otherwise prefer to develop and market ourselves.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following table summarizes our significant contractual obligations as of payment due date by period at December 31, 2020:

	Payments Due by Period				
	Total	Less Than 1 Year	1–3 Years	3–5 Years	More Than 5 Years
	(US dollars in thousands)				
Contractual obligations					
Operating lease commitments	47,785	16,108	23,520	7,902	255
Purchase commitments	123,383	41,681	34,872	24,172	22,658
Debt obligations	518,652	335,015	15,019	63,106	105,512
Interest on debt	59,021	22,238	16,593	13,196	6,994
Co-development funding commitment	1,019,009	259,000	760,009	–	–
Pension plan	8,113	1,357	2,714	2,714	1,328
Capital commitments	44,972	44,972	–	–	–
Total	1,820,935	720,371	852,727	111,090	136,747

MANAGEMENT DISCUSSION AND ANALYSIS

Operating Lease Commitments

We lease office or manufacturing facilities in Beijing, Shanghai, Suzhou and Guangzhou in China; office facilities in California, Massachusetts, Maryland, and New Jersey in the United States; and in Basel, Switzerland under non-cancelable operating leases expiring on various dates. Payments under operating leases are expensed on a straight-line basis over the respective lease terms. The aggregate future minimum payments under these non-cancelable operating leases are summarized in the table above.

Purchase Commitments

As of December 31, 2020, purchase commitments amounted to US\$123.4 million, of which US\$101.3 million related to minimum purchase requirements for supply purchased from CMOs and US\$22.1 million related to binding purchase order obligations of inventory from BMS and Amgen. We do not have any minimum purchase requirements for inventory from BMS or Amgen.

Debt Obligations

The following table summarizes our short-term debt and long-term bank loans as of December 31, 2020 (amounts in thousands, except for percentage data):

Lender	Agreement Date	Line of Credit US\$' 000/RMB' 000	Term	Maturity Date	Interest Rate	December 31, 2020	
						US\$' 000	RMB' 000
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	307	2,000
China Minsheng Bank (the "Senior Loan")	September 24, 2020	US\$200,000		(2)	5.8%	198,320	1,294,010
Zuhai Hillhouse (the "Related Party Loan")	September 24, 2020	RMB500,000		(3)	5.8%	15,326	100,000
Other short-term debt (4)						<u>121,062</u>	<u>789,918</u>
Total short-term debt						<u>335,015</u>	<u>2,185,928</u>
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	88,584	578,000
China Merchants Bank	January 22, 2020	(5)	9-year	January 20, 2029	(5)	53,641	350,000
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(6)	<u>41,412</u>	<u>270,206</u>
Total long-term bank loans						<u>183,637</u>	<u>1,198,206</u>

MANAGEMENT DISCUSSION AND ANALYSIS

Notes:

1. The outstanding borrowings bear a floating interest rate benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.9% as of December 31, 2020.
2. US\$120.0 million of the Senior Loan was designated to fund the JV share repurchase and repayment of the shareholder loan and US\$80.0 million was designated for general working capital purposes. The Senior Loan has an original maturity date of October 8, 2021, which is the first anniversary of the first date of utilization of the loan. We may extend the original maturity date for up to two additional twelve-month periods. On October 9, 2020, we drew down US\$80.0 million of the working capital facility and US\$118.3 million of the acquisition facility to be used for the JV share repurchase.
3. RMB100.0 million of the Related Party Loan was designated for general corporate purposes and RMB400.0 million was designated for repayment of the Senior Loan, including principal, interest and fees. The loan matures at the earlier of: (i) November 9, 2021, which is one month after the Senior Loan maturity date, if not extended, or (ii) ten business days after the Senior Loan is fully repaid. On September 30, 2020, we drew down the first tranche of US\$14.7 million (RMB100.0 million).
4. We entered into additional short-term working capital loans with China Industrial Bank and China Merchants Bank to borrow up to RMB1.5 billion in aggregate, with maturity dates ranging from April 19, 2021 to December 16, 2021 during the year ended December 31, 2020. The weighted average interest rate for the short-term working capital loans was approximately 4.4% as of December 31, 2020.
5. On January 22, 2020, our BeiGene Guangzhou Factory subsidiary entered into a nine-year bank loan with China Merchants Bank to borrow up to RMB1.1 billion at a floating interest rate benchmarked against prevailing interest rates of certain PRC financial institutions. In connection with our short-term loan agreements with China Merchants Bank entered into during the year ended December 31, 2020, the line of credit was reduced from RMB1.1 billion to RMB350.0 million. The loan interest rate was 4.4% as of December 31, 2020.
6. The outstanding borrowings bear a floating interest rate benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.3% as of December 31, 2020.

Interest on Debt

Interest on bank loans and the Related Party Loan is paid quarterly until the respective loans are fully settled. For the purpose of contractual obligations calculation, current interest rates on floating rate obligations were used for the remainder contractual life of the outstanding borrowings.

Co-Development Funding Commitments

Under our collaboration with Amgen, we are responsible for co-funding global development costs for the licensed oncology pipeline assets, up to a total cap of US\$1.25 billion. We are funding our portion of the co-development costs by contributing cash and/or development services. As of December 31, 2020, our remaining co-development funding commitment was US\$1.0 billion.

MANAGEMENT DISCUSSION AND ANALYSIS

Pension Plan

We maintain a defined benefit pension plan in Switzerland. Funding obligations under the defined benefit pension plan are equivalent to US\$1.4 million per year based on annual funding contributions in effect as of December 31, 2020 to achieve fully funded status where the market value of plan assets equals the projected benefit obligations. Future funding requirements will be subject to change as a result of future changes in staffing and compensation levels, various actuarial assumptions and actual investment returns on plan assets.

Capital Commitments

We had capital commitments amounting to US\$45.0 million for the acquisition of property, plant and equipment as of December 31, 2020, which was primarily for BeiGene Guangzhou Factory's manufacturing facility, expansion of BGC's research and development activities in Guangzhou, China, and research and development operations at our Changping facility in Beijing, China.

Other Business Agreements

We enter into agreements in the ordinary course of business with CROs to provide research and development services. These contracts are generally cancelable at any time by us with prior written notice.

We also enter into collaboration agreements with institutions and companies to license intellectual property. We may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with these agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. These commitments are not recorded on our balance sheet because the achievement and timing of these milestones are not fixed and determinable. When the achievement of these milestones or sales have occurred, the corresponding amounts are recognized in our financial statements.

Off-Balance Sheet Arrangements

During the periods presented we did not have, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

MANAGEMENT DISCUSSION AND ANALYSIS

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”). The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Our most critical accounting policies are summarized below. See Note 2 to our consolidated financial statements included in this Annual Report for a description of our other significant accounting policies.

Revenue Recognition

Effective January 1, 2018, we adopted Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* (“ASC 606”) using the modified retrospective approach.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

Once a contract is determined to be within the scope of ASC 606 at contract inception, we review the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. We recognize as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Product Revenue

The Company generates product revenue in China through the sale of its internally developed drugs tislelizumab and BRUKINSA®, and the sale of in-licensed products in China through its agreements with Amgen and BMS. Under the commercial profit share arrangement with Amgen, the Company is the principal for in-licensed product sales to customers in China during the commercialization period and recognizes 100% of net product revenue on these sales. Amounts due to Amgen for its portion of net product sales are recorded as cost of sales. In the United States, the Company generates product revenue from the sale of BRUKINSA®.

MANAGEMENT DISCUSSION AND ANALYSIS

In China, the Company sells its internally developed products to multiple distributors, who in turn sell the products to hospitals or pharmacies within their authorized territories to be sold ultimately to patients. In-licensed products are sold to a first-tier distributor who subsequently resells the products to second-tier distributors who ultimately sell the products to health care providers and patients. In the United States, the Company distributes BRUKINSA® through specialty pharmacies and specialty distributors. The specialty pharmacies and specialty distributors subsequently resell the product to health care providers and patients. We are the principal under the product sales, as we control the products with the ability to direct the use of, and obtain substantially all the remaining benefits, from the products before they are sold to the customer. For product sales transactions, we have a single performance obligation, which is to sell the products to our customer. We include variable consideration in the transaction price to the extent it is probable that a significant reversal will not occur and estimate variable consideration from rebates, chargebacks, trade discounts and allowances, sales returns allowances, and other incentives using the expected value method. Revenues for product sales are recognized at a point in time when the single performance obligation is satisfied upon delivery to the customer. Our payment terms are approximately 45-90 days. Actual amounts of consideration ultimately received may differ from our estimates. We will reassess estimates for variable consideration periodically. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

In China, rebates are offered to distributors. We record a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include the level of distributor inventories, sales volumes and contract pricing and estimated acceptance of government pricing or reimbursement amounts (such as provincial acceptance of the NRDL pricing in the PRC). We regularly review the information related to these estimates and adjust the provision accordingly.

In the United States, estimates for variable consideration for which reserves are established at the time of sale include government rebates, chargebacks, trade discounts and allowances, sales returns allowances and other incentives that are offered within contracts between the Company and our U.S. customers, health care providers and other indirect customers. Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns.

We base our sales returns allowance on estimated distributor inventories, customer demand as reported by third-party sources, and actual returns history, as well as other factors, as appropriate. For newly launched products where actual returns history is not yet available, the sales returns allowance is initially calculated based on benchmarking data from similar products and industry experience. If the historical or benchmarking data we use to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Any changes from the historical trend rates are considered in determining the current sales return allowance. To date, sales returns have not been significant.

MANAGEMENT DISCUSSION AND ANALYSIS

Collaboration Revenue

At contract inception, we analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements (“ASC 808”) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our agreements, we perform the five-step model under ASC 606 noted above.

Our collaborative arrangements may contain more than one unit of account, or performance obligation, including grants of licenses to intellectual property rights, agreements to provide research and development services and other deliverables. The collaborative arrangements do not include a right of return for any deliverable. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. In developing the stand-alone selling price for a performance obligation, we consider competitor pricing for a similar or identical product, market awareness of and perception of the product, expected product life and current market trends. In general, the consideration allocated to each performance obligation is recognized when the respective obligation is satisfied either by delivering a good or providing a service, limited to the consideration that is not constrained. Non-refundable payments received before all of the relevant criteria for revenue recognition are satisfied are recorded as advances from customers.

Licenses of Intellectual Property: Upfront non-refundable payments for licensing our intellectual property are evaluated to determine if the license is distinct from the other performance obligations identified in the arrangement. For licenses determined to be distinct, we recognize revenues from non-refundable up-front fees allocated to the license at a point in time, when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Research and Development Services: The portion of the transaction price allocated to research and development services performance obligations is deferred and recognized as collaboration revenue overtime as delivery or performance of such services occurs. R&D reimbursement revenue for revenue attributable to the clinical trials that BMS had opted into is recognized as delivery or performance of such services occurs.

MANAGEMENT DISCUSSION AND ANALYSIS

Milestone Payments: At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestones related to our development-based activities may include initiation of various phases of clinical trials. Due to the uncertainty involved in meeting these development-based targets, they are generally fully constrained at contract inception. We will assess whether the variable consideration is fully constrained each reporting period based on the facts and circumstances surrounding the clinical trials. Upon changes to constraint associated with the developmental milestones, variable consideration will be included in the transaction price when a significant reversal of revenue recognized is not expected to occur and allocated to the separate performance obligations. Regulatory milestones are fully constrained until the period in which those regulatory approvals are achieved due to the inherent uncertainty with the approval process. Regulatory milestones are included in the transaction price in the period regulatory approval is obtained.

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Research and Development Expenses

Research and development expenses represent costs associated with our research and development activities, which primarily include (1) payroll and related costs (including share-based compensation) associated with research and development personnel; (2) costs related to clinical trials and preclinical testing of our technologies under development; (3) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses; (4) expenses for research services provided by universities and contract laboratories, including sponsored research funding; and (5) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to our research and development services and have no alternative future uses.

Clinical trial costs are a significant component of our research and development expenses. We have a history of contracting with third parties that perform various clinical trial activities on behalf of us in the ongoing development of our product candidates. Expenses related to clinical trials are accrued based on our estimates of the actual services performed by the third parties for the respective period. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), we will modify the related accruals accordingly on a prospective basis. Revisions in the scope of a contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

MANAGEMENT DISCUSSION AND ANALYSIS

The process of estimating our research and development expenses involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting expenses that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of research and development expenses.

Acquired In-Process Research and Development Expense

We have acquired rights to develop and commercialize drug products and product candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a “business” as defined under GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. Royalties owed on sales of the products licensed pursuant to the agreements are expensed in the period the related revenues are recognized.

Income Taxes

We use the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

We evaluate our uncertain tax positions using the provisions of ASC 740, *Income Taxes*, which prescribes a recognition threshold that a tax position is required to meet before being recognized in the financial statements. We recognize in the financial statements the benefit of a tax position which is “more likely than not” to be sustained under examination based solely on the technical merits of the position assuming a review by tax authorities having all relevant information. Tax positions that meet the recognition threshold are measured using a cumulative probability approach, at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. It is our policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

MANAGEMENT DISCUSSION AND ANALYSIS

RECENT ACCOUNTING PRONOUNCEMENTS

See Note 2 to our consolidated financial statements included in this Annual Report for information regarding recent accounting pronouncements.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

INTEREST AND CREDIT RISK

Financial instruments that are potentially subject to credit risk consist of cash and cash equivalents, restricted cash, and short term investments. The carrying amounts of cash, cash equivalents, restricted cash and short term investments represent the maximum amount of loss due to credit risk. We had cash and cash equivalents of US\$1.4 billion and US\$618.0 million restricted cash of US\$8.1 million and US\$2.8 million and short-term investments of US\$3.3 billion and US\$364.7 million at December 31, 2020 and 2019, respectively. Our cash and cash equivalents are deposited with various major reputable financial institutions located within or without the PRC. The deposits placed with these financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, we may be unlikely to claim our deposits back in full. We believe that these financial institutions are of high credit quality, and we continually monitor the credit worthiness of these financial institutions. At December 31, 2020, our short-term investments consisted primarily of U.S. treasury securities. We believe that U.S. treasury securities are of high credit quality and continually monitor the credit worthiness of these institutions.

The primary objectives of our investment activities are to preserve principal, provide liquidity, and maximize income without significant increasing risk. Our primary exposure to market risk relates to fluctuations in the interest rates, which are affected by changes in the general level of PRC and U.S. interest rates. Given the short-term nature of our cash equivalents, we believe that a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We estimate that a hypothetical 100-basis point increase or decrease in market interest rates would result in a decrease of US\$17.1 million or increase of US\$4.3 million, respectively, in the fair value of our investment portfolio as of December 31, 2020.

We do not believe that our cash, cash equivalents, and short-term investments have significant risk of default or illiquidity. While we believe our cash, cash equivalents, and short-term investments do not contain excessive risk, we cannot provide absolute assurance that in the future investments will not be subject to adverse changes in market value.

MANAGEMENT DISCUSSION AND ANALYSIS

CURRENCY CONVERTIBILITY RISK

A significant portion of our expenses, assets, and liabilities are denominated in RMB. In 1994, the PRC government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China (the "PBOC"). However, the unification of exchange rates does not imply that the RMB may be readily convertible into U.S. dollars or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approvals of foreign currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

Additionally, the value of the RMB is subject to changes in central government policies and international economic and political developments affecting supply and demand in the PRC foreign exchange trading system market.

FOREIGN CURRENCY EXCHANGE RATE RISK

We are exposed to foreign exchange risk arising from various currency exposures. Our reporting currency is the U.S. dollar, but a portion of our operating transactions and assets and liabilities are in other currencies, such as RMB, Euro, and Australian dollar.

RMB is not freely convertible into foreign currencies for capital account transactions. The value of RMB against the U.S. dollar and other currencies is affected by, among other things, changes in China's political and economic conditions and China's foreign exchange prices. Since 2005, the RMB has been permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. The RMB compared to the U.S. dollar appreciated approximately 6.3% and depreciated approximately 1.3% for the years ended December 31, 2020 and 2019, respectively. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

To the extent that we need to convert U.S. dollars into RMB for capital expenditures, working capital and other business purposes, appreciation of RMB against the U.S. dollar would have an adverse effect on the RMB amount we would receive from the conversion. Conversely, if we decide to convert RMB into U.S. dollars for the purpose of making payments for dividends on our ordinary shares, strategic acquisitions or investments or other business purposes, appreciation of the U.S. dollar against RMB would have a negative effect on the U.S. dollar amount available to us.

In addition, a significant depreciation of the RMB against the U.S. dollar may significantly reduce the U.S. dollar equivalent of our foreign cash balances and trade receivables. Further, volatility in exchange rate fluctuations may have a significant impact on the foreign currency translation adjustments recorded in other comprehensive income (loss). We have not used derivative financial instruments to hedge exposure to foreign exchange risk during the year ended December 31, 2020.

MANAGEMENT DISCUSSION AND ANALYSIS

EFFECTS OF INFLATION

Inflation generally affects us by increasing our cost of labor and clinical development costs. We do not believe that inflation has had a material effect on our results of operations during the year ended December 31, 2020.

GEARING RATIO

The gearing ratio of the Group, which was calculated by dividing total interest-bearing loans by total equity as of the end of the year, was 13.4% as of December 31, 2020, decreased from 24.6% as of December 31, 2019. The decrease was primarily due to the increase in equity.

SIGNIFICANT INVESTMENTS HELD

For the breakdown of our significant investment held, please refer to notes 6 and 21 to the consolidated financial statements. Regarding the discussion of the Company's investment strategy for our significant investment held, please refer to the section of "Investment Risk Management and Treasury Policy" under Corporate Governance Report of this annual report.

Except as disclosed in notes to the consolidated financial statements and Corporate Governance Report, we did not hold any other significant investments as of December 31, 2020.

FUTURE PLANS FOR MATERIAL INVESTMENTS AND CAPITAL ASSETS

As of December 31, 2020, we did not have other plans for material investments and capital assets.

MATERIAL ACQUISITIONS AND DISPOSALS OF SUBSIDIARIES, ASSOCIATES AND JOINT VENTURES

During the year ended December 31, 2020, except as disclosed in notes to the consolidated financial statement, we did not have any material acquisitions and disposals of subsidiaries, associates and joint ventures.

EMPLOYEE AND REMUNERATION POLICY

As of December 31, 2020, we had a global team of approximately 5,100 employees, which increased from 3,359 employees as of December 31, 2019. Most of our employees are full-time.

The remuneration policy and package of the Group's employees are periodically reviewed. In addition to cash compensation and benefits, we may issue share options, share appreciation rights, restricted shares, restricted share units, unrestricted shares, performance share awards, cash-based awards and dividend equivalent rights to our employees in accordance with our equity plans. We also provide external and internal training programs to our employees. The packages were set by benchmarking with companies in similar industries and companies with similar size. The total remuneration cost incurred by the Group for the year ended December 31, 2020 was US\$663.8 million (2019: US\$434.6 million).

MANAGEMENT DISCUSSION AND ANALYSIS

PLEDGE OF ASSETS

As of December 31, 2020, we pledged restricted deposits of US\$8.1 million (December 31, 2019: US\$2.8 million) held in designated bank accounts for collateral for letters of credit and letter of guarantee. Guangzhou Factory's land use right and certain Guangzhou Factory fixed assets of the first phase of the Guangzhou manufacturing facility's build out with a total carrying amount of US\$148.6 million (December 31, 2019: US\$11.2 million) were secured for a long-term bank loan, and the Innerway's research and development facility in Beijing and the associated land use right with a total carrying amount of US\$34.6 million was secured for a short-term working capital loan which was drawn down in 2020.

CONTINGENT LIABILITIES

As of December 31, 2020, we did not have any material contingent liabilities (as of December 31, 2019: nil).

FINAL DIVIDEND

The Board does not recommend any final dividend for the year ended December 31, 2020.

DIRECTORS AND SENIOR MANAGEMENT

Our Board of Directors (“Board”) consists of 11 Directors, comprising one executive Director, two non-executive Directors, and eight independent non-executive Directors. The following table provides certain information about our Directors as of April 21, 2021:

Name	Age	Position
Mr. John V. Oyler	53	Executive Director, Chairman and Chief Executive Officer
Dr. Xiaodong Wang	58	Non-executive Director
Mr. Anthony C. Hooper	66	Non-executive Director
Mr. Timothy Chen	64	Independent non-executive Director
Mr. Donald W. Glazer	76	Independent non-executive Director
Mr. Michael Goller	46	Independent non-executive Director
Mr. Ranjeev Krishana	47	Independent non-executive Director
Mr. Thomas Malley	52	Independent non-executive Director
Dr. Corazon (Corsee) D. Sanders	64	Independent non-executive Director
Mr. Jing-Shyh (Sam) Su	68	Independent non-executive Director
Mr. Qingqing Yi	49	Independent non-executive Director

EXECUTIVE DIRECTOR

Mr. John V. Oyler, aged 53, is our Co-Founder, Chief Executive Officer and Chairman of our Board of Directors. He has served as a member of our Board of Directors since October 2010. From 2005 to 2009, Mr. Oyler served as President and Chief Executive Officer of BioDuro, LLC, a drug discovery outsourcing company, which was acquired by Pharmaceutical Product Development Inc. From 2002 to 2004, Mr. Oyler served as Chief Executive Officer of Galenea Corp., a biopharmaceutical company dedicated to the discovery of novel therapies for central nervous system diseases, which initially were developed at Massachusetts Institute of Technology. From 1998 to 2002, Mr. Oyler was a Founder and the President of Telephia, Inc. which was bought by The Nielsen Company in 2007. From 1997 to 1998, Mr. Oyler served as Co-Chief Executive Officer of Genta Incorporated, an oncology-focused biopharmaceutical company that was listed on the NASDAQ. Mr. Oyler began his career as a management consultant at McKinsey & Company. Mr. Oyler received his B.S. from the Massachusetts Institute of Technology in June 1990 and an MBA from Stanford University in January 1996. Mr. Oyler’s qualifications to serve on our Board of Directors include his extensive leadership, executive, managerial, business and pharmaceutical and biotechnology company experience, along with his years of industry experience in the development and commercialization of pharmaceutical products.

DIRECTORS AND SENIOR MANAGEMENT

NON-EXECUTIVE DIRECTORS

Dr. Xiaodong Wang, Ph.D., aged 58, is our Co-Founder and has served as a member of our Board of Directors since February 2016. He has also served as the Chairman of our Scientific Advisory Board since 2011. Dr. Wang has served as the founding Director of the National Institute of Biological Sciences in Beijing since 2003 and became its Director and Investigator in 2010. In addition, Dr. Wang has served as a Chair Professor at Tsinghua University since 2020. Previously, he was a Howard Hughes Medical Institute Investigator from 1997 to 2010 and held the position of the George L. MacGregor Distinguished Chair Professor in Biomedical Sciences at the University of Texas Southwestern Medical Center in Dallas, Texas from 2001 to 2010. In 2004, Dr. Wang founded Joyant Pharmaceuticals, Inc., a venture capital-backed biotechnology company focused on the development of small molecule therapeutics for cancer. Dr. Wang received his B.S. in Biology from Beijing Normal University in July 1984 and his Ph.D. in Biochemistry from the University of Texas Southwestern Medical Center in May 1991. Dr. Wang has been a member of the National Academy of Science, USA since 2004 and a foreign associate of the Chinese Academy of Sciences since 2013. We believe that Dr. Wang's extensive experience in cancer drug research, combined with his experience in the biotech industry, qualify him to serve as a member of our Board of Directors.

Mr. Anthony C. Hooper, aged 66, has served as a member of our Board of Directors since January 2020. Mr. Hooper retired from Amgen in January 2020, where he was Executive Vice President from September 2018 to January 2020, and Executive Vice President, Global Commercial Operations from 2011 to August 2018. From 2010 to 2011, Mr. Hooper was Senior Vice President, Commercial Operations and President, U.S., Japan and Intercontinental of Bristol Myers Squibb Company (BMS Company). From 2009 to 2010, Mr. Hooper was President, Americas of BMS Company. From 2004 to 2009, Mr. Hooper was President, U.S. Pharmaceuticals, Worldwide Pharmaceuticals Group, a division of BMS Company. Prior to that, Mr. Hooper held various senior leadership positions at BMS Company. Prior to joining BMS Company, Mr. Hooper was Assistant Vice President of Global Marketing for Wyeth Laboratories. Mr. Hooper earned law and MBA degrees from the University of South Africa in 1978 and 1988 respectively. Mr. Hooper serves on the board of MannKind Corporation, a company listed on the NASDAQ (ticker symbol: MNKD). Mr. Hooper is a consultant of Amgen. We believe Mr. Hooper's extensive experience and knowledge in the healthcare sector and broad international experience in pharmaceutical commercial operations qualify him to serve on, and contributes to the diversity of, the Board.

DIRECTORS AND SENIOR MANAGEMENT

INDEPENDENT NON-EXECUTIVE DIRECTORS

Mr. Timothy Chen, aged 64, has served as a member of our Board of Directors since February 2016. Mr. Chen has served as Co-Chairman of Suirui Technology Group Limited, a company listed on the China National Equities Exchange and Quotations since December 2018. From January 2018 to November 2018, Mr. Chen served as the Chairman of Foxconn Industrial Internet Company, a company listed on the Shanghai Stock Exchange since June 2018. From January 2016 to March 2018, he served as the President and Chief Executive Officer of Asia Pacific Telecom and as the Corporate Vice President of Hon Hai Technology Group. He served as the President of Telstra International Group and Advisor to Telstra Chief Executive Officer from November 2012 to December 2015. He was also the Chairman of Autohome, a company listed on the NASDAQ and a director of Qingdao Haier Co., Ltd., a company listed on the Shanghai Stock Exchange. He was a Non-Executive Director on the board of Telstra Corporation Limited, a company listed on the Australian Securities Exchange between April 2012 and November 2012, and an Independent Director of Guiyang Longmaster Information and Technology Company Limited, a company listed on the Shenzhen Stock Exchange from October 2010 to October 2013. Previously, Mr. Chen was a partner of a China Opportunities Fund within GL Capital Group. He was the Chief Executive Officer of National Basketball Association China from 2007 to 2010; the Corporate Vice President of Microsoft and the Chief Executive Officer of its Greater China Region from 2003 to 2007; and the Corporate Vice President of Motorola and the Chairman and President of Motorola (China) Electronics from 2001 to 2003. Before Motorola, he was the Chief Executive Officer of 21CN Cybernet, a company listed on the HKEx from 2000 to 2001. Prior to 2000, Mr. Chen spent eight years in China with Motorola, including serving as the General Manager responsible for the sales and marketing for the Greater China Cellular Infrastructure Division. He also spent nine years with AT&T Bell Laboratories in the United States. Mr. Chen currently serves as an Independent Non-Executive Director of CCID Consulting Company Limited, a company listed on the HKEx. Mr. Chen also serves as a Director of Asia Pacific Telecom, a company listed on the Taiwan Stock Exchange. Mr. Chen earned an MBA Degree from the University of Chicago in August 1991 and a master's degree in both computer science and mathematics from Ohio State University in June 1982. We believe that Mr. Chen's extensive business expertise in Asia and globally qualify him to serve as a member of our Board of Directors.

Mr. Donald W. Glazer, aged 76, has served as a member of our Board of Directors since February 2013. Mr. Glazer has served as a member of the Board of Trustees of GMO Trust, a mutual fund group, since 2000 and as the Chairman of the board of GMO Trust since 2005. Mr. Glazer was a Co-Founder and Secretary, and from 2002 until 2010, Vice Chairman, of Provant, Inc., a provider of performance improvement training solutions. From 1992 to 1995 Mr. Glazer was President of Mugar/Glazer Holdings and from 1992 to 1993 served as Vice Chairman-Finance of New England Television Corp. and WHDH-TV, Inc. From 1997 to the present, Mr. Glazer has served as Advisory Counsel to the law firm Goodwin Procter LLP. From 1970 to 1978 Mr. Glazer was an associate and from 1978 to 1992 a partner at the law firm Ropes & Gray LLP. At Ropes & Gray, Mr. Glazer chaired the firm's Emerging Companies Group. Mr. Glazer was also a Lecturer in Law at Harvard Law School from 1978 to 1991, teaching a course called The Business Lawyer. In addition to Provant, Inc. and New England Television Corp., Mr. Glazer is a former member of the boards of directors of EnviroNics Inc.; Kronos Incorporated; Reflective Technologies, Inc.; and Teleco Oilfield Services Inc. Mr. Glazer received his A.B. from Dartmouth College in June 1966; J.D. from Harvard Law School in June 1969, where he was an editor of the Harvard Law Review; and L.L.M. from the University of Pennsylvania Law School in May 1970. Additionally, Mr. Glazer is a co-author of both Glazer and FitzGibbon on Legal Opinions, Third Edition (Aspen Publishers) and Massachusetts Corporation Law & Practice, Second Edition (Aspen Publishers). We believe that Mr. Glazer's qualifications to serve on our Board of Directors include his extensive leadership, executive, managerial, business, and corporate legal experience.

DIRECTORS AND SENIOR MANAGEMENT

Mr. Michael Goller, aged 46, has served as a member of our Board of Directors since April 2015. Mr. Goller is a Partner at Baker Brothers Investments. Prior to joining Baker Brothers in 2005, Mr. Goller was as an Associate of JPMorgan Partners, LLC, where he focused on venture investments in the life sciences sector from 1999 to 2003. Mr. Goller began his career as an investment banker with Merrill Lynch and Co. from 1997 to 1999. Mr. Goller received a B.S. in Molecular and Cell Biology from The Pennsylvania State University in May 1997, and a Master's in both Biotechnology (School of Engineered and Applied Sciences) and Business Administration (Wharton School) from the University of Pennsylvania in May 2005. Mr. Goller serves on the boards of DBV Technologies SA, a company listed on the NASDAQ and on Euronext Paris and Levo Therapeutics, Inc. We believe that Mr. Goller is qualified to serve on our Board of Directors based on his experience in the life sciences industry and for his knowledge in financial and corporate development matters.

Mr. Ranjeev Krishana, aged 47, has served as a member of our Board of Directors since October 2014 and our Lead Director since February 2020. Mr. Krishana has worked at Baker Brothers from 2011 to the present and currently serves as Head of International Investments. Prior to joining Baker Brothers, Mr. Krishana held a series of commercial, strategy, and business development leadership roles for Pfizer, Inc.'s pharmaceutical business across a variety of international regions and markets, including Asia, Eastern Europe, and Latin America. Mr. Krishana was at Pfizer from 2003 to 2007 and from 2008 to 2011. From 2008 to 2010, Mr. Krishana was based in Beijing, China, where he served as a Senior Director and a member of the Pfizer China Leadership Team. Mr. Krishana began his career as a strategy consultant at Accenture plc. Mr. Krishana received a B.A. in Economics and Political Science from Brown University in May 1995, and a Master's of Public Policy from Harvard University in June 2011. We believe Mr. Krishana's knowledge of the healthcare sector across international markets qualifies him to serve on our Board of Directors.

Mr. Thomas Malley, aged 52, has served as a member of our Board of Directors since January 2016. Mr. Malley has served as president of Mossrock Capital, LLC, a private investment firm, since May 2007. Mr. Malley worked for Janus Mutual Funds in positions of increasing responsibility from April 1991 to May 2007. From January 1999 to May 2007, Mr. Malley served as the portfolio manager of the Janus Global Life Sciences Fund and also led the Janus healthcare team of analysts. From 1991 to 1998, Mr. Malley served as an equity analyst for Janus covering, among others, healthcare and biotechnology stocks. Mr. Malley received a B.S. in Biology from Stanford University in June 1991. Mr. Malley has held directorships in the following listed companies: Kura Oncology, Inc., a company listed on the NASDAQ, as a director since 2015; Kiniksa Pharmaceuticals, a company listed on the NASDAQ, as a director since 2016; OvaScience, Inc., a company listed on the NASDAQ prior to its merger with Millendo Therapeutics, Inc. in December 2018, as a director from 2012 to 2017; Synageva BioPharma Corp., a Company listed on the NASDAQ prior to its delisting in May 2015 in connection with the sale of the company, as a director from 2006 to 2015; Puma Biotechnology, Inc., a company listed on the NASDAQ, as a director from 2011 to 2015; and Cougar Biotechnology, Inc., a company listed on the NASDAQ prior to its delisting in July 2009 in connection with the sale of the company, as a director from 2007 to 2009. Our Board of Directors believes that Mr. Malley's experience in the biopharmaceutical industry, including serving on other boards of directors, and his financial and executive experience qualify him to serve on our Board of Directors.

DIRECTORS AND SENIOR MANAGEMENT

Dr. Corazon (Corsee) D. Sanders, aged 64, has served as a member of our Board of Directors since August 2020. Dr. Sanders most recently served as an Interim Transition Advisor to the Global Development Group of Bristol Myers Squibb Corporation from November 2019, following its acquisition of Celgene Corporation, until February 2020. Previously, Dr. Sanders served as a Strategic Advisor to the Office of the Celgene Chief Medical Officer from March 2018 to November 2019. From January 2017 to March 2018, she was a member of the Juno Therapeutics Executive Committee as Executive Vice President of Development Operations, with responsibilities for strategic operations, quantitative sciences, biosample and clinical operations. From 1994 to 2017, Dr. Sanders held leadership positions at Genentech/Roche, including as a member of the Genentech/Roche Late Stage Portfolio Committee, Global Head of the Genentech/Roche Late Stage Clinical Operations, Global Head of the Genentech/Roche Biometrics group, and Genentech Head of DATA (Design, Analysis, Technology & Administration) prior to the Roche acquisition. Dr. Sanders currently serves as a member of the Board of Trustees of the Fred Hutchinson Cancer Research Center in Seattle, WA, and as a director of the following biotechnology companies: Molecular Templates Inc. (NASDAQ: MTEM), Legend Biotech Corporation (NASDAQ: LEGN), and AltruBio Inc. (formerly AbGenomics) (privately held). Dr. Sanders earned her B.S. and M.S. in statistics, graduating Magna Cum Laude from the University of the Philippines, and her M.A. and Ph.D. in statistics from the Wharton Doctoral Program at the University of Pennsylvania. We believe that Dr. Sanders' extensive experience and knowledge in the healthcare sector and her scientific and leadership experience qualify her to serve on, and contributes to the diversity of, the Board.

Mr. Jing-Shyh (Sam) Su, aged 68, has served as a member of our Board since April 2018. Mr. Su retired from Yum! Brands, Inc., a company listed on the New York Stock Exchange ("Yum! Brands"), in May 2016, where he served as Vice Chairman of the Board, and was the Chairman and CEO of the company's China division. During Mr. Su's 26 years with Yum! Brands, its China division grew from just four restaurants to over 7,000 to become the largest multinational restaurant chain in China, contributing more than half of Yum! Brands' worldwide revenues in 2015. Mr. Su started his career with Yum! Brands in 1989 as KFC International's director of marketing for the North Pacific region. In 1993, he became vice president of North Asia for both KFC and Pizza Hut. Mr. Su was named president of Greater China for Tricon Global Restaurants International upon Pepsi's spin-off of the restaurant business in 1997. Before joining Yum! Brands, Mr. Su worked with Procter & Gamble in Germany and Taiwan. Mr. Su earned his undergraduate degree at the National Taiwan University in June 1974, an M.Sc. degree in Chemical Engineering at Pennsylvania State University in May 1978, and an MBA at the Wharton School of the University of Pennsylvania in May 1983. Mr. Su currently serves as a director of Li Ning Company Limited, a company listed on the Main Board of the HKEx (stock code: 2331), and of Peet's Coffee China. We believe that Mr. Su is qualified to serve on our Board of Directors based on his operating and management experience, expertise in marketing and brand development, particularly in China, and expertise in strategic planning and international business development.

Mr. Qingqing Yi, aged 49, has served as a member of our Board of Directors since October 2014. Mr. Yi is a Partner at Hillhouse Capital. He has worked with Hillhouse since the inception of the firm in 2005. Prior to joining Hillhouse, Mr. Yi was an Equity Research Analyst at China International Capital Corporation. Mr. Yi's work at Hillhouse includes investments in the healthcare and consumer sectors in both its public and private equity portfolios. Mr. Yi received a B.S. degree in Engineering from Shanghai Maritime University in July 1995 and an MBA from University of Southern California in May 2003. We believe Mr. Yi's extensive experience in capital markets and knowledge of the healthcare sector qualifies him to serve on our Board of Directors.

DIRECTORS AND SENIOR MANAGEMENT

SENIOR MANAGEMENT

The following table provides information about members of our senior management, as of April 21, 2021, other than Mr. John Oyler, who is included above as an executive Director:

Name	Age	Position
Xiaobin Wu, Ph.D.	59	President, Chief Operating Officer and General Manager of China
Howard Liang, Ph.D.*	57	Chief Financial Officer and Chief Strategy Officer
Lai Wang, Ph.D.	44	Global Head of R&D
Jane Huang, M.D.	48	Chief Medical Officer, Hematology

* Dr. Liang plans to retire from the Company on June 30, 2021, at which time Julia Wang, Senior Vice President, Enterprise Optimization and Deputy Chief Financial Officer of the Company, will become Chief Financial Officer, as announced in our announcement filed with the HKEx on March 31, 2021.

Xiaobin Wu, Ph.D., aged 59, joined our Company in April 2018 as our President and General Manager of China and has been appointed to an additional position of Chief Operating Officer, effective April 1, 2021. He has more than 25 years of experience in the pharmaceutical industry, including 17 years leading China operations of multinational companies, with expertise in research and development, strategy, commercialization and general management. Before joining the Company in April 2018, Dr. Wu served as the Country Manager of Pfizer China from 2009 to April 2018 and Regional President of Pfizer Essential Health in the Greater China Region from 2017 to April 2018. Under his leadership, Pfizer China experienced significant growth to become a leading multinational pharmaceutical company in China. Prior to Pfizer, Dr. Wu served as President and Managing Director of Wyeth China and Hong Kong from 2004 to 2009. Before joining Wyeth, Dr. Wu served as the General Manager of Bayer Healthcare in China from 2001 to 2004. He started his career in 1992 in sales and marketing with Bayer in Germany. Dr. Wu served as a Vice Chairman of the R&D Based Pharmaceutical Association Committee (RDPAC) in China from 2008 to 2018. He also serves as Vice Chairman of the Pharmaceutical Chamber of Commerce of China's National Association of Industry & Commerce. He is also a research fellow at the Research Center of National Drug Policy and Ecosystem (NDPE) of China Pharmaceutical University in Nanjing, China. In addition to his duties in industry associations, Dr. Wu has received numerous industry awards, including most recently "Person of the Year" in Healthy China Awards 2017, "2017 Top 10 Most Influential Persons in the Chinese Healthcare Industry" and the "2017 Social Responsibility Eminent Person Award." Dr. Wu earned a Ph.D. in Biochemistry and Pharmacology and a Diploma in Biology in April 1993 and January 1990, respectively, from the University of Konstanz in Germany.

DIRECTORS AND SENIOR MANAGEMENT

Howard Liang, Ph.D., aged 57, has served as our Chief Financial Officer and Chief Strategy Officer since July 2015. Prior to joining us, from 2005 to 2015, Dr. Liang was at Leerink Partners LLC, a leading investment bank specializing in the healthcare industry (now SVB Leerink LLC), where he served as a Managing Director and Head of Biotechnology Equity Research. Dr. Liang served as a Senior Biotechnology Analyst at two full-service investment banks: A.G. Edwards Inc., from 2004 to 2005, and JMP Securities, from 2003 to 2004. From 2000 to 2003, Dr. Liang served as an Associate Analyst at Prudential Securities, where he covered major and specialty pharmaceuticals. Before Wall Street, from 1992 to 2000, Dr. Liang was with Abbott Laboratories, where he was a Senior Scientist and a member of one of the pharmaceutical industry's leading structure-based discovery teams. During his career as a scientist, Dr. Liang authored a review and 13 papers including six in Nature, Science, and Proceedings of the National Academy of Sciences. Dr. Liang currently serves as a member of the Biotech Advisory Panel of the HKEx. Dr. Liang received his B.S. in Chemistry from Peking University in July 1985, and both his MBA and Ph.D. in Biochemistry and Molecular Biology from the University of Chicago in June 2001 and March 1992 respectively.

Lai Wang, Ph.D., aged 44, has served as our Global Head of R&D since April 2021. Dr. Wang joined our Company in May 2011 with increasing responsibilities over the years and most recently as Senior Vice President, Head of Global Research, Clinical Operation & Biometrics and APAC Clinical Development. Dr. Wang has over 20 years of experience in the oncology field and over 10 years of experience in the pharmaceutical industry in both research and development. Prior to joining us, Dr. Wang was the director of research at Joyant Pharmaceuticals, a biotech company based in Dallas, Texas. Dr. Wang received his B.S. from Fudan University in 1996 and Ph.D. from University of Texas Health Science Center at San Antonio in 2001.

Jane Huang, M.D., aged 48, joined our Company in September 2016 as our Chief Medical Officer, Hematology. Prior to joining us, Dr. Huang served as the Vice President, Clinical Development at Acerta Pharma from April 2015 to September 2016, where she oversaw global clinical development of the BTK inhibitor, acalabrutinib. Previously, she worked at Genentech, Inc. from 2005 to March 2015, serving most recently as Group Medical Director, where she played a leading role in drug development programs for several molecules at all stages of development, including venetoclax and obinutuzumab. She is also an Adjunct Clinical Assistant Professor in Oncology at Stanford University, specializing in thoracic oncology. Dr. Huang received her Bachelor of Science degree in Biological Sciences from Stanford University in 1994 and her M.D. from University of Washington School of Medicine in 1998. She is board certified in hematology, oncology, and internal medicine, and she completed her residency in internal medicine and fellowships in hematology and oncology at Stanford University.

DIRECTORS AND SENIOR MANAGEMENT

DISCLOSURE OF CHANGES IN DIRECTORS' INFORMATION PURSUANT TO RULE 13.51(B) (1) OF THE HK LISTING RULES

Upon specific inquiry by the Company and following confirmations from Directors, except as disclosed hereunder, there is no change in information for any of the Directors which would require disclosure pursuant to Rule 13.51(B) (1) of the HK Listing Rules during the year ended December 31, 2020. The change of Director's information is set out below.

Directors	Changes in Positions held with the Company
Dr. Corazon (Corsee) D. Sanders	Appointed as an independent non-executive Director of the Company and a member of the Audit Committee and the scientific advisory committee of the Board (the "Scientific Advisory Committee") effective August 24, 2020.
Mr. Timothy Chen	Appointed as a member of the commercial and medical affairs advisory committee of the Board (the "Commercial and Medical Affairs Advisory Committee") effective February 26, 2020; ceased to be a member of the Audit Committee effective August 24, 2020. Mr. Timothy Chen remains to serve as a member of the Board and a member of the Compensation Committee and the Commercial and Medical Affairs Advisory Committee.
Mr. Jing-Shyh (Sam) Su	Appointed as a member of the Commercial and Medical Affairs Advisory Committee effective February 26, 2020; ceased to be a member of the Audit Committee effective May 1, 2020. Mr. Jing-Shyh (Sam) Su remains to serve as a member of the Board and a member of the Commercial and Medical Affairs Advisory Committee.
Mr. Anthony C. Hooper	Appointed as a Director effective January 2, 2020; appointed as the chairman of the Commercial and Medical Affairs Advisory Committee effective February 26, 2020; appointed as a member of the Audit Committee effective May 1, 2020.
Dr. Xiaodong Wang	Appointed as the chairman of the Scientific Advisory Committee effective February 26, 2020.
Mr. Michael Goller	Appointed as a member of the Scientific Advisory Committee effective February 26, 2020.
Mr. Thomas Malley	Appointed as a member of the Scientific Advisory Committee effective February 26, 2020.
Mr. Qingqing Yi	Appointed as a member of the Scientific Advisory Committee effective February 26, 2020.
Mr. Ranjeev Krishana	Appointed as the lead director of the Board and as a member of the Commercial and Medical Affairs Advisory Committee effective February 26, 2020.

The Scientific Advisory Committee was established on February 26, 2020. The Commercial Advisory Committee was established on February 26, 2020 and has been renamed the Commercial and Medical Affairs Advisory Committee effective February 24, 2021.

REPORT OF THE DIRECTORS

The Board is pleased to present this Report of Directors, together with the consolidated financial statements of the Group for the year ended December 31, 2020.

GENERAL INFORMATION

The Company was incorporated in the Cayman Islands on October 28, 2010 as an exempted limited liability company under the laws of the Cayman Islands. The Company's Shares have been listed on the Main Board of the HKEx since August 8, 2018 under the stock code 06160. The Company's ADSs have been listed on the NASDAQ Global Select Market since February 3, 2016 under the symbol "BGNE".

PRINCIPAL ACTIVITIES

The Company is a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide. The Company has built substantial commercial capabilities in China and the United States. The Company currently market two internally discovered oncology medicines and also market or plan to market additional oncology products in China licensed from Amgen, BMS, and EUSA Pharma; and have entered a collaboration with Novartis Pharma AG for Novartis to develop, manufacture and commercialize tislelizumab in North America, Europe and Japan. The analysis of the Group's revenues and contribution to results are set out in Note 3 and Note 17 to the consolidated financial statements.

BUSINESS REVIEW

The business review of the Group is set out in the sections headed "Management Discussion and Analysis" of this annual report. A description of principal risks and uncertainties that the Group may be facing can be found on page 190 of this annual report. In addition, a discussion on relationships with key stakeholders is included in the section headed "Environmental, Social and Governance Report" of this annual report. The review and discussion form part of this Report of Directors.

SHARE CAPITAL

Details of movements in the share capital of the Company for the year ended December 31, 2020 are set out in the consolidated statements of shareholders' equity.

SUBSIDIARIES

Particulars of the Company's subsidiaries are set out in Note 1 to the consolidated financial statements.

FINANCIAL SUMMARY

A summary of the consolidated results and financial position of the Group is set out on page 145 of this annual report.

REPORT OF THE DIRECTORS

RESULTS

The results of the Group for the year ended December 31, 2020 are set out in the consolidated statements of comprehensive loss on page 300 of this annual report.

MAJOR CUSTOMERS AND SUPPLIERS

For the year ended December 31, 2020, the Group's sales to its five largest customers accounted for approximately 82.6% of the Group's product revenue and the Group's single largest customer accounted for approximately 38.7% of the Group's product revenue. During the year ended December 31, 2019, we generated 52.0% of our revenues from a product distributor in China in connection with the sales of our drugs licensed from BMS, and 48.0% from BMS in connection with our strategic collaboration for tislelizumab, including research and development reimbursement revenue for the trials that BMS had opted into through the termination of the collaboration agreement, research and development services revenue of the remaining upfront consideration, and other collaboration revenue related to the payment received from BMS in connection with the termination of the collaboration agreement.

For the year ended December 31, 2020 and 2019, the five largest suppliers of the Group accounted for approximately 45.3% and 48.0% of the Group's total purchases, respectively, while the largest supplier of the Group accounted for approximately 21.8% and 11.0% of the Group's total purchases, respectively.

During the year ended December 31, 2020, none of our Directors, their close associates or any of our shareholders, who, to the knowledge of our Directors, owns more than 5% of our issued share capital had any interest in any of the above customers or suppliers.

ENVIRONMENTAL POLICIES AND PERFORMANCE

The Group is committed to fulfilling social responsibility, promoting employee benefits and development, protecting the environment and giving back to the community and achieving sustainable growth. Details of these commitments are set out in the section headed "Environmental, Social and Governance Report" in this annual report.

COMPLIANCE WITH THE RELEVANT LAWS AND REGULATIONS

During the year ended December 31, 2020, as far as the Board is aware, the Group has complied with the relevant laws and regulations that have a significant impact on the Group in all material respects.

IMPORTANT EVENTS AFTER THE REPORTING PERIOD

Except as disclosed in Note 31 to the consolidated financial statements contained in this annual report, there were no important events affecting the Group which occurred after the Reporting Period and up to the date of this annual report.

REPORT OF THE DIRECTORS

PRINCIPAL RISKS AND UNCERTAINTIES

As further disclosed in the section headed “Risks Factors” in this annual report, the following list is a summary of certain principal risks and uncertainties facing the Group, some of which are beyond its control:

- Our medicines may fail to achieve and maintain the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.
- We have limited experience in launching and marketing our internally developed and in-licensed medicines. If we are unable to further develop marketing and sales capabilities or enter into agreements with third parties to market and sell our medicines, we may not be able to generate substantial product sales revenue.
- The market opportunities for our medicines may be limited to those patients who are ineligible for or have failed prior treatments and may be small.
- We face substantial competition, which may result in others discovering, developing, or commercializing competing medicines before or more successfully than we do.
- If we are not able to continue to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize our medicines and drug candidates, and our ability to generate revenue will be materially impaired.
- We have limited manufacturing capability and must rely on third-party manufacturers to manufacture our commercial products and clinical supplies, and if they fail to meet their obligations, the development and commercialization of our medicines and drug candidates could be adversely affected.
- If we or any third parties with which we may collaborate to market and sell our medicines are unable to achieve and maintain coverage and adequate level of reimbursement, our commercial success and business operations could be adversely affected.
- We depend substantially on the success of the clinical development of our medicines and drug candidates. If we are unable to successfully complete clinical development, obtain additional regulatory approvals and commercialize our medicines and drug candidates, or experience significant delays in doing so, our business will be materially harmed.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.
- If clinical trials of our drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

REPORT OF THE DIRECTORS

- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- All material aspects of the research, development, manufacturing and commercialization of pharmaceutical products are heavily regulated, and we may face difficulties in complying with or be unable to comply with such regulations, which could have a material adverse effect on our business.
- The approval processes of regulatory authorities in the United States, China, Europe and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our drug candidates, our business will be substantially harmed.
- Our medicines and any future approved drug candidates will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our medicines and drug candidates.
- Even if we are able to commercialize our medicines and any approved drug candidates, the medicines may become subject to unfavorable pricing regulations or third-party reimbursement practices or healthcare reform initiatives, which could harm our business.
- We have incurred significant net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may not become profitable.
- We have a limited experience in obtaining regulatory approvals and commercializing pharmaceutical products, which may make it difficult to evaluate our current business and predict our future performance.
- We may need to obtain additional financing to fund our operations, and if we are unable to obtain such financing, we may be unable to complete the development of our drug candidates or achieve profitability.
- If we are unable to obtain and maintain patent protection for our medicines and drug candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties may compete against us.
- If we fail to maintain an effective distribution channel for our medicines, our business and sales could be adversely affected.
- We rely on third parties to manufacture some of our commercial and clinical drug supplies. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

REPORT OF THE DIRECTORS

- If third-party manufacturers fail to comply with manufacturing regulations, our financial results and financial condition could be adversely affected.
- We have entered into licensing and collaboration arrangements and may enter into additional collaborations, licensing arrangements, or strategic alliances in the future, and we may not realize the benefits of such arrangements.
- If we are not able to successfully develop and/or commercialize Amgen's oncology products, the expected benefits of the collaboration will not materialize.
- We have significantly increased and expect to continue to increase our research, development, manufacturing, and commercial capabilities, and we may experience difficulties in managing our growth.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- Our business is subject to complex and evolving industry-specific laws and regulations regarding collection and transfer of personal data. These laws and regulations can be complex and stringent, and many are subject to change and uncertain interpretation, which could result in claims, changes to our data and other business practices, significant penalties, increased cost of operations, or otherwise adversely impact our business.
- We manufacture some of our medicines and intend to manufacture some of our drug candidates, if approved. Delays in completing and receiving regulatory approvals for our manufacturing facilities, or damage to, destruction of or interruption of production at such facilities, could delay our development plans or commercialization efforts.
- Changes in the political and economic policies of the PRC government or in relations between China and the United States or other governments may materially and adversely affect our business, financial condition, and results of operations and may result in our inability to sustain our growth and expansion strategies.
- The audit report included in our Annual Report on Form 10-K filed with the SEC is prepared by auditors who are not inspected fully by the Public Company Accounting Oversight Board, and as such, investors are deprived of the benefits of such inspection.
- The trading prices of our ordinary shares and/or ADSs can be volatile, which could result in substantial losses to you.

REPORT OF THE DIRECTORS

USE OF NET PROCEEDS FROM LISTING

The net proceeds from the listing of our ordinary shares on the Main Board of the HKEx on August 8, 2018 (the “Listing”) amounted to approximately US\$869.7 million and have been fully utilized as of December 31, 2020.

The net proceeds from the Listing (adjusted on a pro rata basis based on the actual net proceeds) have been utilized in accordance with the purposes set out in the Prospectus. The table below sets out the planned applications of the net proceeds and actual usage up to December 31, 2020:

Use of proceeds	Planned applications (US dollars in thousands)	Percentage of total net proceeds (%)	Actual usage	Actual usage	Unutilized net
			up to December 31, 2019 (US dollars in thousands)	up to December 31, 2020 (US dollars in thousands)	proceeds as of December 31, 2020 (US dollars in thousands)
Zanubrutinib	282,656	32.5%	164,227	282,656	–
Tislelizumab	282,656	32.5%	198,098	282,656	–
Pamiparib	86,970	10.0%	36,339	86,970	–
For core products^(a)	652,282	75.0%	398,664	652,282	–
To fund continued expansion of our product portfolio ^(b)	130,456	15.0%	83,934	130,456	–
For working capital ^(c)	86,971	10.0%	76,347	86,971	–
Total	869,709	100.0%	558,945	869,709	–

Note (a): Usage for core products include ongoing and planned clinical trials of core products, in preparation for registration filings of core products, and preparation for launch and, subject to regulatory approval, commercialization of core products in China and the United States;

Note (b): To fund continued expansion of our product portfolio in cancer and potentially other therapeutic areas through internal research and external licenses and business development collaborations, including the development cost of internal early clinical and preclinical-stage pipeline agents and in-licensed pipeline agents; and

Note (c): For working capital, expanding internal capabilities and general corporate purposes.

REPORT OF THE DIRECTORS

USE OF NET PROCEEDS FROM AMGEN

On January 2, 2020, the Company sold 15,895,001 ADSs, representing 206,635,013 ordinary shares of the Company and approximately 20.5% ownership stake in the Company's outstanding shares as at the same date, to Amgen for aggregate cash proceeds of US\$2,779,241,000, or US\$174.85 per ADS, pursuant to the SPA (as amended) executed in connection with the collaboration agreement dated October 31, 2019 between the Company, BeiGene Switzerland, and Amgen (the "Amgen Collaboration Agreement"). The subscription price represents: (a) a 36% premium to the 30-day volume weighted average price of the Company's ADSs as of October 30, 2019, the day prior to the date of the SPA; (b) assuming a conversion rate of US\$1.00: HK\$7.84, a 26% premium to the closing price of the Company's ordinary shares as quoted on the HKEx on October 31, 2019, the date of the SPA; (c) a 26% premium to the closing price of the Company's ADSs on the NASDAQ on October 31, 2019.

The net proceeds from the sale of the shares have been and will be utilized in accordance with the purposes set out in the proxy statement/circular of the Company dated November 29, 2019. The table below sets out the planned applications of the net proceeds and actual usage up to December 31, 2020:

Use of proceeds	Planned applications (US dollars in thousands)	Percentage of total net proceeds (%)	Actual usage	Unutilized net
			up to December 31, 2020 (US dollars in thousands)	proceeds as of December 31, 2020 (US dollars in thousands)
To fund business operations ^(a)	2,779,241	100.0%	1,095,499	1,683,742

Note (a): To fund the Company's development obligations under the Amgen Collaboration Agreement by contributing cash and development services up to a total cap of approximately US\$1.25 billion, the development, manufacturing and commercialization of the Company's internally development drug candidates, expansion of our commercialization activities, and for future capacity expansion and general corporate use, as appropriate, as previously disclosed in the Company's proxy statement/circular dated November 29, 2019.

As of December 31, 2020, approximately US\$1.1 billion of the net proceeds had been utilized in accordance with the intended use of proceeds and approximately US\$1.68 billion remained unutilized. The Company plans to gradually utilize the remaining net proceeds in accordance with such intended purposes depending on actual business, which is expected to be fully utilized by the end of year 2025. For further details, please refer to the announcements of the Company dated November 1, 2019, December 9, 2019, and January 3, 2020.

REPORT OF THE DIRECTORS

On September 24, 2020, the Company entered into the Restated Second Amendment to amend the Share Purchase Agreement. Pursuant to the Restated Second Amendment, the Company granted Amgen the Direct Purchase Option to subscribe for the Additional Shares in an amount necessary to enable it to increase (and subsequently maintain) its ownership at approximately 20.6% of the Company's outstanding share capital as at the same date. The Direct Purchase Option is exercisable on a monthly basis but only if Amgen's interest in the outstanding share capital of the Company at the monthly reference date drops below 20.4% solely as a result of dilution arising from issuance of new shares by the Company under its equity incentive plans from time to time. The aggregate number of Additional Shares shall not exceed 75,000,000 Shares during the term of the Direct Purchase Option.

The purchase price for the Additional Shares will be the volume-weighted average price of the Company's ADSs for the 90 days preceding the last trading day of the prior month. The exercise period of the Direct Purchase Option commenced on December 1, 2020 and will terminate on the earliest of: (a) the date on which Amgen owns less than 20% of the outstanding share capital of the Company as a result of Amgen's sale of Shares; (b) at least 60-day advance written notice from either Amgen or the Company that such party wishes to terminate the Direct Purchase Option; or (c) the third anniversary of the date on which the exercise period of the Direct Purchase Option commences. The Direct Purchase Option has no vesting period.

For illustration purposes only, assuming the Direct Purchase Option were exercised in full on September 24, 2020, being the date of the Restated Second Amendment, at an assumed purchase price of US\$16.46 per ordinary share or US\$213.93 per ADS, the gross proceeds from the allotment and issue of the Additional Shares equal to 0.1% of the outstanding share capital of the Company would theoretically be approximately US\$19,466,300 (approximately HK\$150,863,825), and the gross proceeds from the allotment and issue of the maximum amount of the Additional Shares would theoretically be approximately US\$1,234,211,500 (approximately HK\$9,565,139,125), which would be expected to be used to fund the Company's business operations, including commercialization of approved products, research and development of product candidates and other general corporate purposes. The expected timeframe of use of proceeds will be disclosed when the allotment and issuance is completed.

For further details, please refer to the announcements of the Company dated March 18, 2020 and September 25, 2020 and the Company's proxy statement/circular dated October 9, 2020.

There was no allotment or issuance of the Additional Shares under the Restated Second Amendment for the year ended December 31, 2020 and as at the date of this annual report.

REPORT OF THE DIRECTORS

USE OF NET PROCEEDS FROM JULY SHARE SUBSCRIPTION

On July 15, 2020, the Company allotted and issued 145,838,979 ordinary shares of the Company to eight existing investors for an aggregate cash consideration of approximately US\$2.08 billion at a purchase price of US\$14.2308 per ordinary share of the Company (equivalent to US\$185 per ADS), in accordance with a share purchase agreement dated July 12, 2020 pursuant to the general mandate granted to the Board pursuant to an ordinary resolution of the Shareholders passed at the 2020 annual general meeting of Shareholders to allot, issue and deal with up to 202,995,338 ordinary shares.

The net proceeds from the sale of the shares are being used to: (a) fund the Company's research and clinical development activities, including expanding indications of its approved products, advancing its pipeline assets, including both internally developed molecules and in-licensed compounds, and progressing and expanding its preclinical programs; (b) advance business development activities to expand the Company's commercial and development-stage portfolio through in-licensing or acquisitions, as applicable, of additional technologies, drugs or drug candidates, other assets or businesses, both within oncology and outside of oncology, or for other strategic investments or opportunities; (c) invest in the commercialization of the Company's approved products in China, the United States and potentially other geographical markets; and (d) expand and further build out the Company's global organization and capabilities in areas including commercialization, manufacturing, and research and development. For further details, please refer to the announcements of the Company dated July 13, 2020 and July 16, 2020.

As of December 31, 2020, the net proceeds amounted to approximately US\$2.07 billion had not been utilized, and the Company plans to gradually utilize the net proceeds in accordance with such intended purposes depending on actual business, which is expected to be fully utilized in next three to five years.

DIVIDEND POLICY AND RESERVES

The Board has adopted a dividend policy which provides that we currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Subject to applicable law and our Articles, any future determination to pay dividends will be made at the discretion of the Board and may be based on a number of factors, including our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the Board may deem relevant. This dividend policy reflects the Board's current views on our financial and cash flow position. We intend to continue to review our dividend policy from time to time, and there can be no assurance that dividends will be paid in any particular amount, if at all, for any given period.

REPORT OF THE DIRECTORS

We have never declared or paid any dividends on our ordinary shares or any other securities. If we pay dividends in the future, in order for us to distribute dividends to our shareholders and holders of ADSs, we may rely to some extent on dividends distributed by our PRC subsidiaries. PRC regulations may restrict the ability of our PRC subsidiaries to pay dividends to us, and such distributions will be subject to PRC withholding tax. In addition, PRC regulations currently permit payment of dividends of a PRC company only out of accumulated distributable after-tax profits, as determined in accordance with our Articles and the accounting standards and regulations in the PRC.

The Board does not recommend any final dividend for the year ended December 31, 2020.

Details of movements in the reserves of the Group and the Company during the year ended December 31, 2020 are set out in the consolidated statement of shareholders' equity on page 303 and in Note 33 to the consolidated financial statements, respectively, among which the information of the distributable reserves is set forth in Note 33 to the consolidated financial statements.

PROPERTY AND EQUIPMENT

Details of movements in the property, plant and equipment of the Group during the year ended December 31, 2020 are set out in Note 11 to the consolidated financial statements.

BORROWINGS

The Group had US\$518.7 million in outstanding borrowings from banks and other financial institutions as of December 31, 2020 (2019: US\$240.7 million).

DONATION

During the year ended December 31, 2020, the Group made charitable donations of approximately US\$0.7 million (2019: approximately US\$0.07 million).

DEBENTURE ISSUED

The Group has not issued any debentures during the year ended December 31, 2020.

EQUITY-LINKED AGREEMENTS

Pursuant to a share purchase agreement dated October 31, 2019, as amended, by and between the Company and Amgen Inc., the Company issued 206,635,013 ordinary shares in the form of 15,895,001 ADSs on January 2, 2020, representing approximately 20.5% of our outstanding shares to Amgen Inc., for aggregate gross proceeds of approximately US\$2.78 billion, or US\$13.45 per ordinary share, or US\$174.85 per ADS. Further details on the share purchase agreement are disclosed in the announcements of the Company dated November 1, 2019, December 9, 2019 and January 3, 2020.

REPORT OF THE DIRECTORS

On July 15, 2020, the Company allotted and issued 145,838,979 ordinary shares to eight purchasers for an aggregate cash consideration of approximately US\$2.08 billion at a purchase price of US\$14.2308 per ordinary share (equivalent to US\$185 per ADS), in accordance with a share purchase agreement dated July 12, 2020 pursuant to a general mandate. For details, please refer to the Company's announcements dated July 13, 2020 and July 16, 2020.

Except as disclosed above and in the section headed "Share Option and Award Schemes", no equity-linked agreements were entered into by the Group or existed during the year ended December 31, 2020.

DIRECTORS

The Directors who held office during the year ended December 31, 2020 and up to the date of this annual report are:

Executive Director

Mr. John V. Oyler (*Chairman and Chief Executive Officer*)

Non-Executive Directors

Mr. Anthony C. Hooper (*Note (1)*)

Dr. Xiaodong Wang

Independent Non-Executive Directors

Mr. Timothy Chen

Mr. Donald W. Glazer

Mr. Michael Goller

Mr. Ranjeev Krishana

Mr. Thomas Malley

Dr. Corazon (Corsee) D. Sanders (*Note (2)*)

Mr. Jing-Shyh (Sam) Su

Mr. Qingqing Yi

Notes:

(1) Mr. Anthony C. Hooper has been appointed as a non-executive Director effective January 2, 2020.

(2) Dr. Corazon (Corsee) D. Sanders has been appointed as an independent non-executive Director effective August 24, 2020.

REPORT OF THE DIRECTORS

Our Articles provide that our Board is divided into three groups designated as Class I, Class II and Class III, with as nearly equal a number of Directors in each group as possible. Each Director in each class shall serve for a three-year term and until such Director's successor has been duly elected. Upon the expiration of his or her term, each Director shall be eligible for re-election at the next annual general meeting to hold office for another three-year term and until such Director's successor has been duly elected. The terms of the Class I Directors are scheduled to expire on the date of our 2023 annual general meeting, the terms of the Class II Directors are scheduled to expire on the date of our 2021 annual general meeting, and the terms of the Class III Directors are scheduled to expire on the date of our 2022 annual general meeting, in each case subject to such Director's earlier resignation or removal. Based on the recommendation of the Nominating and Corporate Governance Committee, the Board's nominees for election by the shareholders at the 2021 annual general meeting are the current Class II members: Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Thomas Malley and Dr. Corazon (Corsee) D. Sanders. Additionally, Dr. Corazon (Corsee) D. Sanders was appointed to the Board in August 2020 by the Board through the filling of a vacancy, as permitted by our Articles. Based on the recommendation of the Nominating and Corporate Governance Committee, the Board nominates Dr. Corazon (Corsee) D. Sanders for election by the shareholders at the 2021 annual general meeting of shareholders to serve as a Class II Director. If elected, Dr. Corazon (Corsee) D. Sanders will serve as a Director until the annual general meeting of shareholders in 2024 and until her successor is duly elected and qualified, subject to her earlier resignation or removal.

For the year ended December 31, 2020, the Company has received from each of the independent non-executive Directors an annual confirmation of independence pursuant to Rule 3.13 of the HK Listing Rules and considers each of the independent non-executive Directors are independent.

BOARD OF DIRECTORS AND SENIOR MANAGEMENT

Biographical details of the Directors and senior management of the Group are set out in the section headed "Directors and Senior Management" in this annual report.

EMOLUMENT POLICY AND DIRECTORS' REMUNERATION

Mr. John V. Oyler, our Co-Founder, Chief Executive Officer and Chairman of the Board, receives no compensation for his service as a Director. Dr. Xiaodong Wang, our Co-Founder and Chairman of our Scientific Advisory Board, also receives no compensation for his service as a Director.

REPORT OF THE DIRECTORS

We have adopted an Independent Director Compensation Policy, which was most recently amended on April 5, 2021 by the Board. The amended Independent Director Compensation Policy is part of a total compensation package designed to enable us to attract and retain, on a long-term basis, high calibre independent Directors as defined under the listing rule of NASDAQ (the “NASDAQ Listing Rules”). Under the amended Independent Director Compensation Policy, all independent Directors are paid cash compensation as set forth below, including an annual cash retainer of US\$60,000, which is an increase of US\$10,000 from the existing annual retainer adopted in 2018, and additional fees for service as a member or chair of each committee of the Board on which they serve, ranging from US\$7,500 to US\$22,500 per year, as specified in the policy, which reflect increases of US\$1,500 or US\$2,500 from the existing fees adopted in 2018 for service as a member of each committee and no changes for service as a chair of each committee. The changes for the cash retainers, which are paid quarterly, are effective as of April 1, 2021.

	Annual Retainer (US\$)
Board of Directors:	
All independent directors	60,000 ^{(Note (1))}
Audit Committee:	
Chairperson	22,500
Non-Chairperson members	12,500 ^{(Note (2))}
Compensation Committee:	
Chairperson	17,500
Non-Chairperson members	10,000 ^{(Note (3))}
Nominating and Corporate Governance Committee:	
Chairperson	12,500
Non-Chairperson members	7,500 ^{(Note (4))}
Commercial Advisory Committee:	
Chairperson	16,500
Non-Chairperson members	9,000 ^{(Note (3))}
Scientific Advisory Committee:	
Chairperson	16,500
Non-Chairperson members	9,000 ^{(Note (3))}

Notes:

- (1) Increased from US\$50,000.
- (2) Increased from US\$10,000.
- (3) Increased from US\$7,500.
- (4) Increased from US\$5,000.

REPORT OF THE DIRECTORS

Under the amended Independent Director Compensation Policy, each independent director, as defined under NASDAQ Listing Rules, are granted equity awards in the form of share options valued at US\$400,000 in connection with their initial election or appointment to the Board, pro-rated for the portion of the year served leading up to the first anniversary of the last annual meeting of shareholders, and annual equity awards valued at US\$400,000 on the date of each annual meeting of shareholders, which reflect an increase from the existing US\$300,000 awards adopted in 2018. Each of the awards will consist of 50% share options and 50% RSUs, compared to the 2018 policy of granting 100% share options; provided, however, that to the extent that a grant of RSUs is subject to shareholder approval pursuant to applicable listing rules (as is currently the case under the HK Listing Rules), (i) the initial grant shall consist of 100% share options and (ii) the annual grant shall include RSUs only upon shareholder approval and, in the absence of such shareholder approval, the annual grant shall consist of 100% share options. As under the current policy, the equity awards will vest in full on the earlier of the first anniversary of date of grant or the date of the next annual general meeting, and in full upon death, disability or the occurrence of specified events in connection with a change of control of the Company. Subject to specific terms and conditions designed for compliance with applicable tax and other regulations, Directors generally may elect to defer settlement of their RSUs until six months following the date that the Director ceases to serve as a Director. The options have an exercise price equal to the greater of (i) the fair market value of the Company's ordinary shares on the date of grant and (ii) the average fair market value of the Company's ordinary shares over the five trading days immediately preceding the date of grant, in each case as determined in reference to the closing price of the Company's ADSs on the NASDAQ. The equity awards are granted under the 2016 Plan and form of award agreement thereunder. In addition, under the terms of the 2016 Plan, the value of all equity awards and other cash compensation paid to each independent Director for their service as an independent Director may not exceed US\$1,000,000 in any calendar year (except in a Director's first year of service). We also reimburse all reasonable out-of-pocket expenses incurred by independent Directors in attending board and committee meetings.

In February 2019, our Compensation Committee adopted share ownership guidelines applicable to our non-employee Directors and our executive officers, including our Chief Executive Officer, to further align the interests of the leadership of our Company with those of our shareholders. The share ownership guidelines are as follows: our Chief Executive Officer must hold equity worth at least six times his annual base salary; our President must hold equity worth at least three times his annual based salary; each of our other executive officers must hold equity worth at least one times his or her base salary; and each of our non-employee Directors must hold equity worth at least five times the annual Board cash retainer. Covered individuals and newly appointed or elected persons have five years to achieve the ownership guideline.

The aggregate amount of remuneration (including basic salaries, housing allowances, other allowances and benefits in kind, contributions to pension plans and discretionary bonuses) for our Directors for the financial years ended December 31, 2019 and 2020 was approximately US\$16.5 million and US\$18.9 million, respectively. Details of the remuneration of Mr. John V. Oyler as chief executive officer of the Company, Dr. Xiaodong Wang as the Company's consultant, the Directors, senior management and the five highest paid individuals are set out in Note 26, Note 27 and Note 28, respectively, to the consolidated financial statements.

Except as disclosed in this annual report, none of the Directors waived or agreed to waive any remuneration and there were no emoluments paid by the Group to any of the Directors as an inducement to join, or upon joining the Group, or as compensation for loss of office.

REPORT OF THE DIRECTORS

DIRECTORS' SERVICE CONTRACTS

Employee Agreements with Mr. John V. Oyler

Mr. John V. Oyler and the Company and certain of our subsidiaries entered into employment agreements on April 25, 2017, pursuant to which Mr. Oyler serves as our Chief Executive Officer. Mr. Oyler currently receives a base salary of US\$740,000, which is subject to review and adjustment in accordance with the Company's policy. Mr. Oyler's base salary is allocated between the Company and certain of our subsidiaries. Mr. Oyler is eligible for an annual cash merit bonus, with a current target level of 90% of his base salary, based on performance as recommended by the Compensation Committee and determined by the Board of Directors. Mr. Oyler's employment agreements also provide for certain transportation and international travel benefits and tax preparation and equalization payments. His employment agreements have an initial three-year term and automatically renew for additional one-year terms unless either party provides written notice of nonrenewal. Mr. Oyler's employment can be terminated by the Company at any time. Mr. Oyler may resign upon 60 days advance notice; so long as his resignation is not due to his employment with a competing business, he may receive payment in lieu of notice. Upon termination of Mr. Oyler's employment for any reason, we will pay (i) accrued but unpaid base salary during the final payroll period of employment; (ii) unpaid vacation time; (iii) unpaid annual bonus from the previous calendar year; and (iv) any business expenses incurred, documented and substantiated but not yet reimbursed (collectively, the "Final Compensation"). If Mr. Oyler's employment is terminated by us other than for "cause" (as defined in his employment agreements) or if Mr. Oyler terminates his employment for "good reason" (as defined in his employment agreements), Mr. Oyler is entitled to (i) the Final Compensation, (ii) a lump sum equal to the base salary divided by 12, then multiplied by the Severance Period (as defined below), (iii) the post-termination bonus calculated based on the target bonus for the year and the number of days passed through the date of termination, (iv) a US\$20,000 one-time bonus and (v) acceleration by 20 months of the vesting of his initial equity award in 2015 and all of his awards granted commencing in 2017, when he signed his employment agreement (the "accelerated awards"). The "Severance Period" is 20 months; provided that if Mr. Oyler's employment terminates during the 12-month period following a "change in control" (as defined in his employment agreements), then the Severance Period will be 24 months. His employment agreement provides that unvested portion of his accelerated awards will immediately vest upon a "change in control." Mr. Oyler's employment agreements also prohibit Mr. Oyler from engaging in certain competitive and solicitation activities during his employment and for 18 months after the termination of his employment.

REPORT OF THE DIRECTORS

Consulting Agreement with Dr. Xiaodong Wang

Dr. Xiaodong Wang, our Co-Founder, Chairman of our Scientific Advisory Board and Director, has been providing scientific and strategic advisory services to us since our founding in 2010. On July 24, 2018, we entered into a Consulting Agreement with Dr. Wang for a term of three years (the “2018 Consulting Agreement”). On February 24, 2021, we entered into a consulting agreement (the “2021 Consulting Agreement”) with Dr. Wang to renew the consulting arrangement between the Company and Dr. Wang on substantially the same terms and conditions as his 2018 Consulting Agreement. Pursuant to the 2021 Consulting Agreement, Dr. Wang will continue to provide certain scientific and strategic advisory services to the Company as requested by the Company from time to time and will continue to receive an annual fixed consulting fee of US\$100,000 for such services and such additional compensation, if any, that will be determined in the sole discretion of the Company, subject to compliance with the requirements of the applicable stock exchange listing rules. The 2021 Consulting Agreement is effective from January 1, 2021 and will expire on December 31, 2023. The Company may terminate the 2021 Consulting Agreement upon 30 days’ prior notice to Dr. Wang, provided that Dr. Wang will be entitled to payment for services performed prior to such date.

Except as disclosed above, none of the Directors proposed for re-election at the 2021 annual general meeting of shareholders has a service contract with members of the Group that is not terminable by the Group within one year without payment of compensation, other than statutory compensation.

DIRECTORS’ INTERESTS IN TRANSACTIONS, ARRANGEMENTS OR CONTRACTS OF SIGNIFICANCE

Except as disclosed in the sections headed “Directors’ Service Contracts”, “Connected Transaction”, “Related Party Transaction” and Note 28 to the consolidated financial statements contained in this annual report, none of the Directors nor any entity connected with the Directors had a material interest, either directly or indirectly, in any transactions, arrangements or contracts of significance to which the Company or any of its subsidiaries was a party subsisting during or at the end of the year ended December 31, 2020.

REPORT OF THE DIRECTORS

PERMITTED INDEMNITY

Pursuant to our Articles and subject to the applicable laws and regulations, every Director shall be indemnified and held harmless out of the assets and profits of the Company against all actions, proceedings, costs, charges, expense losses, damages or liabilities which they or any of them may incur or sustain in or about the execution of their duty in their offices, other than by reason of such person's dishonesty, willful default or fraud.

Such permitted indemnity provision has been in force for the year ended December 31, 2020. The Company has taken out liability insurance to provide appropriate coverage for the Directors.

MANAGEMENT CONTRACTS

Except as disclosed in the section headed "Directors' Service Contracts" in this annual report, no contract concerning the management and administration of the whole or any substantial part of the business of the Company was entered into or existed during the year ended December 31, 2020.

DIRECTORS' RIGHTS TO ACQUIRE SHARES OR DEBENTURES

Except as disclosed in this annual report, at no time during the year ended December 31, 2020 was the Company or any of its subsidiaries a party to any arrangements to enable the Directors to acquire benefits by means of the acquisition of shares in, or debentures of the Company or any other body corporate; and none of the Directors, or any of their spouse or children under the age of 18, had any right to subscribe for equity or debt securities of the Company or any other body corporate, or had exercised any such right.

DIRECTORS' INTERESTS IN COMPETING BUSINESS

During the year ended December 31, 2020, none of our Directors had any interest in a business, apart from the business of our Group, which competes or is likely to compete, directly or indirectly, with our business, which would require disclosure under Rule 8.10 of the HK Listing Rules.

REPORT OF THE DIRECTORS

DIRECTORS' AND CHIEF EXECUTIVE'S INTERESTS AND SHORT POSITIONS IN SHARES AND UNDERLYING SHARES AND DEBENTURES OF THE COMPANY OR ANY OF ITS ASSOCIATED CORPORATIONS

As at December 31, 2020, the interests and short positions of the Directors and chief executive of the Company in the ordinary shares ("Shares"), underlying Shares and debentures of the Company or its associated corporations within the meaning of Part XV of the Securities and Futures Ordinance ("SFO"), which were required (a) to be notified to the Company and the HKEx pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which they were taken or deemed to have under such provisions of the SFO); or (b) to be recorded in the register required to be kept by the Company pursuant to Section 352 of the SFO; or (c) as otherwise notified to the Company and the HKEx pursuant to the Model Code were as follows:

Name of Director	Nature of interest	Number of ordinary shares	Approximate percentage of holding ⁽¹⁾
John V. Oyler	Beneficial owner	27,495,812 ⁽²⁾	2.32%
	Settlor of a trust/Beneficiary of a trust	10,000,000 ⁽³⁾	0.84%
	Settlor of a trust/Interest of a minor child	102,188 ⁽⁴⁾	0.01%
	Settlor of a trust/Beneficiary of a trust	7,727,927 ⁽⁵⁾	0.65%
	Settlor of a trust/Beneficiary of a trust	29,439,115 ⁽⁶⁾	2.48%
	Settlor of a trust	510,941 ⁽⁷⁾	0.04%
	Interest of a minor child	545,597 ⁽⁸⁾	0.05%
	Other	1,591,317 ⁽⁹⁾	0.13%
Xiaodong Wang	Beneficial owner	15,297,612 ⁽¹⁰⁾	1.29%
	Interest of a minor child	172,372 ⁽¹¹⁾	0.01%
	Interest in controlled corporation	4,253,998 ⁽¹²⁾	0.36%
	Other	1,244,542 ⁽¹³⁾	0.105%
	Interest of spouse	50 ⁽¹⁴⁾	0.000004%
Timothy Chen	Beneficial owner	460,340 ⁽¹⁵⁾	0.04%
Donald W. Glazer	Beneficial owner	3,235,247 ⁽¹⁶⁾	0.27%
Michael Goller	Person having a security interest in shares	336,700 ⁽¹⁷⁾	0.03%
Anthony C. Hooper	Beneficial owner	67,353 ⁽¹⁸⁾	0.006%
Ranjeev Krishana	Person having a security interest in shares	336,700 ⁽¹⁹⁾	0.03%
Thomas Malley	Beneficial owner	1,249,448 ⁽²⁰⁾	0.11%
Corazon (Corsee) D. Sanders	Beneficial owner	27,482 ⁽²¹⁾	0.002%
Jing-Shyh (Sam) Su	Beneficial owner	173,277 ⁽²²⁾	0.02%
Qingqing Yi	Beneficial owner	327,418 ⁽²³⁾	0.03%

REPORT OF THE DIRECTORS

Notes:

- (1) The calculation is based on the total number of 1,185,464,217 Shares in issue as at December 31, 2020.
- (2) Includes (1) 6,280,245 Shares held by Mr. Oyler, (2) Mr. Oyler's entitlement to receive up to 20,705,156 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of those options, and (3) Mr. Oyler's entitlement to restricted share units equivalent to 510,411 Shares, subject to vesting conditions.
- (3) These Shares are held in a Roth IRA PENSCO trust account for the benefit of Mr. Oyler.
- (4) These Shares are held by The John Oyler Legacy Trust for the benefit of Mr. Oyler's minor child, of which Mr. Oyler's father is a trustee and Mr. Oyler is the settlor.
- (5) These Shares are held by a grantor retained annuity trust for the benefit of Mr. Oyler, of which Mr. Oyler's father is a trustee and Mr. Oyler is the settlor.
- (6) These Shares are held by Oyler Investment LLC, the interest of which is 99% owned by a grantor retained annuity trust for the benefit of Mr. Oyler, of which Mr. Oyler's father is a trustee and Mr. Oyler is the settlor.
- (7) These Shares are held by The Oyler Family Legacy Trust for the benefit of Mr. Oyler's family members, of which Mr. Oyler's father is a trustee and Mr. Oyler is the settlor.
- (8) Mr. Oyler made a gift of 545,597 Shares to a trust. These Shares are held by a trust, the beneficiaries of which include Mr. Oyler's minor child and others, in which Mr. Oyler is deemed to be interested for the purpose of the SFO.
- (9) Mr. Oyler made a gift of 1,591,317 Shares to a private foundation. These Shares are held by a private foundation of which Mr. Oyler and the other(s) serve as directors, in which Mr. Oyler is deemed to be interested for the purpose of the SFO.
- (10) Includes (1) 5,553,565 Shares held by Dr. Wang, (2) Dr. Wang's entitlement to receive up to 9,594,450 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of those options, and (3) Dr. Wang's entitlement to restricted share units equivalent to 149,597 Shares, subject to vesting conditions.
- (11) These Shares are held in a Uniform Transfers to Minors Act account for Dr. Wang's minor child, in which Dr. Wang is deemed to be interested for the purposes of the SFO.
- (12) These Shares are held by Wang Investment LLC, the interest of which is 99% owned by two grantor retained annuity trusts, of which Dr. Wang's wife is a trustee and Dr. Wang is the settlor.
- (13) Dr. Wang made a gift of 1,244,542 Shares to a family trust. These Shares are held by a family trust which Dr. Wang's family members are beneficiaries, in which Dr. Wang is deemed to be interested for the purpose of the SFO.
- (14) These Shares are held by Dr. Wang's spouse, in which Dr. Wang is deemed to be interested for the purposes of the SFO.
- (15) Includes Mr. Chen's entitlement to receive up to 460,340 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of these options.

REPORT OF THE DIRECTORS

- (16) Includes (1) 2,907,829 Shares held by Mr. Glazer; and (2) Mr. Glazer's entitlement to receive up to 327,418 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of these options.
- (17) Includes (1) 9,282 Shares held by Mr. Goller; and (2) Mr. Goller's entitlement to receive up to 327,418 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of these options.
- (18) Includes Mr. Hooper's entitlement to receive up to 67,353 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of those options.
- (19) Includes (1) 9,282 Shares held by Mr. Krishana and (2) Mr. Krishana's entitlement to receive up to 327,418 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of these options.
- (20) Includes (1) 399,282 Shares held by Mr. Malley and (2) Mr. Malley's entitlement to receive up to 850,166 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of those options.
- (21) Includes Dr. Sanders' entitlement to receive up to 27,482 Shares pursuant to the exercise of options granted to her, subject to the conditions (including vesting conditions) of those options.
- (22) Includes Mr. Su's entitlement to receive up to 173,277 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of those options.
- (23) Includes Mr. Yi's entitlement to receive up to 327,418 Shares pursuant to the exercise of options granted to him, subject to the conditions (including vesting conditions) of these options.

Except as disclosed above, as at December 31, 2020, so far as was known to the Directors and chief executive of the Company, none of the Directors or chief executive of the Company had any interests or short positions in the Shares, underlying Shares or debentures of the Company or its associated corporations which were required to be (a) notified to the Company and the HKEx pursuant to Divisions 7 and 8 of Part XV of the SFO (including interests and short positions which they were taken or deemed to be interested under such provisions of the SFO); or (b) recorded in the register required to be kept by the Company pursuant to Section 352 of the SFO; or (c) notified to the Company and the HKEx pursuant to the Model Code.

REPORT OF THE DIRECTORS

SUBSTANTIAL SHAREHOLDERS' INTERESTS AND SHORT POSITIONS IN SHARES AND UNDERLYING SHARES

As at December 31, 2020, so far as was known to the Directors or chief executive of the Company, the following persons (other than the Directors and chief executive of the Company) had interests and/or short positions in the Shares or underlying Shares which would be required to be disclosed to the Company pursuant to Divisions 2 and 3 of Part XV of the SFO or recorded in the register required to be kept by the Company pursuant to Section 336 of the SFO:

Name of Shareholder	Capacity/Nature of interest	Number of Shares/ underlying Shares	Approximate percentage of holding ⁽¹⁾
Amgen Inc.	Beneficial owner	244,117,549	20.59%
Julian C. Baker ⁽²⁾	Beneficial owner/Interest in controlled corporations/ Person having a security interest in shares/Trustee	152,831,254	12.89%
Felix J. Baker ⁽²⁾	Beneficial owner/Interest in controlled corporations/ Person having a security interest in shares/Trustee	152,831,254	12.89%
Baker Bros. Advisors (GP) LLC ⁽²⁾	Investment manager/Other	152,369,107	12.85%
Baker Bros. Advisors LP ⁽²⁾	Investment manager/Other	152,369,107	12.85%
Baker Brothers Life Sciences Capital, L.P. ⁽²⁾	Interest in controlled corporations/Other	141,217,049	11.91%
Gaoling Fund, L.P. ⁽³⁾	Beneficial owner	129,433,059	10.92%
Hillhouse Capital Advisors, Ltd. ⁽³⁾	Investment manager	133,587,655	11.27%
Fidelity Management & Research Company ⁽⁴⁾	Interest in controlled corporations	76,202,408	6.43%
FMR Co., Inc. ⁽⁴⁾	Beneficial owner/Interest in controlled corporations	71,180,714	6.00%
FMR LLC ⁽⁴⁾	Interest in controlled corporations	64,580,279	5.45%
The Capital Group Companies, Inc. ⁽⁵⁾	Interest in controlled corporations	92,437,662	7.80%
JPMorgan Chase & Co. ⁽⁶⁾	Interest in controlled corporations	5,044,374	0.43%
		5,493,959 (S)	0.46% (S)
	Investment manager	910,003	0.08%
		26,767 (S)	0.002% (S)
	Person having a security interest in shares	594,050	0.05%
	Trustee	40,092	0.003%
	Approved lending agent	75,827,936	6.40%

REPORT OF THE DIRECTORS

Notes:

Unless otherwise specified, the above Shares are long position. (S) denotes short position.

- (1) The calculation is based on the total number of 1,185,464,217 Shares in issue as at December 31, 2020.
- (2) Julian C. Baker and Felix J. Baker are the managing members of Baker Bros. Advisors (GP) LLC. Baker Bros. Advisors (GP) LLC is the general partner of Baker Bros. Advisors LP (“BBA”). BBA is the manager for securities held by 667, L.P. and Baker Brothers Life Sciences, L.P.. Also, Baker Brothers Life Sciences Capital, L.P. is the general partner of Baker Brothers Life Sciences, L.P. (the “Funds”). Unlisted derivatives include stock options and restricted stock received as compensation by two BBA employees (Michael Goller and Ranjeev Krishana) for their service on the Board of Directors of BeiGene, Ltd. and are controlled by BBA, with the Funds entitled to the pecuniary interest.

According to the corporate substantial shareholder notice for the date of relevant event of December 2, 2020 submitted by Baker Brothers Life Sciences Capital, L.P. to HKEx on December 7, 2020, 140,543,649 Shares held by Baker Brothers Life Sciences, L.P. directly. For the purposes of the SFO, Julian C. Baker, Felix J. Baker, Baker Bros. Advisors (GP) LLC and BBA are deemed to be interested in the 11,152,058 Shares held by 667, L.P. and the 140,543,649 Shares held by Baker Brothers Life Sciences, L.P., and 673,400 Shares which unlisted derivatives are controlled by BBA, with the Funds entitled to the pecuniary interest. In addition, for the purposes of the SFO, Baker Brothers Life Sciences Capital, L.P. is deemed to be interested in the 140,543,649 Shares held by Baker Brothers Life Sciences, L.P., and 673,400 Shares which unlisted derivatives are controlled by BBA, with the Funds entitled to the pecuniary interest.

Outside the Funds, each of Julian C. Baker and Felix J. Baker further interests in (in the form of ADSs) 311,143 Shares personally and 151,004 Shares through FBB3 LLC, a controlled corporation.

- (3) (i) 133,587,655 Shares are held by Gaoling Fund, L.P. and YHG Investment, L.P.; and (ii) 13,447,603 Shares are held by Hillhouse BGN Holdings Limited. Hillhouse Capital Advisors, Ltd. acts as the sole general partner of YHG Investment, L.P. and the sole management company of Gaoling Fund, L.P.. Hillhouse Capital Management, Ltd. is the sole management company of Hillhouse Fund II, L.P., which owns Hillhouse BGN Holdings Limited. Under the SFO, Hillhouse Capital Advisors, Ltd. is deemed to be interested in the 133,587,655 Shares held by Gaoling Fund, L.P. and YHG Investment, L.P. and Hillhouse Capital Management, Ltd. is deemed to be interested in the 13,447,603 Shares held by Hillhouse BGN Holdings Limited. Under the SFO, Hillhouse Fund II, L.P. is deemed to be interested in the 13,447,603 Shares held by Hillhouse BGN Holdings Limited.
- (4) Members of the Johnson family including Abigail P. Johnson, are the predominant owners, directly or through trusts, of series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other series B shareholders have entered into a shareholders’ voting agreement under which all series B voting common shares will be voted in accordance with the majority vote of series B voting common shares.

Fidelity Management & Research Company is interested in 76,202,408 Shares, of which 69,720,508 are physically settled listed derivatives. FMR Co., Inc., is interested in 71,180,714 Shares, of which 66,563,614 are physically settled listed derivatives and indirectly interested in 12,048,805 Shares. Fidelity Management & Research Company, FIAM Holdings LLC and Fidelity Advisory Holdings LLC are wholly owned by FMR LLC. Under the SFO, FMR LLC is deemed to be interested in 64,580,279 Shares held by Fidelity Management & Research Company, FIAM Holdings LLC and Fidelity Advisory Holdings LLC, respectively, of which 63,498,853 are Shares physically settled listed derivatives.

- (5) (i) 16,177,895 Shares are held by Capital International, Inc.; (ii) 688,402 Shares held by Capital International Limited; (iii) 1,968,858 Shares are held by Capital International Sarl; and (iv) 71,491,190 Shares are held by Capital Research and Management Company; and (v) 2,111,317 Shares are held by Capital Bank and Trust Company.

REPORT OF THE DIRECTORS

Capital Group International, Inc. is wholly owned by Capital Research and Management Company. Capital International, Inc., Capital International Limited and Capital International Sarl are wholly owned by Capital Group International, Inc. Capital Bank and Trust Company is wholly owned by The Capital Group Companies, Inc. For the purposes of the SFO, Capital Research and Management Company and Capital Group International, Inc. are deemed to be interested in the 18,835,155 Shares held by Capital International, Inc., Capital International Limited and Capital International Sarl, and The Capital Group Companies, Inc. is deemed to be interested in the 2,111,317 Shares held by Capital Bank and Trust Company.

Capital Research and Management Company is wholly owned by The Capital Group Companies Inc. For the purposes of the SFO, The Capital Group Companies Inc. is deemed to be interested in the 90,326,345 Shares held by Capital Research and Management Company directly and indirectly.

- (6) According to the shareholding disclosures notice regarding the relevant event dated October 6, 2020 submitted by JPMorgan Chase & Co. to HKEx, an aggregated 82,416,455 Shares (long position), 5,520,726 Shares (short position) and 75,827,936 Shares (lending pool) of the Company are held by JPMorgan Chase & Co. indirectly through its certain subsidiaries. Among them, 566 Shares (short position) are cash settled listed derivatives, and 12,004 Shares (long position) and 585,942 (short position) are cash settled unlisted derivatives.

Except as disclosed above, as at December 31, 2020, the Directors have not been notified by any person (other than the Directors or chief executive of the Company) who had interests or short positions in the Shares or underlying Shares which would be required to be disclosed to the Company pursuant to Divisions 2 and 3 of Part XV of the SFO, or recorded in the register required to be kept by the Company pursuant to Section 336 of the SFO.

SHARE OPTION AND AWARD SCHEMES

1. 2011 Option Plan

The 2011 Plan was approved by the Board on April 15, 2011 and most recently amended on April 17, 2015. The terms of the 2011 Plan are not subject to the provisions of Chapter 17 of the HK Listing Rules, as our Board determined not to grant any further options under the 2011 Plan after February 2, 2016 when the 2016 Plan became effective.

As at December 31, 2020, the Company had conditionally granted options to 240 participants under the 2011 Plan. All of the options under the 2011 Plan were granted between May 20, 2011 and January 31, 2016 (both days inclusive). The exercise price of all of the options granted under the 2011 Plan is between US\$0.01 and US\$1.85 per Share.

Further details of the 2011 Plan are set out in the prospectus of the Company dated July 30, 2018 (the "Prospectus").

REPORT OF THE DIRECTORS

As at January 1, 2020, 15,089,586 Shares were outstanding pursuant to options granted under the 2011 Plan, and as at December 31, 2020, 5,671,093 Shares were outstanding under the 2011 Plan. Details of the movements of the options granted under the 2011 Plan from January 1, 2020 to December 31, 2020 are as follows:

Name of grantee	Role	Date of grant	Option period	Exercise price	Number of options				
					Outstanding as of January 1, 2020	Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Directors of the Company									
Xiaodong Wang	Non-executive Director	May 20, 2011 ⁽¹⁾	10 years from the date of grant	US\$0.01	88,235	-	-	-	88,235
		April 3, 2013 ⁽¹⁾	10 years from the date of grant	US\$0.01	879,267	-	-	-	879,267
		June 29, 2015 ⁽¹⁾	10 years from the date of grant	US\$0.50	500,000	-	-	-	500,000
Thomas Malley	Independent Non-executive Director	January 25, 2016 ⁽²⁾	10 years from the date of grant	US\$1.85	552,752	-	-	-	552,752
Senior Management of the Company									
Howard Liang	Chief Financial Officer and Chief Strategy Officer	June 29, 2015 ⁽³⁾	10 years from the date of grant	US\$0.50	3,795,000	-	2,964,000	-	831,000
Other grantees									
In aggregate		Between May 20, 2011 and January 31, 2016 ⁽⁴⁾	10 years from the date of grant	Between US\$0.01 to US\$1.85	9,274,332	-	6,453,304	1,189	2,819,839
Total					<u>15,089,586</u>	<u>-</u>	<u>9,417,304</u>	<u>1,189</u>	<u>5,671,093</u>

- (1) 20% of the options become exercisable on the first anniversary of the grant date. The remaining 80% become exercisable in 48 equal monthly installments, each of which shall become exercisable on the last day of each month following the vest of the initial 20%.
- (2) One-third of the options become exercisable on each anniversary of the grant date.
- (3) 25% of the options become exercisable on July 15, 2016, and the remaining 75% become exercisable in 36 successive equal monthly installments, each of which shall become exercisable on the last day of each month following the vest of the initial 25%. Certain options may be subject to accelerated vesting upon change in control and/or termination.
- (4) 20%/25% of the options become exercisable on the first anniversary of the grant date. The remaining 80%/75% become exercisable in 48/36 equal monthly installments, each of which shall become exercisable on the last day of each month following the vest of the initial 20%/25%. Certain options may be subject to accelerated vesting upon change in control and/or termination.

REPORT OF THE DIRECTORS

2. Second Amended and Restated 2016 Share Option and Incentive Plan

The 2016 Plan was approved by our Board on November 7, 2018 and by our shareholders on December 7, 2018 to amend and restate the 2016 Share Option and Incentive Plan originally adopted by the Company on January 14, 2016. As at December 31, 2020, the total number of Shares available for option grants under the 2016 Plan was 67,471,091 Shares (including the additional Shares added as further described below), representing 5.7% of the issued share capital of the Company.

In order to continue to provide incentive opportunities under the 2016 Plan, an amendment to the 2016 Plan (the “Amendment No. 1”, and the 2016 Plan as amended by the Amendment No. 1, the “Amended 2016 Plan”) to increase the number of authorized Shares available for issuance under the 2016 Plan by 57,200,000 Shares, and to extend the term of the 2016 Plan through 2030, was approved by our Board on April 13, 2020 and by our shareholders on June 17, 2020.

Purpose

The Amended 2016 Plan provides the Company with the flexibility to use various equity-based incentive and other awards as compensation tools to attract, retain and motivate our (and our subsidiaries’) workforce. These tools include share options, share appreciation rights, restricted shares, restricted share units, unrestricted shares, performance share awards, cash-based awards and dividend equivalent rights.

Eligible Participants

Full-time and part-time officers, employees, non-employee Directors and other key persons (including consultants) as selected from time to time by our Compensation Committee are eligible to participate in the Amended 2016 Plan.

Maximum Number of Shares

The maximum number of Shares reserved and available for issuance under the Amended 2016 Plan and our other equity plans may not exceed 10% of the Shares issued and outstanding as of June 17, 2020 and the aggregate number of Shares that may be issued upon exercise of all outstanding options granted and yet to be exercised under the Amended 2016 Plan and outstanding options granted and yet to be exercised under any other plan of the Company at any time may not exceed 30% of the Shares in issue from time to time.

Limit of Each Grantee

Unless approved by our shareholders in a general meeting, the total number of Shares issued and to be issued upon the exercise of share options granted and to be granted under the 2016 Plan and any other equity plans of the Company to a grantee within any 12-month period shall not exceed 1% of the Shares in issue at the date of any grant.

REPORT OF THE DIRECTORS

Option Period

Our Compensation Committee may determine at the time of grant any minimum period(s) for which a share option must be held and/or any minimum performance target(s) that must be achieved, before the share option can be exercised in whole or in part, and may include at the discretion of our Compensation Committee such other terms either on a case by case basis or generally.

The term of each share option will be fixed by our Compensation Committee and may not exceed 10 years from the date of grant. Any share option granted but not exercised by the end of its option term will automatically lapse and be cancelled. Our Compensation Committee will determine at what time or times each option may be exercised.

Exercise Price

The exercise price of each share option will be determined by our Compensation Committee but may not be less than the higher of: (i) 1/13th of the closing price of one ADS on the NASDAQ on the date of grant; and (ii) 1/13th of the average closing price of one ADS on the NASDAQ for the five business days immediately preceding the date of grant.

Consideration

No consideration is required to be paid by the grantees for the grant of options under the 2016 Plan.

Expiration of the 2016 Plan

The 2016 Plan will expire on April 13, 2030.

Movements in the 2016 Plan

As at December 31, 2020, the Company has conditionally granted options to 787 participants under the Amended 2016 Plan. All of the options under the Amended 2016 Plan were granted between February 8, 2016 and November 30, 2020 (both days inclusive). The exercise price of all the options granted under the 2016 Plan is between US\$0.5 and US\$23.07 per Share.

Further details of the 2016 Plan are set out in Note 20 to the consolidated financial statements.

REPORT OF THE DIRECTORS

As at January 1, 2020, 78,047,638 Shares were outstanding pursuant to options granted under the 2016 Plan, and as at December 31, 2020, 64,082,595 Shares were outstanding pursuant to options granted under the 2016 Plan. Details of the movements of the options granted during the Reporting Period were as follows:

Name of grantee	Role	Date of grant	Option period	Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Number of options			Outstanding as of December 31, 2020
								Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	
Directors of the Company											
John V. Oyler	Executive Director, Chairman and Chief Executive Officer	November 16, 2016 ⁽³⁾	10 years from the date of grant	US\$2.79	N/A	US\$2.84	2,047,500	-	-	-	2,047,500
		September 27, 2017 ⁽³⁾	10 years from the date of grant	US\$6.73	N/A	US\$7.70	935,000	-	-	-	935,000
		April 30, 2018 ⁽³⁾	10 years from the date of grant	US\$13.37	N/A	US\$13.04	996,810	-	-	-	996,810
		June 26, 2018 ⁽³⁾	10 years from the date of grant	US\$12.70	N/A	US\$12.34	1,310,088	-	-	-	1,310,088
		June 5, 2019 ⁽³⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	2,193,282	-	-	-	2,193,282
		June 17, 2020 ⁽³⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	1,821,976	-	-	1,821,976
Xiaodong Wang	Non-executive Director	November 16, 2016 ⁽³⁾	10 years from the date of grant	US\$2.79	N/A	US\$2.84	1,613,430	-	-	-	1,613,430
		September 27, 2017 ⁽³⁾	10 years from the date of grant	US\$6.73	N/A	US\$7.70	750,000	-	-	-	750,000
		June 26, 2018 ⁽³⁾	10 years from the date of grant	US\$12.70	N/A	US\$12.34	655,044	-	-	-	655,044
		June 5, 2019 ⁽³⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	747,708	-	-	-	747,708
		June 17, 2020 ⁽³⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	560,599	-	-	560,599

REPORT OF THE DIRECTORS

Name of grantee	Role	Date of grant	Option period	Number of options							
				Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Anthony C. Hooper	Non-executive Director	March 3, 2020 ⁽⁵⁾	10 years from the date of grant	US\$12.62	N/A	US\$12.22	-	21,970	-	-	21,970
		June 17, 2020 ⁽⁵⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	45,383	-	-	45,383
Timothy Chen	Independent Non-executive Director	February 8, 2016 ⁽⁴⁾	10 years from the date of grant	US\$2.61	N/A	US\$2.42	357,926	-	91,000	-	266,926
		June 2, 2017 ⁽⁵⁾	10 years from the date of grant	US\$2.94	N/A	US\$3.15	65,988	-	-	-	65,988
		June 6, 2018 ⁽⁵⁾	10 years from the date of grant	US\$15.73	N/A	US\$16.15	17,442	-	-	-	17,442
		June 5, 2019 ⁽⁵⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	64,610	-	-	-	64,610
		June 17, 2020 ⁽⁵⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	45,383	-	-	45,383
Donald W. Glazer	Independent Non-executive Director	April 19, 2017 ⁽⁴⁾	10 years from the date of grant	US\$2.84	N/A	US\$2.83	199,992	-	-	-	199,992
		June 6, 2018 ⁽⁵⁾	10 years from the date of grant	US\$15.73	N/A	US\$16.15	17,442	-	-	-	17,442
		June 5, 2019 ⁽⁵⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	64,610	-	-	-	64,610
		June 17, 2020 ⁽⁵⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	45,383	-	-	45,383

REPORT OF THE DIRECTORS

Name of grantee	Role	Date of grant	Option period	Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Number of options				Outstanding as of December 31, 2020
								Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period		
Michael Goller	Independent Non-executive Director	April 19, 2017 ⁽⁴⁾	10 years from the date of grant	US\$2.84	N/A	US\$2.83	199,992	-	-	-	199,992	
		June 6, 2018 ⁽⁵⁾	10 years from the date of grant	US\$15.73	N/A	US\$16.15	17,442	-	-	-	17,442	
	June 5, 2019 ⁽⁵⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	64,610	-	-	-	64,610		
	June 17, 2020 ⁽⁵⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	45,383	-	-	45,383		
Ranjeev Krishana	Independent Non-executive Director	April 19, 2017 ⁽⁴⁾	10 years from the date of grant	US\$2.84	N/A	US\$2.83	199,992	-	-	-	199,992	
		June 6, 2018 ⁽⁵⁾	10 years from the date of grant	US\$15.73	N/A	US\$16.15	17,442	-	-	-	17,442	
	June 5, 2019 ⁽⁵⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	64,610	-	-	-	64,610		
	June 17, 2020 ⁽⁵⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	45,383	-	-	45,383		
Thomas Malley	Independent Non-executive Director	June 2, 2017 ⁽⁵⁾	10 years from the date of grant	US\$2.94	N/A	US\$3.15	169,988	-	-	-	169,988	
		June 6, 2018 ⁽⁵⁾	10 years from the date of grant	US\$15.73	N/A	US\$16.15	17,442	-	-	-	17,442	
	June 5, 2019 ⁽⁵⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	64,610	-	-	-	64,610		
	June 17, 2020 ⁽⁵⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	45,383	-	-	45,383		

REPORT OF THE DIRECTORS

Name of grantee	Role	Date of grant	Option period	Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Number of options				Outstanding as of December 31, 2020
								Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period		
Corazon (Corsee)	Independent Non-executive Director	August 24, 2020 ⁽⁵⁾	10 years from the date of grant	US\$18.50	N/A	US\$18.26	-	27,482	-	-	-	27,482
Jing-Shyh (Sam) Su	Independent Non-executive Director	April 1, 2018 ⁽⁴⁾ June 5, 2019 ⁽⁵⁾	10 years from the date of grant	US\$12.92	N/A	US\$12.72	63,290	-	-	-	-	63,290
		June 17, 2020 ⁽⁵⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	64,610	-	-	-	-	64,610
			10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	45,383	-	-	-	45,383
Qingqing Yi	Independent Non-executive Director	April 19, 2017 ⁽⁴⁾ June 6, 2018 ⁽⁵⁾	10 years from the date of grant	US\$2.84	N/A	US\$2.83	199,992	-	-	-	-	199,992
		June 5, 2019 ⁽⁵⁾	10 years from the date of grant	US\$15.73	N/A	US\$16.15	17,442	-	-	-	-	17,442
		June 17, 2020 ⁽⁵⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	64,610	-	-	-	-	64,610
			10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	45,383	-	-	-	45,383
Senior Management of the Company												
Howard Liang	Chief Financial Officer and Chief Strategy Officer	November 16, 2016 ⁽³⁾ June 29, 2017 ⁽³⁾ June 26, 2018 ⁽³⁾ June 5, 2019 ⁽³⁾ June 17, 2020 ⁽³⁾	10 years from the date of grant	US\$2.79	N/A	US\$2.84	1,752,500	-	-	-	-	1,752,500
			10 years from the date of grant	US\$3.50	N/A	US\$3.45	1,250,000	-	-	-	-	1,250,000
			10 years from the date of grant	US\$12.70	N/A	US\$12.34	364,208	-	-	-	-	364,208
			10 years from the date of grant	US\$9.25	N/A	US\$9.23	558,285	-	-	-	-	558,285
			10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	315,341	-	-	-	315,341

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Name of grantee	Role	Date of grant	Option period	Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Number of options			
								Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Jane Huang	Chief medical Officer, Hematology	September 2, 2016 ⁽³⁾	10 years from the date of grant	US\$2.26	US\$13.04	US\$2.27	578,075	-	253,500	-	324,575
		June 27, 2017 ⁽³⁾	10 years from the date of grant	US\$3.50	N/A	US\$3.49	850,465	-	-	-	850,465
		June 26, 2018 ⁽³⁾	10 years from the date of grant	US\$12.70	US\$15.41	US\$12.34	310,180	-	97,500	-	212,680
		June 5, 2019 ⁽³⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	462,579	-	-	-	462,579
		June 17, 2020 ⁽³⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	273,286	-	-	273,286
Xiaboin Wu	President, Chief Operating Officer and General Manager of China	April 30, 2018 ⁽³⁾	10 years from the date of grant	US\$13.37	N/A	US\$13.04	766,599	-	-	-	766,599
		June 5, 2019 ⁽³⁾	10 years from the date of grant	US\$9.25	N/A	US\$9.23	797,550	-	-	-	797,550
		June 17, 2020 ⁽³⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	756,821	-	-	756,821

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Name of grantee	Role	Date of grant	Option period	Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Number of options			
								Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Other grantees											
In Aggregate		July 13, 2016 ⁽³⁾	10 years from the date of grant	US\$2.27	US\$17.41	US\$2.29	7,940,251	-	3,409,536	5	4,530,710
		July 22, 2016 ⁽³⁾	10 years from the date of grant	US\$2.13	US\$13.20	US\$2.10	688,381	-	398,801	4,186	285,394
		July 22, 2016 ⁽³⁾	10 years from the date of grant	US\$2.13	US\$15.40	US\$2.10	2,427,276	-	871,767	16,582	1,538,927
		July 29, 2016 ⁽³⁾	10 years from the date of grant	US\$2.11	US\$16.07	US\$2.02	186,810	-	186,732	-	78
		August 9, 2016 ⁽³⁾	10 years from the date of grant	US\$2.04	N/A	US\$2.10	55,552	-	-	-	55,552
		August 22, 2016 ⁽³⁾	10 years from the date of grant	US\$2.28	US\$12.91	US\$2.24	624,988	-	624,988	-	-
		September 12, 2016 ⁽³⁾	10 years from the date of grant	US\$2.33	US\$12.78	US\$2.42	16,065	-	12,597	-	3,468
		September 19, 2016 ⁽³⁾	10 years from the date of grant	US\$2.51	US\$17.18	US\$2.38	110,999	-	53,989	15,679	41,331
		September 26, 2016 ⁽³⁾	10 years from the date of grant	US\$2.35	US\$14.22	US\$2.27	35,325	-	33,228	-	2,097
		October 12, 2016 ⁽³⁾	10 years from the date of grant	US\$2.48	US\$17.39	US\$2.42	238,498	-	39,000	-	199,498
		October 12, 2016 ⁽³⁾	10 years from the date of grant	US\$2.48	US\$13.50	US\$2.42	9,340	-	8,320	-	1,020
		October 17, 2016 ⁽³⁾	10 years from the date of grant	US\$2.42	N/A	US\$2.55	89,999	-	-	-	89,999
		November 1, 2016 ⁽³⁾	10 years from the date of grant	US\$2.56	US\$12.39	US\$2.57	128,089	-	54,860	73,229	-
		November 7, 2016 ⁽³⁾	10 years from the date of grant	US\$2.43	US\$17.94	US\$2.46	298,948	-	272,779	26,169	-
		November 8, 2016 ⁽³⁾	10 years from the date of grant	US\$2.46	US\$12.51	US\$2.51	43,459	-	23,296	20,163	-
		November 16, 2016 ⁽³⁾	10 years from the date of grant	US\$2.79	US\$12.34	US\$2.84	77,493	-	59,059	-	18,434
		November 21, 2016 ⁽³⁾	10 years from the date of grant	US\$2.46	US\$16.35	US\$2.42	239,083	-	197,756	8,437	32,890
		November 28, 2016 ⁽³⁾	10 years from the date of grant	US\$2.49	US\$13.59	US\$2.38	113,607	-	45,136	-	68,471

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Name of grantee	Role	Date of grant	Option period	Number of options							
				Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Other grantees											
		November 30, 2016 ⁽³⁾	10 years from the date of grant	US\$2.43	US\$20.77	US\$2.44	15,990	-	14,716	-	1,274
		December 1, 2016 ⁽³⁾	10 years from the date of grant	US\$2.44	US\$18.23	US\$2.37	188,461	-	144,690	-	43,771
		December 9, 2016 ⁽³⁾	10 years from the date of grant	US\$2.07	US\$15.26	US\$2.09	119,990	-	85,891	-	34,099
		January 3, 2017 ⁽³⁾	10 years from the date of grant	US\$2.34	US\$15.89	US\$2.39	132,015	-	92,976	-	39,039
		January 5, 2017 ⁽³⁾	10 years from the date of grant	US\$2.44	US\$18.54	US\$2.39	309,998	-	65,000	-	244,998
		January 9, 2017 ⁽³⁾	10 years from the date of grant	US\$2.37	US\$13.85	US\$2.43	249,496	-	65,000	-	184,496
		January 17, 2017 ⁽³⁾	10 years from the date of grant	US\$2.51	US\$17.33	US\$2.53	31,317	-	23,673	-	7,644
		January 17, 2017 ⁽⁶⁾	10 years from the date of grant	US\$2.51	US\$16.84	US\$2.53	213,161	-	88,621	4,758	119,782
		January 23, 2017 ⁽³⁾	10 years from the date of grant	US\$2.46	US\$16.36	US\$2.49	238,368	-	76,193	5,135	157,040
		January 30, 2017 ⁽³⁾	10 years from the date of grant	US\$2.80	US\$14.18	US\$2.62	86,307	-	74,620	5,486	6,201
		February 1, 2017 ⁽³⁾	10 years from the date of grant	US\$2.68	US\$13.66	US\$2.77	416,676	-	119,678	-	296,998
		February 6, 2017 ⁽³⁾	10 years from the date of grant	US\$2.76	US\$17.69	US\$2.76	105,001	-	52,000	-	53,001
		February 8, 2017 ⁽³⁾	10 years from the date of grant	US\$2.67	US\$18.35	US\$2.78	4,849	-	2,925	-	1,924
		February 13, 2017 ⁽³⁾	10 years from the date of grant	US\$2.77	US\$17.05	US\$2.77	568,893	-	377,624	-	191,269
		February 27, 2017 ⁽³⁾	10 years from the date of grant	US\$2.97	US\$16.18	US\$2.93	497,796	-	412,737	17,641	67,418
		March 6, 2017 ⁽³⁾	10 years from the date of grant	US\$3.14	US\$14.03	US\$3.06	143,052	-	114,439	-	28,613
		March 13, 2017 ⁽³⁾	10 years from the date of grant	US\$3.08	US\$13.67	US\$3.02	312,689	-	131,963	38,025	142,701

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Name of grantee	Role	Date of grant	Option period	Number of options							
				Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Other grantees											
		March 20, 2017 ⁽³⁾	10 years from the date of grant	US\$3.04	US\$18.51	US\$3.04	319,098	-	113,581	-	205,517
		March 27, 2017 ⁽³⁾	10 years from the date of grant	US\$2.79	US\$17.87	US\$2.79	230,373	-	147,875	-	82,498
		March 31, 2017 ⁽⁶⁾	10 years from the date of grant	US\$2.81	US\$15.53	US\$2.82	354,315	-	140,205	16,744	197,366
		April 3, 2017 ⁽³⁾	10 years from the date of grant	US\$2.82	US\$16.13	US\$2.82	24,999	-	15,418	-	9,581
		April 10, 2017 ⁽³⁾	10 years from the date of grant	US\$2.86	US\$15.61	US\$2.91	237,835	-	167,544	30,329	39,962
		April 11, 2017 ⁽³⁾	10 years from the date of grant	US\$2.91	US\$23.25	US\$2.95	149,994	-	127,972	-	22,022
		April 17, 2017 ⁽³⁾	10 years from the date of grant	US\$2.92	US\$19.10	US\$2.95	409,110	-	150,956	-	258,154
		April 24, 2017 ⁽³⁾	10 years from the date of grant	US\$2.82	US\$18.62	US\$2.89	107,341	-	19,084	-	88,257
		April 26, 2017 ⁽³⁾	10 years from the date of grant	US\$3.01	US\$14.71	US\$3.09	116,818	-	43,641	-	73,177
		May 1, 2017 ⁽³⁾	10 years from the date of grant	US\$3.14	US\$16.17	US\$3.13	977,769	-	246,389	-	731,380
		May 2, 2017 ⁽⁶⁾	10 years from the date of grant	US\$3.13	US\$16.59	US\$3.12	362,713	-	66,118	25,532	271,063
		May 3, 2017 ⁽³⁾	10 years from the date of grant	US\$3.12	US\$16.20	US\$3.12	70,447	-	39,208	-	31,239
		May 8, 2017 ⁽³⁾	10 years from the date of grant	US\$3.02	US\$16.05	US\$2.98	219,492	-	146,172	-	73,320
		May 10, 2017 ⁽³⁾	10 years from the date of grant	US\$2.88	US\$15.51	US\$2.92	54,457	-	33,176	-	21,281
		May 15, 2017 ⁽³⁾	10 years from the date of grant	US\$2.81	US\$19.01	US\$2.90	192,686	-	39,195	-	153,491
		May 30, 2017 ⁽³⁾	10 years from the date of grant	US\$2.88	US\$19.35	US\$2.88	192,504	-	132,444	-	60,060
		June 1, 2017 ⁽³⁾	10 years from the date of grant	US\$2.83	US\$17.36	US\$2.94	1,602,653	-	345,553	26,507	1,230,593
		June 12, 2017 ⁽³⁾	10 years from the date of grant	US\$2.99	US\$14.99	US\$3.00	110,968	-	66,898	-	44,070

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Name of grantee	Role	Date of grant	Option period	Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Number of options			
								Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Other grantees											
		June 14, 2017 ⁽³⁾	10 years from the date of grant	US\$3.04	US\$15.80	US\$3.05	2,042,638	-	772,850	131,313	1,138,475
		June 15, 2017 ⁽⁶⁾	10 years from the date of grant	US\$3.05	US\$15.86	US\$3.04	6,807,398	-	1,625,494	166,998	5,014,906
		June 21, 2017 ⁽³⁾	10 years from the date of grant	US\$3.31	US\$15.38	US\$3.45	98,267	-	59,033	-	39,234
		June 23, 2017 ⁽³⁾	10 years from the date of grant	US\$3.41	US\$12.70	US\$3.45	35,880	-	35,880	-	-
		June 27, 2017 ⁽³⁾	10 years from the date of grant	US\$3.50	US\$19.09	US\$3.49	5,300,225	-	1,540,201	67,855	3,692,169
		June 29, 2017 ⁽³⁾	10 years from the date of grant	US\$3.50	US\$14.54	US\$3.45	136,032	-	85,709	-	50,323
		July 10, 2017 ⁽³⁾	10 years from the date of grant	US\$5.40	US\$15.99	US\$5.45	271,596	-	55,367	-	216,229
		July 17, 2017 ⁽³⁾	10 years from the date of grant	US\$5.67	US\$12.30	US\$4.19	165,802	-	83,928	-	81,874
		July 17, 2017 ⁽⁶⁾	10 years from the date of grant	US\$5.67	US\$16.73	US\$4.19	911,326	-	381,212	60,437	469,677
		July 24, 2017 ⁽³⁾	10 years from the date of grant	US\$5.95	US\$15.85	US\$5.65	5,057	-	2,717	-	2,340
		July 31, 2017 ⁽³⁾	10 years from the date of grant	US\$5.58	US\$15.52	US\$5.42	216,996	-	58,422	-	158,574
		July 31, 2017 ⁽⁶⁾	10 years from the date of grant	US\$5.58	US\$16.47	US\$5.42	790,296	-	254,774	58,812	476,710
		August 1, 2017 ⁽³⁾	10 years from the date of grant	US\$5.42	US\$15.34	US\$5.58	1,300,000	-	455,000	-	845,000
		August 2, 2017 ⁽⁶⁾	10 years from the date of grant	US\$5.58	US\$13.10	US\$5.45	153,348	-	69,888	-	83,460
		August 3, 2017 ⁽³⁾	10 years from the date of grant	US\$5.45	N/A	US\$5.51	19,994	-	-	-	19,994
		August 7, 2017 ⁽³⁾	10 years from the date of grant	US\$5.56	US\$21.58	US\$5.95	424,996	-	106,249	-	318,747
		August 8, 2017 ⁽³⁾	10 years from the date of grant	US\$5.95	US\$15.48	US\$6.03	24,089	-	11,440	-	12,649
		August 10, 2017 ⁽³⁾	10 years from the date of grant	US\$5.95	US\$15.95	US\$5.59	54,795	-	23,439	-	31,356

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Name of grantee	Role	Date of grant	Option period	Number of options							
				Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Other grantees											
		August 11, 2017 ⁽³⁾	10 years from the date of grant	US\$5.59	N/A	US\$5.46	120,809	-	-	120,809	-
		August 17, 2017 ⁽³⁾	10 years from the date of grant	US\$5.39	US\$12.93	US\$5.32	671,229	-	419,367	173,992	77,870
		August 25, 2017 ⁽³⁾	10 years from the date of grant	US\$5.38	US\$20.42	US\$5.29	78,741	-	54,600	24,141	-
		August 28, 2017 ⁽³⁾	10 years from the date of grant	US\$5.29	US\$18.99	US\$5.28	218,582	-	143,663	40,456	34,463
		August 31, 2017 ⁽³⁾	10 years from the date of grant	US\$5.30	US\$15.75	US\$5.30	312,000	-	221,000	91,000	-
		August 31, 2017 ⁽⁶⁾	10 years from the date of grant	US\$5.30	US\$15.75	US\$5.30	580,736	-	190,710	22,282	367,744
		September 5, 2017 ⁽³⁾	10 years from the date of grant	US\$5.78	US\$15.50	US\$5.68	334,178	-	51,311	-	282,867
		September 12, 2017 ⁽³⁾	10 years from the date of grant	US\$5.39	US\$17.31	US\$5.43	109,993	-	89,271	-	20,722
		September 13, 2017 ⁽³⁾	10 years from the date of grant	US\$5.43	US\$15.55	US\$5.82	52,754	-	27,456	25,298	-
		September 18, 2017 ⁽³⁾	10 years from the date of grant	US\$6.22	US\$14.72	US\$6.37	51,090	-	24,921	-	26,169
		September 22, 2017 ⁽³⁾	10 years from the date of grant	US\$6.53	US\$16.77	US\$6.55	469,729	-	282,724	-	187,005
		September 25, 2017 ⁽³⁾	10 years from the date of grant	US\$6.55	US\$19.17	US\$6.56	278,980	-	98,111	-	180,869
		September 26, 2017 ⁽³⁾	10 years from the date of grant	US\$6.56	US\$16.94	US\$8.71	143,871	-	81,120	-	62,751
		September 29, 2017 ⁽³⁾	10 years from the date of grant	US\$7.49	N/A	US\$7.96	199,992	-	-	-	199,992
		November 1, 2017 ⁽³⁾	10 years from the date of grant	US\$7.10	US\$14.52	US\$6.84	706,290	-	286,026	135,954	284,310
		November 30, 2017 ⁽³⁾	10 years from the date of grant	US\$6.38	US\$16.88	US\$6.15	78,819	-	42,588	-	36,231
		January 5, 2018 ⁽³⁾	10 years from the date of grant	US\$7.72	US\$12.92	US\$7.58	202,488	-	89,700	-	112,788
		January 31, 2018 ⁽³⁾	10 years from the date of grant	US\$9.52	US\$20.59	US\$10.44	124,490	-	13,000	-	111,490

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Name of grantee	Role	Date of grant	Option period	Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Number of options			
								Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Other grantees											
		February 28, 2018 ⁽³⁾	10 years from the date of grant	US\$11.61	N/A	US\$11.04	32,604	-	-	-	32,604
		April 30, 2018 ⁽³⁾	10 years from the date of grant	US\$13.37	US\$19.77	US\$13.04	68,146	-	29,419	-	38,727
		June 26, 2018 ⁽³⁾	10 years from the date of grant	US\$12.70	US\$19.89	US\$12.34	2,709,408	-	541,476	220,051	1,947,881
		June 29, 2018 ⁽³⁾	10 years from the date of grant	US\$11.90	US\$17.62	US\$11.83	80,966	-	48,763	-	32,203
		August 31, 2018 ⁽³⁾	10 years from the date of grant	US\$13.67	US\$14.69	US\$13.66	24,934	-	3,731	-	21,203
		August 31, 2018 ⁽⁷⁾	10 years from the date of grant	US\$13.67	US\$17.72	US\$13.66	115,570	-	7,033	-	108,537
		September 28, 2018 ⁽³⁾	10 years from the date of grant	US\$13.28	N/A	US\$13.25	65,433	-	-	-	65,433
		September 28, 2018 ⁽⁸⁾	10 years from the date of grant	US\$13.28	N/A	US\$13.25	39,260	-	-	-	39,260
		November 30, 2018 ⁽³⁾	10 years from the date of grant	US\$11.07	N/A	US\$11.79	43,827	-	-	-	43,827
		December 31, 2018 ⁽³⁾	10 years from the date of grant	US\$10.53	US\$17.55	US\$10.79	418,925	-	129,051	2,717	287,157
		December 31, 2018 ⁽⁸⁾	10 years from the date of grant	US\$10.53	N/A	US\$10.79	47,996	-	-	-	47,996
		January 25, 2019 ⁽³⁾	10 years from the date of grant	US\$9.62	US\$18.26	US\$10.44	143,806	-	39,507	31,278	73,021
		February 28, 2019 ⁽³⁾	10 years from the date of grant	US\$10.77	US\$19.05	US\$10.54	348,426	-	126,100	-	222,326
		March 5, 2019 ⁽³⁾	10 years from the date of grant	US\$11.68	N/A	US\$11.51	98,735	-	-	-	98,735
		May 10, 2019 ⁽³⁾	10 years from the date of grant	US\$9.33	N/A	US\$10.32	44,213	-	-	-	44,213
		June 5, 2019 ⁽³⁾	10 years from the date of grant	US\$9.25	US\$18.47	US\$9.23	6,093,569	-	722,670	644,567	4,726,332
		June 28, 2019 ⁽³⁾	10 years from the date of grant	US\$9.67	US\$17.62	US\$9.53	239,304	-	83,720	-	155,584
		August 30, 2019 ⁽³⁾	10 years from the date of grant	US\$11.14	US\$21.04	US\$11.06	200,148	-	61,672	-	138,476

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Name of grantee	Role	Date of grant	Option period	Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise (Grant) price	Outstanding as of January 1, 2020	Number of options			
								Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	Outstanding as of December 31, 2020
Other grantees											
		November 29, 2019 ⁽³⁾	10 years from the date of grant	US\$15.71	N/A	US\$15.83	39,221	-	-	-	39,221
		December 31, 2019 ⁽³⁾	10 years from the date of grant	US\$12.80	N/A	US\$12.92	54,431	-	-	-	54,431
		March 3, 2020 ⁽³⁾	10 years from the date of grant	US\$12.62	N/A	US\$12.19	-	36,244	-	-	36,244
		March 31, 2020 ⁽³⁾	10 years from the date of grant	US\$9.65	N/A	US\$9.67	-	404,235	-	-	404,235
		May 12, 2020 ⁽³⁾	10 years from the date of grant	US\$12.56	N/A	US\$12.18	-	38,597	-	-	38,597
		May 29, 2020 ⁽³⁾	10 years from the date of grant	US\$12.49	N/A	US\$12.73	-	21,281	-	-	21,281
		June 17, 2020 ⁽³⁾	10 years from the date of grant	US\$13.33	N/A	US\$13.42	-	3,726,710	-	320,580	3,406,130
		June 30, 2020 ⁽³⁾	10 years from the date of grant	US\$14.55	N/A	US\$14.66	-	317,525	-	-	317,525
		August 7, 2020 ⁽³⁾	10 years from the date of grant	US\$17.24	N/A	US\$16.99	-	40,248	-	-	40,248
		August 31, 2020 ⁽³⁾	10 years from the date of grant	US\$18.69	N/A	US\$18.85	-	14,040	-	-	14,040
		September 30, 2020 ⁽³⁾	10 years from the date of grant	US\$21.65	N/A	US\$22.03	-	8,021	-	-	8,021
		November 6, 2020 ⁽³⁾	10 years from the date of grant	US\$23.08	N/A	US\$23.07	-	175,708	-	-	175,708
		November 30, 2020 ⁽³⁾	10 years from the date of grant	US\$21.99	N/A	US\$20.99	-	33,319	-	-	33,319
Total							<u>78,047,607</u>	<u>8,956,467</u>	<u>20,248,332</u>	<u>2,673,147</u>	<u>64,082,595</u>

(1) The stated price was the closing price as quoted on the NASDAQ, divided by 13, on the trading day immediately prior to the grant date.

(2) The stated price was the weighted-average closing price as quoted on the NASDAQ, divided by 13, on the trading day immediately prior to the date which the options were exercised.

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- (3) 25% of the options become exercisable on the first anniversary of the grant date or, for new employees, the first anniversary of the last trading day of the month following the date on which such grantee starts his or her service relationship with the Company or its subsidiaries. The remaining 75% become exercisable in 36 equal monthly installments, each of which shall become exercisable on the last day of each month following the vest of the initial 25%. Certain options may be subject to accelerated vesting upon change in control and/or termination.
- (4) One-third of the options become exercisable on each anniversary of the grant date.
- (5) 100% of the options become exercisable on the earlier of the first anniversary of the grant date or the date of the next annual general meeting. Certain options may be subject to accelerated vesting upon change in control and/or termination.
- (6) 20% of the options become exercisable on the first anniversary of the grant date. The remaining 80% become exercisable in 48 equal monthly installments, each of which shall become exercisable on the last day of each month following the vest of the initial 20%. Certain options may be subject to accelerated vesting upon change in control and/or termination.
- (7) The options become exercisable in 48 equal monthly installments, beginning on the last day of the first month after grant.
- (8) The options become exercisable upon satisfaction of specified performance targets.

3. Second Amended and Restated 2018 Employee Share Purchase Plan

The 2018 ESPP was approved by our Board on November 7, 2018 and by our shareholders on December 7, 2018 to amend and restate the 2018 Employee Share Purchase Plan originally adopted by the Company on June 6, 2018. On June 5, 2019, the Board approved Amendment No. 1 to the 2018 ESPP. The 2018 ESPP is not a share option scheme subject to the provisions of Chapter 17 of the HK Listing Rules.

As at December 31, 2020, 1,299,259 Shares had been granted, exercised, cancelled or lapsed pursuant to the 2018 ESPP.

Summary

The 2018 ESPP allows eligible employees to purchase our Shares (including in the form of ADSs) at a 15% discount to the market price of our Shares or ADSs. Employees would purchase our Shares or ADSs at the end of an offering period using funds deducted from their payroll during the offering period.

The 2018 ESPP is administered under the direction of our Compensation Committee, which has the authority to interpret the provisions of the 2018 ESPP and to make all other determinations necessary or advisable in administering it.

All employees of our Company and participating subsidiaries who are employed as of the first day of the applicable offering and have been employed as of the commencement of the enrollment period for such offering are eligible to participate in the 2018 ESPP, other than employees who would own 5% or more of the voting power of our Shares after exercising their rights to purchase Shares under the 2018 ESPP.

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To participate in the 2018 ESPP, an eligible employee authorizes payroll deductions in an amount not less than 1% nor greater than 10% of his or her “eligible earnings” (i.e., gross cash compensation, including regular base pay (including overtime pay and commissions, to the extent determined by our Compensation Committee) to a maximum of US\$25,000 per year, but excluding incentive or bonus awards, allowances and reimbursements for expenses such as relocation allowances or travel expenses, income or gain on the exercise of share options, and similar items) for each full payroll period in the offering period.

Eligible employees enroll in an offering period (which generally will begin on each March 1 and September 1 and last for six months unless otherwise determined by our Compensation Committee in advance) during the open enrollment period prior to the start of that offering period. Shares are purchased at a price equal to 85% of the fair market value of our ordinary shares on either the first local business day of the offering period or the last local business day of the offering period, whichever is lower.

If a participating employee voluntarily resigns or is terminated by us prior to the last day of an offering period, the employee’s option to purchase terminates and the cash amount in the employee’s account is returned to the employee.

In the event of a recapitalization, reclassification, share split, reverse split, combination of shares, exchange of shares, share dividend, or similar event, the number and kind of shares that may be purchased under the 2018 ESPP will be adjusted proportionately such that the proportionate interest of participating employees remains the same, to the extent practicable. In the event of a change in control, each outstanding option will be assumed or an equivalent option will be substituted. In the event outstanding options are not assumed or substituted, the offering period with respect to which such outstanding option relates will be shortened by setting a new exercise date prior to the date of the change in control.

4. Amended and Restated 2018 Inducement Equity Plan

On June 6, 2018, the Company adopted the 2018 Inducement Plan and reserved 12,000,000 Shares to be used exclusively for grants of awards to individuals that were not previously employees of the Company or its subsidiaries, as an inducement to the individual’s entry into employment with the Company or its subsidiaries. The 2018 Inducement Plan was approved by the Board upon recommendation of our Compensation Committee. On August 7, 2018, the Company amended the 2018 Inducement Plan to comply with Chapter 17 of the HK Listing Rules.

As at December 31, 2020, the Company has conditionally granted options to 2 participants under the 2018 Inducement Plan. All the options under the 2018 Inducement Plan were granted on August 31, 2018. The exercise price of all the options granted under the 2018 Inducement Plan was US\$13.66. As at December 31, 2020, the total number of Shares available for option grants under the 2018 Inducement Plan was 9,103,756, representing 0.8% of the issued share capital of the Company.

Further details of the 2018 Inducement Plan are set out in Note 20 to the consolidated financial statements.

REPORT OF THE DIRECTORS

As at January 1, 2020, 79,404 Shares were outstanding pursuant to options granted under the 2018 Inducement Plan, and as at December 31, 2020, 37,453 Shares were outstanding pursuant to options granted under the 2018 Inducement Plan. Details of the movements of the options granted during the Reporting Period were as follows:

Name of grantee	Role	Date of grant	Option period	Price on day prior to grant ⁽¹⁾	Price on day prior to exercise date ⁽²⁾	Exercise price	Outstanding as of January 1, 2020	Number of options			Outstanding as of December 31, 2020
								Granted during the Reporting Period	Exercised during the Reporting Period	Cancelled/ Lapsed during the Reporting Period	
Grantees											
In aggregate		August 31, 2018 ⁽³⁾	10 years from the date of grant	US\$13.67	US\$18.13	US\$13.66	79,404	-	41,951	-	37,453
Total							<u>79,404</u>	<u>-</u>	<u>41,951</u>	<u>-</u>	<u>37,453</u>

- (1) The stated price was the closing price as quoted on the NASDAQ, divided by 13, on the trading day immediately prior to the grant date.
- (2) The stated price was the weighted-average closing price as quoted on the NASDAQ, divided by 13, on the trading day immediately prior to the date which the options were exercised.
- (3) 25% of the options become exercisable on the first anniversary of the last trading day of the month following the date on which such grantee starts his or her service relationship with the Company or its subsidiaries. The remaining 75% become exercisable in 36 equal monthly installments, each of which shall become exercisable on the last day of each month following the vest of the initial 25%.

Purpose

The 2018 Inducement Plan provides the Company with the flexibility to grant equity awards to induce highly-qualified prospective officers and employees who are not currently employed by the Company or its subsidiaries to accept employment and to provide them with a proprietary interest in the Company. It is anticipated that providing such persons with a direct stake in the Company will assure a closer identification of their interests with those of the Company and its shareholders, thereby stimulating their efforts on the Company's behalf and strengthening their desire to remain with the Company.

Eligible Participants

Full-time and part-time employees of the Company and its subsidiaries for whom the Company may issue securities without shareholder approval in accordance with Rule 5635 (c) (4) of the Marketplace Rules of the NASDAQ Stock Market, Inc., as selected from time to time by our Compensation Committee, are eligible to participate in the 2018 Inducement Plan.

REPORT OF THE DIRECTORS

Maximum Number of Shares

The maximum number of Shares reserved and available for issuance under the 2018 Inducement Plan is 12,000,000.

Expiration of the 2018 Inducement Plan

The 2018 Inducement Plan remains in effect until discontinued by the Board.

Limit of Each Grantee

Unless approved by our shareholders in a general meeting, the total number of Shares issued and to be issued upon the exercise of share options granted and to be granted under the 2018 Inducement Plan and any other equity plans of the Company to a grantee within any 12-month period shall not exceed 1% of the Shares in issue at the date of any grant.

Option Period

Our Compensation Committee may determine at the time of grant any minimum period(s) for which a share option must be held and/or any minimum performance target(s) that must be achieved, before the share option can be exercised in whole or in part, and may include at the discretion of our Compensation Committee such other terms either on a case by case basis or generally.

The term of each share option will be fixed by our Compensation Committee and may not exceed 10 years from the date of grant. Any share option granted but not exercised by the end of its option term will automatically lapse and be cancelled. Our Compensation Committee will determine at what time or times each option may be exercised.

Exercise Price

The exercise price of each share option will be determined by our Compensation Committee but may not be less than the higher of: (i) 1/13th of the closing price of one ADS on the NASDAQ on the date of grant; and (ii) 1/13th of the average closing price of one ADS on the NASDAQ for the five business days immediately preceding the date of grant.

Consideration

No consideration is required to be paid by the grantees for the grant of options under the 2018 Inducement Plan.

REPORT OF THE DIRECTORS

PRE-EMPTIVE RIGHTS

There are no provisions for pre-emptive rights under our Articles or the laws of the Cayman Islands that would oblige the Company to offer new Shares on a pro-rata basis to existing shareholders.

TAX RELIEF AND EXEMPTION

The Directors are not aware of any tax relief and exemption available to shareholders by reason of their holding of the Company's securities.

CORPORATE GOVERNANCE

The Company is committed to maintaining a high standard of corporate governance through its continuous effort in improving its corporate governance practices. Details about the corporate governance practices adopted by the Company are set out in the "Corporate Governance Report" contained in this annual report.

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

On July 15, 2020, the Company allotted and issued 145,838,979 Shares to eight existing investors for an aggregate cash consideration of approximately US\$2.08 billion at a purchase price of US\$14.2308 per Share (equivalent to US\$185 per ADS), in accordance with a share purchase agreement dated July 12, 2020 pursuant to a general mandate, for the purpose of replenishing its working capital and other general corporate purposes. For details, please refer to the Company's announcements dated July 13, 2020 and July 16, 2020.

On January 2, 2020, the Company sold 15,895,001 ADSs representing 206,635,013 Shares of the Company, which represented approximately 20.5% ownership stake in the Company's outstanding Shares as at the same date, to Amgen for aggregate cash proceeds of US\$2,779,241,000, at the price of US\$13.45 per Share (equivalent to US\$174.85 per ADS), pursuant to the SPA dated October 31, 2019, as amended, executed in connection with the Collaboration Agreement with Amgen.

During the Reporting Period, except as disclosed above, neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's securities listed on the HKEx.

REPORT OF THE DIRECTORS

AUDIT COMMITTEE REVIEW OF FINANCIAL STATEMENTS

Our Audit Committee reviews the adequacy of our internal controls to ensure that our internal control system is effective in identifying, managing and mitigating risks involved in our business operations. The Audit Committee currently consists of three members, namely Mr. Thomas Malley, Mr. Anthony C. Hooper and Dr. Corazon (Corsee) D. Sanders. Mr. Thomas Malley and Dr. Corazon (Corsee) D. Sanders are independent non-executive Directors and Mr. Anthony C. Hooper is a non-executive Director. Mr. Thomas Malley is the chairman of the Audit Committee. Effective May 1, 2020, Mr. Anthony C. Hooper was appointed to serve as a member of Audit Committee in place of Mr. Jing-Shyh (Sam) Su. Effective August 24, 2020, Dr. Corazon (Corsee) D. Sanders was appointed to serve as a member of the Audit Committee in place of Mr. Timothy Chen.

The Audit Committee has reviewed the consolidated financial statements and annual results of the Group for the year ended December 31, 2020. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with members of senior management and the external auditor of the Company, Ernst & Young.

CONTINUING DISCLOSURE OBLIGATIONS PURSUANT TO THE HK LISTING RULES

The Company does not have any other disclosure obligations under Rules 13.20, 13.21 and 13.22 of the HK Listing Rules.

PUBLIC FLOAT

As at April 21, 2021 and based on the information that is publicly available to the Company and to the knowledge of the Directors of the Company, the Company has maintained the minimum public float required by the HKEx.

AUDITORS

The Company's shares have been listed on the Main Board of the HKEx since August 8, 2018, and there has been no change in auditors since the Listing.

The consolidated financial statements of the Group for Hong Kong financial reporting and United States financial reporting have been audited by Ernst & Young and Ernst & Young Hua Ming LLP respectively, both will retire and, being eligible, offer themselves for respective re-appointment at the 2021 annual general meeting of shareholders of the Company.

On behalf of the Board

John V. Oyler

Chairman

Hong Kong

April 21, 2021

CORPORATE GOVERNANCE REPORT

The Board is pleased to present the corporate governance report for the Company for the year ended December 31, 2020.

CORPORATE GOVERNANCE PRACTICES

The Company is committed to maintaining and promoting stringent corporate governance. The principle of the Company's corporate governance is to promote effective internal control measures, uphold a high standard of ethics, transparency, responsibility and integrity in all aspects of business, to ensure that its affairs are conducted in accordance with applicable laws and regulations, and to enhance the transparency and accountability of the Board to the Company's shareholders.

The Board believes that good corporate governance standards are essential in providing a framework for the Company to safeguard the interests of shareholders, enhance corporate value and formulate its business strategies and policies.

In 2020, the Company has applied the principles in the Corporate Governance Code and Corporate Governance Report (the "Corporate Governance Code") as set out in Appendix 14 to the HK Listing Rules which are applicable to the Company.

Pursuant to code provision A.2.1 of the Corporate Governance Code, companies listed on the HKEx are expected to comply with, but may choose to deviate from the requirement that the responsibilities of the Chairman and the Chief Executive Officer should be segregated and should not be performed by the same individual. We do not have a separate Chairman and Chief Executive Officer and Mr. John V. Oyler currently performs these two roles. Our Board believes that Mr. John V. Oyler is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as a Co-Founder and our Chief Executive Officer. Our Board also believes that the combined role of Chairman and Chief Executive Officer can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board. Our Board will continue to review and consider splitting the roles of Chairman and the Chief Executive Officer at a time when it is appropriate by taking into account the circumstances of our Group as a whole. Our Corporate Governance Guidelines provide the Board with the flexibility to choose the appropriate Board leadership structure of the Company based upon its view of what is in the best interest of the Company. Our Corporate Governance Guidelines also provide that if the same person holds the Chairman and Chief Executive Officer roles or if the Chairman does not otherwise qualify as independent, the independent Directors may elect a Lead Director. Mr. Ranjeev Krishana, an independent non-executive Director, currently serves as the Lead Director. The Board believes our current Board leadership structure will help ensure continuity of strong and effective leadership. The Lead Director has responsibilities that are set forth in our Corporate Governance Guidelines, including presiding at meetings of the Board at which the Chairman is not present, including executive sessions of the independent Directors; consulting with management regarding Board meeting schedules, locations, agendas and materials; and calling meetings of the independent and non-management Directors of the Board, when appropriate.

CORPORATE GOVERNANCE REPORT

Our Audit Committee is in compliance with Rule 3.21 of the HK Listing Rules and the Corporate Governance Code set out in Appendix 14 to the HK Listing Rules, except for the terms of reference required by paragraphs C.3.3 and C.3.7 of the Corporate Governance Code. However, the Charter of our Audit Committee complies with the NASDAQ Listing Rules and the rules of the SEC. The primary duties of the Audit Committee are, among other things, to monitor the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters, review the adequacy of our internal control over financial reporting, and review all related party transactions for potential conflict of interest situations and approving all such transactions. The Audit Committee comprises two independent non-executive Directors, namely Mr. Thomas Malley and Dr. Corazon (Corsee) D. Sanders and one non-executive Director, namely Mr. Anthony C. Hooper. Mr. Thomas Malley, being the chairman of the Audit Committee, is appropriately qualified as required under Rules 3.10(2) and 3.21 of the HK Listing Rules.

Our Compensation Committee is in compliance with Rule 3.25 of the HK Listing Rules and the Corporate Governance Code set out in Appendix 14 to the HK Listing Rules, except for the terms of reference required by paragraph B.1.2 of the Corporate Governance Code. However, the Charter of our Compensation Committee complies with the NASDAQ Listing Rules. The primary duties of the Compensation Committee are to review and make recommendations to the Board with respect to director compensation, evaluate the performance of our Chief Executive Officer, President, Chief Operating Officer and General Manager of China, and Chief Financial Officer and review and make recommendations to the Board regarding the terms of their compensation, and review and approve the compensation of our other executive officers and senior management. The Compensation Committee comprises three independent non-executive Directors, namely Mr. Qingqing Yi, Mr. Ranjeev Krishana and Mr. Timothy Chen. Mr. Qingqing Yi is the chairman of the Compensation Committee.

Our Nominating and Corporate Governance Committee complies with the Corporate Governance Code set out in Appendix 14 to the HK Listing Rules, except for the terms of reference required by paragraph A.5.2 of the Corporate Governance Code. However, the Charter of our Nominating and Corporate Governance Committee complies with the NASDAQ Listing Rules. The primary duties of the Nominating and Corporate Governance committee are among other things, to develop and recommend to the Board criteria for board and committee membership, recommend to the Board the persons to be nominated for election as Directors and to each of the Board's committees, and develop and recommend to the Board a set of corporate governance guidelines. The Nominating and Corporate Governance committee comprises three independent non-executive Directors, namely, Mr. Donald W. Glazer, Mr. Michael Goller and Mr. Jing-Shyh (Sam) Su and one non-executive Director, namely Mr. Anthony C. Hooper. Mr. Donald W. Glazer is the chairman of the Nominating and Corporate Governance Committee.

CORPORATE GOVERNANCE REPORT

Except as disclosed above, the Company has complied with all of the provisions set out in the Corporate Governance Code during the year ended December 31, 2020.

The Board will continue to regularly review and monitor its corporate governance practices to ensure compliance with the Corporate Governance Code and maintain a high standard of corporate governance practices of the Company.

MODEL CODE FOR SECURITIES TRANSACTIONS

Except as disclosed below, the Company has adopted its own insider dealing policies on terms no less exacting than those in the Model Code for Securities Transactions as set out in Appendix 10 to the HK Listing Rules regarding the Directors' dealings in the securities of the Company.

Pursuant to Rule B.8 of the Model Code for Securities Transactions, a director must not deal in any securities of the issuer without first notifying in writing the chairman or a director (otherwise than himself) designated by the board for the specific purpose and receiving a dated written acknowledgement. Under the Company's insider dealing policies, Mr. Scott A. Samuels, Senior Vice President, General Counsel of the Company, has been designated as the insider trading compliance officer whom a Director who intends to deal in the Company's securities must notify. Our Board believes that our insider trading compliance officer, despite not being a member of the Board, is able to carry out his duties properly and competently in accordance with the Company's insider dealing policies, the terms of which are otherwise no less exacting than those in the Model Code for Securities Transactions.

Having made specific enquiry of all the Directors, all the Directors confirmed that they have strictly complied with the required standards set out in the Company's own insider dealing policies throughout the period from January 1, 2020 up to the date of this annual report.

CORPORATE GOVERNANCE REPORT

BOARD OF DIRECTORS

The Board currently comprises 11 members, consisting of one executive Director, two non-executive Directors and eight independent non-executive Directors.

During the period from January 1, 2020 and up to the date of this annual report, the composition of the Board comprised the following Directors:

Executive Director

Mr. John V. Oyler (*Chairman and Chief Executive Officer*)

Non-executive Directors

Dr. Xiaodong Wang
Mr. Anthony C. Hooper

Independent non-executive Directors

Mr. Timothy Chen
Mr. Donald W. Glazer
Mr. Michael Goller
Mr. Ranjeev Krishana
Mr. Thomas Malley
Dr. Corazon (Corsee) D. Sanders
Mr. Jing-Shyh (Sam) Su
Mr. Qingqing Yi

The biographical details of the Directors are set out in the section headed “Directors and Senior Management” of this annual report. None of the members of the Board is related to one another.

INDEPENDENT NON-EXECUTIVE DIRECTORS

In 2020, the Board at all times met the requirements of the HK Listing Rule relating to the appointment of at least three independent non-executive Directors representing one-third of the Board, with one possessing appropriate professional qualifications or accounting or related financial management expertise.

The Board has received from each of the independent non-executive Directors a written annual confirmation of his or her independence pursuant to Rule 3.13 of the HK Listing Rules and considers each of them to be independent.

CORPORATE GOVERNANCE REPORT

APPOINTMENT AND RE-ELECTION OF DIRECTORS

Code provision A.4.1 of the Corporate Governance Code stipulates that non-executive directors should be appointed for a specific term, subject to re-election, and code provision A.4.2 states that all directors appointed to fill a casual vacancy should be subject to election by shareholders at the first general meeting after appointment and that every director, including those appointed for a specific term, shall be subject to retirement by rotation at least once every three years.

Our Articles provide that our Board is divided into three groups designated as Class I, Class II and Class III with as nearly equal a number of Directors in each group as possible. Each Director in each class shall serve for a three-year term and until such Director's successor has been duly elected. Upon the expiration of his or her term, each Director shall be eligible for re-election at the next annual general meeting to hold office for another three-year term and until such Director's successor has been duly elected. The terms of the Class I Directors are scheduled to expire on the date of our 2023 annual general meeting, the terms of the Class II Directors are scheduled to expire on the date of our 2021 annual general meeting, and the terms of the Class III Directors are scheduled to expire on the date of our 2022 annual general meeting, in each case subject to such Director's earlier resignation or removal.

We undertook to the HKEx to require Directors appointed to fill a casual vacancy to retire and seek re-election at the next annual general meeting following their appointment. For details, please refer to our Prospectus.

RESPONSIBILITIES, ACCOUNTABILITIES AND CONTRIBUTIONS OF THE BOARD AND MANAGEMENT

The Board is responsible for leadership and control of the Company, and is collectively responsible for directing and supervising the Company's affairs.

The Board directly, and indirectly through its committees, leads and provides direction to management by laying down strategies and overseeing their implementation, monitors the Group's operational and financial performance, and ensures that sound internal control and risk management systems are in place.

All Directors, including non-executive Directors and independent non-executive Directors, have brought a wide spectrum of valuable business experience, knowledge and professionalism to the Board for its efficient and effective functioning.

The independent non-executive Directors are responsible for ensuring a high standard of regulatory reporting of the Company and providing a balance in the Board for bringing effective independent judgement on corporate actions and operations.

All Directors have full and timely access to all the information of the Company and may, upon request, seek independent professional advice in appropriate circumstances, at the Company's expenses for discharging their duties to the Company.

CORPORATE GOVERNANCE REPORT

The Directors shall disclose to the Company details of other offices held by them.

The Board reserves for its decision all major matters relating to policy matters, strategies and budgets, internal control and risk management, material transactions (in particular those that may involve conflict of interests), financial information, appointment of directors and other significant operational matters of the Company. Responsibilities relating to implementing decisions of the Board, directing and coordinating the daily operation and management of the Company are delegated to the management.

The Company has arranged appropriate insurance coverage on Directors' and officers' liabilities in respect of any legal actions taken against Directors and senior management arising out of corporate activities. The insurance coverage is reviewed on an annual basis.

BOARD COMMITTEES

The Board has established five committees, namely the Audit Committee, the Compensation Committee, the Nominating and Corporate Governance Committee, the Scientific Advisory Committee and the Commercial and Medical Affairs Advisory Committee, for overseeing particular aspects of the Company's affairs. Each of these committees is established with a charter which is available on the websites of the Company and the HKEx.

Audit Committee

The Audit Committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firms;
- approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firms;
- reviewing the internal audit plan with the independent registered public accounting firms and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firms our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of financial and accounting-related complaints and concerns;

CORPORATE GOVERNANCE REPORT

- recommending, based upon the Audit Committee’s review and discussions with management and the independent registered public accounting firms, whether our audited financial statements shall be included in our Annual Report on Form 10-K and our annual results announcement filed with the HKEx;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the Audit Committee report;
- reviewing all related party transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing our earnings releases and unaudited financial statements to be included in our quarterly and interim filings with the SEC and HKEx.

Currently, the Audit Committee consists of three members, namely Mr. Thomas Malley, Mr. Anthony C. Hooper and Dr. Corazon (Corsee) D. Sanders. Mr. Thomas Malley and Dr. Corazon (Corsee) D. Sanders are independent non-executive Directors and Mr. Anthony C. Hooper is a non-executive Director. Mr. Thomas Malley, being the chairman of the Audit Committee, is appropriately qualified as required under Rules 3.10(2) and 3.21 of the HK Listing Rules. Effective May 1, 2020, Mr. Anthony C. Hooper was appointed to serve as a member of Audit Committee in place of Mr. Jing-Shyh (Sam) Su. Effective August 24, 2020, Dr. Corazon (Corsee) D. Sanders was appointed to serve as a member of the Audit Committee in place of Mr. Timothy Chen. Dr. Corazon (Corsee) D. Sanders is an independent non-executive Director appropriately qualified as required under Rules 3.10(2) and 3.21 of the HK Listing Rules.

The Audit Committee held 14 meetings during the year ended December 31, 2020. Individual attendance of each committee member is set out on page 244 of this annual report. During the meetings, among other things, the Audit Committee reviewed the financial results of the Group and the internal control and risk management systems of the Group. The Audit Committee operates under a written charter that satisfies the applicable standards of the SEC, the NASDAQ and the HKEx. A copy of the Audit Committee charter is available on our website at www.beigene.com under “Investors — HKEX investors — Corporate Governance” and the website of the HKEx. During 2020, the Audit Committee’s major work included reviewing the 2019 annual report as well as the related results announcement, the 2020 interim report and interim results announcement, and the 2020 quarterly financial reports, reviewing the external auditors’ plans, reports, fees, involvement in non-audit services and their terms of engagement, and reviewing the effectiveness of the Company’s financial reporting system, internal control systems and associated procedures.

CORPORATE GOVERNANCE REPORT

Compensation Committee

The Compensation Committee's responsibilities include:

- annually reviewing and approving corporate goals and objectives relevant to the compensation of our Chief Executive Officer, President, Chief Operating Officer and General Manager of China, and Chief Financial Officer;
- evaluating the performance of our Chief Executive Officer, President, Chief Operating Officer and General Manager of China, and Chief Financial Officer in light of such corporate goals and objectives and recommending to the Board for approval their compensation based on that evaluation;
- reviewing and approving the compensation of our other executive officers and key officers;
- developing and implementing our overall management compensation and policy to align the interests of management with our shareholders';
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential current compensation advisors in accordance with the independence standards;
- retaining and approving the compensation of any compensation advisors;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and making recommendations to the Board with respect to director compensation;
- preparing the compensation committee report;
- reviewing and discussing with management the compensation discussion and analysis; and
- reviewing and discussing with the Board corporate succession plans for the Chief Executive Officer and other key officers.

The Compensation Committee comprises Mr. Qingqing Yi, Mr. Ranjeev Krishana and Mr. Timothy Chen. Mr. Qingqing Yi is the chairman of the Compensation Committee.

Details of the remuneration payable to each Director of the Company for the year ended December 31, 2020 are set out in Note 26 to the consolidated financial statements. The remuneration payable to each of our senior management ranges from HK\$25,000,000 to HK\$65,000,000.

CORPORATE GOVERNANCE REPORT

The Compensation Committee held seven meetings during the year ended December 31, 2020. Individual attendance of each committee member is set out on page 244 of this annual report. During the meetings, the Compensation Committee reviewed the compensation structure and made recommendations to the Board on determining the annual compensation packages of the Directors and the senior management. The Compensation Committee operates under a written charter adopted by the Board, which is available on our website at www.beigene.com under “Investors — HKEX investors — Corporate Governance” and the website of the HKEx. During 2020, the Compensation Committee’s major work included reviewing and recommending to the Board in respect of the compensation policy and structure by benchmarking peer companies with a similar scale to ensure that the Company’s compensation packages are competitive to recruit the best talents in the industry and to retain key staff; reviewing and recommending to the Board on the compensation packages for the directors; assessing performance; and reviewing and approving adjustments to the compensation packages for the senior managements.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee’s responsibilities include:

- developing and recommending to the Board criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by shareholders;
- identifying individuals qualified to become members of the Board;
- recommending to the Board the persons to be nominated for election as directors and to each of the board’s committees;
- developing and recommending to the Board a set of corporate governance guidelines; and
- overseeing the evaluation of the Board and management.

Currently, the Nominating and Corporate Governance Committee comprises Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Anthony C. Hooper and Mr. Jing-Shyh (Sam) Su. Mr. Donald W. Glazer is the chairman of the Nominating and Corporate Governance Committee. Effective February 24, 2021, Mr. Anthony C. Hooper and Mr. Jing-Shyh (Sam) Su have been appointed as members of the Nominating and Corporate Governance Committee.

The Nominating and Corporate Governance Committee held two meetings during the year ended December 31, 2020. Individual attendance of each committee member is set out on page 244 of this annual report. During the meetings, the Nominating and Corporate Governance Committee reviewed the criteria for Board and committee membership and corporate governance matters. The Nominating and Corporate Governance Committee operates pursuant to a written charter adopted by the Board, which is available on our website at www.beigene.com under “Investors — HKEX investors — Corporate Governance” and the website of the HKEx. During 2020, the Nominating and Corporate Governance Committee reviewed the structure, size and composition of the Board, considered and made recommendations to the Board on the director appointment, the re-election of the directors at the 2020 annual general meeting and the board committee membership. The Nominating and Corporate Governance Committee has also assessed the independence of the Directors, taking into account of the independence guidelines set out in Rule 3.13 of the HK Listing Rules and the NASDAQ Listing Rules.

CORPORATE GOVERNANCE REPORT

Scientific Advisory Committee

The Scientific Advisory Committee's responsibilities include:

- receiving and discussing reports from management regarding the Company's research and development plans and programs;
- assisting, to the extent it deems helpful, the Board and the Compensation Committee in setting and evaluating any research or development performance goals under the Company's incentive compensation programs; and
- assisting, to the extent it deems helpful, the Board and the Compensation Committee in assessing the capabilities of and evaluating the performance of the Company's key scientific and technical personnel and the depth and breadth of the Company's scientific resources.

The Scientific Advisory Committee was established on February 26, 2020. The Scientific Advisory Committee may meet at such times as it deems appropriate. The Scientific Advisory Committee held three meetings during the year ended December 31, 2020. Individual attendance of each committee member is set out on page 244 of this annual report. The Scientific Advisory Committee currently comprises Dr. Xiaodong Wang, Mr. Michael Goller, Mr. Thomas Malley, Dr. Corazon (Corsee) D. Sanders and Mr. Qingqing Yi. Dr. Xiaodong Wang and Dr. Corazon (Corsee) D. Sanders serve as the co-chairs of the Scientific Advisory Committee. The Scientific Advisory Committee operates under a written charter adopted by the Board, which is available on our website at www.beigene.com under "Investors — HKEX investors — Corporate Governance" and the website of the HKEX.

Commercial and Medical Affairs Advisory Committee

The Commercial and Medical Affairs Advisory Committee's responsibilities include:

- receiving and discussing reports from management regarding the Company's commercial strategy and plans and competitiveness of the Company's commercial programs;
- receiving and discussing reports from management regarding the Company's medical affairs strategy and plans and competitiveness of the Company's medical affairs programs
- assisting, to the extent it deems helpful, the Board and the Compensation Committee in setting and evaluating any commercial and medical affairs performance goals under the Company's incentive compensation programs; and
- assisting, to the extent it deems helpful, the Board and the Compensation Committee in assessing the capabilities of and evaluating the performance of the Company's key commercial and medical affairs personnel and the depth and breadth of the Company's commercial and medical affairs resources.

CORPORATE GOVERNANCE REPORT

The Commercial Advisory Committee was established on February 26, 2020 and has been renamed the Commercial and Medical Affairs Advisory Committee effective February 24, 2021. The Commercial and Medical Affairs Advisory Committee may meet at such times as it deems appropriate. The Commercial and Medical Affairs Advisory Committee held four meetings during the year ended December 31, 2020. Individual attendance of each committee member is set out on page 244 of this annual report. The Commercial and Medical Affairs Advisory Committee comprises Mr. Anthony C. Hooper, Mr. Timothy Chen, Mr. Ranjeev Krishana, Dr. Corazon (Corsee) D. Sanders and Mr. Jing-Shyh (Sam) Su. Mr. Anthony C. Hooper is the chairman of the Commercial and Medical Affairs Advisory Committee. The Commercial Medical Affairs Advisory Committee operates under a written charter adopted by the Board, which is available on our website at www.beigene.com under “Investors — HKEX investors — Corporate Governance” and the website of the HKEx.

BOARD DIVERSITY POLICY

The Company’s Board Diversity Policy sets out the Company’s approach to diversity on the Board. Pursuant to the Board Diversity Policy, our Nominating and Corporate Governance Committee will review annually the structure, size and composition of the Board and, where appropriate, make recommendations on changes to the Board. In reviewing the Board’s composition, our Nominating and Corporate Governance Committee will consider, among others, the nationality, ethnicity, gender, age, skills, expertise, and industry and regional experience. The Board Diversity Policy further provides that our Nominating and Corporate Governance Committee will discuss and, where necessary, agree on measurable objectives for achieving diversity on the Board and recommend them to the Board for adoption. The Board intends to rate its composition against the factors identified above and to recruit a Director or Directors to address any factors that could bear improvement. The Board has achieved its goal of recruiting at least one female Director in 2020. During the year ended 31 December 2020, the Nominating and Corporate Governance Committee has reviewed the measurable objectives of the Board Diversity Policy and considers that the Board has maintained an appropriate balance in all aspects of member diversity, and satisfy with the current situation. The Board Diversity Policy is available on our website at www.beigene.com under “Investors — HKEX investors — Corporate Governance.”

NOMINATION POLICY

As set forth in the Nominating and Corporate Governance Committee Charter, the Corporate Governance Guidelines and the Board Diversity Policy, the Board will consider and approve from time to time the criteria that it deems necessary or advisable for director candidates. The Board has full authority to modify such criteria as it deems necessary or advisable. The Board has delegated to the Nominating and Corporate Governance Committee the responsibility for developing and recommending to the Board for its consideration and approval criteria for director candidates. The Company has adopted policies and procedures for director candidates. The Board may, however, rescind its delegation and assume the responsibilities it previously delegated to the Nominating and Corporate Governance Committee.

The Board has delegated to the Nominating and Corporate Governance Committee the responsibility to identify candidates for nomination to the Board (including candidates to fill vacancies) and assess their qualifications in light of the policies and principles in our Corporate Governance Guidelines, the Diversity Policy and the Nominating and Corporate Governance Committee Charter. The Nominating and Corporate Governance Committee will recommend director candidates for the Board’s consideration and review the candidates’ qualifications with the Board. The Board retains the authority to nominate a candidate for election by the shareholders as a director and to fill vacancies. From time to time, the Nominating and Corporate Governance Committee utilizes third-party search

CORPORATE GOVERNANCE REPORT

firms to identify director candidates. In identifying director candidates, the Nominating and Corporate Governance Committee may consider all facts and circumstances it deems appropriate, including, among other things, the skills of the candidate, his or her depth and breadth of business experience and other background characteristics, his or her independence and the needs of the Board. The Nominating and Corporate Governance Committee has reviewed the nomination policy during the year ended 31 December 2020.

Our Nominating and Corporate Governance Committee and Board may consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity as set forth in the Board Diversity Policy. Our Nominating and Corporate Governance Committee's and Board's priority in selecting board members is identification of persons who will further the interests of our shareholders through their established record of professional accomplishment, depth and breadth of business experience and other background characteristics.

Any shareholder wishing to recommend a director candidate for consideration by the Nominating and Corporate Governance Committee should provide the following information within the timeframe set forth by our Articles and SEC rules to BeiGene, Ltd., c/o Mourant Governance Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, Grand Cayman KY1-1108, Cayman Islands, Attention: Secretary: (a) the name and address of record of the shareholder; (b) a representation that the shareholder is a record holder of our securities or, if the shareholder is not a record holder, evidence of ownership in accordance with Rule 14a-8(b) (2) of the Securities Exchange Act of 1934, as amended; (c) the candidate's name, age, business and residential address, educational background, current principal occupation or employment, and principal occupation or employment for the past five years; (d) a description of the qualifications and background of the candidate that addresses the criteria for board membership approved by our Board of Directors; (e) a description of all arrangements or understandings between the shareholder and the candidate; (f) the consent of the candidate (i) to be named in the proxy statement/circular for our next shareholder meeting and (ii) to serve as a director if elected at that meeting; and (g) any other information regarding the candidate that is required to be included in a proxy statement/circular filed pursuant to SEC rules and HK Listing Rules. The Nominating and Corporate Governance Committee may seek further information from or about the shareholder making the recommendation, the candidate, or any such other beneficial owner, including information about all business and other relationships between the candidate and the shareholder and between the candidate and any such other beneficial owner.

CORPORATE GOVERNANCE FUNCTION

The Board is responsible for performing the functions set out in code provision D.3.1 of the Corporate Governance Code.

The Board had reviewed the Company's corporate governance policies and practices, training and continuous professional development of Directors and senior management, the Company's policies and practices on compliance with legal and regulatory requirements, the compliance of the Company's securities dealing policies, and the Company's compliance with the Corporate Governance Code and disclosure in this Corporate Governance Report.

CORPORATE GOVERNANCE REPORT

BOARD MEETINGS, COMMITTEE MEETINGS AND SHAREHOLDER MEETINGS

The attendance records of each Director at Board meetings, committee meetings and shareholder meetings during the year ended December 31, 2020 are set out below.

Name of Director	Attendance/Number of Meeting(s)							Shareholder Meetings
	Board	Audit Committee	Compensation Committee	Nominating and Corporate Governance Committee	Scientific Advisory Committee	Commercial and Medical Affairs Advisory Committee		
Executive Director:								
Mr. John V. Oyler	14/14	N/A	N/A	N/A	N/A	N/A	N/A	2/2
Non-executive Directors:								
Mr. Anthony C. Hooper ⁽²⁾	14/14	11/11	N/A	N/A	N/A	N/A	4/4	2/2
Dr. Xiaodong Wang	14/14	N/A	N/A	N/A	N/A	3/3	N/A	1/2
Independent Non-executive Directors:								
Mr. Timothy Chen	14/14	7/8	7/7	N/A	N/A	N/A	4/4	1/2
Mr. Donald W. Glazer	14/14	N/A	N/A	2/2	N/A	N/A	N/A	2/2
Mr. Michael Goller	12/14	N/A	N/A	2/2	3/3	N/A	N/A	2/2
Mr. Ranjeev Krishana	12/14	N/A	7/7	N/A	N/A	N/A	4/4	2/2
Mr. Thomas Malley	14/14	14/14	N/A	N/A	3/3	N/A	N/A	2/2
Dr. Corazon (Corsee) D. Sanders ⁽¹⁾	7/7	6/6	N/A	N/A	3/3	N/A	N/A	1/1
Mr. Jing-Shyh (Sam) Su ⁽²⁾	13/14	3/3	N/A	N/A	N/A	N/A	4/4	2/2
Mr. Qingqing Yi	11/14	N/A	7/7	N/A	1/3	N/A	N/A	1/2

Notes:

- (1) Effective August 24, 2020, Dr. Corazon (Corsee) D. Sanders has been appointed to serve as a Director, and a member of the Audit Committee in place of Mr. Timothy Chen. Effective February 24, 2021, Dr. Sanders has been appointed as a member of the Commercial and Medical Affairs Advisory Committee and co-chair of the Scientific Advisory Committee of the Board.
- (2) Effective February 24, 2021, Mr. Anthony C. Hooper and Mr. Jing-Shyh (Sam) Su have been appointed as members of the Nominating and Corporate Governance Committee of the Board.

In accordance with code provision A.2.7 of the Corporate Governance Code, Mr. John V. Oyler, the Chairman of the Board and our only executive Director, also held meetings with the independent non-executive Directors without the presence of other Directors during the year ended December 31, 2020.

CORPORATE GOVERNANCE REPORT

DIRECTORS' RESPONSIBILITY IN RESPECT OF THE FINANCIAL STATEMENTS

The Directors acknowledge their responsibility for supervising management's preparation of the financial statements of the Company for the year ended December 31, 2020.

The Directors of the Company are responsible for the preparation of the consolidated financial statements for the year ended December 31, 2020 that give a true and fair view in accordance with U.S. generally accepted accounting principles and the disclosure requirements of the Hong Kong Companies Ordinance, and for such internal control as the directors determine is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

The Directors are not aware of any material uncertainties relating to events or conditions that may cast significant doubt upon the Company's ability to continue as a going concern.

The statement of the independent auditor of the Company about its reporting responsibilities on the financial statements is set out in the Independent Auditor's Report contained in this annual report.

CONTINUOUS PROFESSIONAL DEVELOPMENT OF DIRECTORS

The Directors intend to keep abreast of their responsibilities as directors of the Company and of the conduct, business activities and development of the Company.

The Company arranges a formal and comprehensive induction to a newly appointed Director to ensure that the Director has a proper understanding of the Company's operations and business and is fully aware of the director's responsibilities under the HK Listing Rules and SFO, and other legal and regulatory requirements.

The Company arranges trainings to provide Directors with updates on latest development and changes in the HK Listing Rules and other relevant legal and regulatory requirements from time to time. The Directors are also provided with regular updates on the Company's performance, position and prospects to enable the Board as a whole and each Director to discharge his or her duties. The Company also encourages the Directors to attend relevant training courses provided by legal advisors and/or any appropriate institutions.

For the year ended December 31, 2020, all Directors participated in continuing professional development regarding their duties and responsibilities as a director of a listed company which included reading materials and/or attending training. For example, all Directors participated an in-person training session conducted by Skadden, Arps, Slate, Meagher & Flom, our legal adviser as to Hong Kong law.

Effective January 2, 2020, Mr. Anthony C. Hooper was appointed to the Board. In January 2020, Mr. Hooper participated in a training session conducted by Skadden, Arps, Slate, Meagher & Flom, our legal adviser as to Hong Kong law, on directors' duties, responsibilities and obligations under the HK Listing Rules and the SFO. Effective August 24, 2020, Dr. Corazon (Corsee) D. Sanders was appointed to the Board. In August 2020, Dr. Sanders participated in a training session conducted by Skadden, Arps, Slate, Meagher & Flom, our legal adviser as to Hong Kong law, on directors' duties, responsibilities and obligations under the HK Listing Rules and the SFO.

CORPORATE GOVERNANCE REPORT

AUDITORS' REMUNERATION

The remuneration paid/payable to Ernst & Young and Ernst & Young Hua Ming LLP, in respect of audit services and non-audit services for the year ended December 31, 2020 and 2019, is set out below:

Services Category	Fees paid and payable	
	2020 (US\$' 000)	2019 (US\$' 000)
Audit services	3,811	2,190
Non-audit services	<u>97</u>	<u>51</u>
Total	<u><u>3,908</u></u>	<u><u>2,241</u></u>

The 2020 audit services conducted by Ernst & Young mainly included 2020 Hong Kong annual reporting audit services, and statutory audit services associated with our certain subsidiaries outside of China. The 2020 audit services conducted by Ernst & Young Hua Ming LLP mainly included the integrated audit of our 2020 U.S. GAAP consolidated financial statements and internal control over financial reporting, quarterly review of consolidated financial statements included in the Company's Quarterly Reports on Form 10-Q, services related to the Company's proposed offering in the PRC and assurance services associated with our statutory audit of certain subsidiaries.

Non-audit services mainly consist of compliance and tax advisory services.

The statement of the Auditor about their reporting responsibilities for the consolidated financial statements is set out in the "Independent Auditor's Report" contained in this annual report.

CORPORATE GOVERNANCE REPORT

CONNECTED TRANSACTIONS

Collaboration with Amgen

As disclosed in this annual report, on October 31, 2019, the Company's wholly-owned subsidiary, BeiGene Switzerland GmbH ("BeiGene Switzerland"), entered into a collaboration agreement with Amgen, which became effective on January 2, 2020 (the "Amgen Collaboration Agreement") and pursuant to which BeiGene and Amgen agreed to enter into a strategic collaboration on the commercialization of Amgen's oncology products XGEVA[®], BLINCYTO[®] and KYPROLIS[®] (the "In-Line Products") in China (excluding Hong Kong, Macao and Taiwan) and the global development and commercialization of a portfolio of Amgen clinical- and late-preclinical-stage oncology pipeline products. (the "Pipeline Products", together with the In-Line Products, the "Products"). Amgen is a substantial shareholder holding approximately 20.5% of the issued share capital of the Company and, therefore, a connected person of the Company under Chapter 14A of the HK Listing Rules. As a result, the transactions contemplated under the Amgen Collaboration Agreement constitute continuing connected transactions of the Company under Chapter 14A of the HK Listing Rules.

Pursuant to the terms of the Amgen Collaboration Agreement, we are responsible for commercializing Amgen's oncology products XGEVA[®], BLINCYTO[®] and KYPROLIS[®] in China (excluding Hong Kong, Macao and Taiwan) for a period of five or seven years following each product's regulatory approval in China, as specified in the agreement, with the commercialization period for XGEVA[®] commencing following the transition of operational responsibilities for the product. In addition, as specified in the agreement, we will have the option to retain one of the three products to commercialize for as long as the product is sold in China. The parties have agreed to equally share profits and losses for the products in China during each product's commercialization period. After expiration of the commercialization period for each product, the products not retained will be transitioned back to Amgen and we will be eligible to receive tiered mid-single to low-double digit royalties on net sales in China of each product for an additional five years.

Additionally, pursuant to the terms of the Amgen Collaboration Agreement, we and Amgen have agreed to collaborate on the global development and commercialization in China of a portfolio of Amgen clinical- and late-preclinical-stage oncology pipeline products. Starting from the commencement of the Amgen Collaboration Agreement, we and Amgen will co-fund global development costs, with BeiGene Switzerland contributing up to US\$1.25 billion worth of development services and cash over the term of the collaboration. BeiGene will be eligible to receive tiered mid-single digit royalties on net sales of each product globally outside of China, other than sotorasib (AMG 510), on a product-by-product and country-by-country basis, until the latest of the expiration of the last valid patent claim, the expiration of regulatory exclusivity, or the earlier of eight years after the first commercial sale of such product in the country of sale and 20 years from the date of first commercial sale of such product anywhere in the world.

CORPORATE GOVERNANCE REPORT

For each pipeline product that is approved in China, BeiGene will have the right to commercialize the product for seven years, with the parties sharing profits and losses for the product in China equally. In addition, depending on how many of the 20 pipeline products receive approval in China, BeiGene will have the right to retain approximately one of every three approved products, up to a total of six, other than sotorasib (AMG 510), to commercialize for as long as each such product is sold in China. After the expiration of the seven-year commercialization period, each product will be transitioned back to Amgen and BeiGene will be eligible to receive tiered mid-single to low-double digit royalties on net sales in China for an additional five years. The parties are subject to specified exclusivity requirements in China and the rest of the world.

Under Rule 14A.52 of the HK Listing Rules, the period of an agreement for a continuing connected transaction must be fixed. However, the term of the Amgen Collaboration Agreement is for an unspecified term as it will, unless terminated in accordance with its terms, remain in effect. Under Rule 14A.53(1) of the HK Listing Rules, an annual cap in monetary terms must be set for a continuing connected transaction. The Company applied for, and the HKEx granted, a waiver from strict compliance with Rules 14A.52 and 14A.53(1) of the HK Listing Rules, subject to the following conditions:

- (a) the Company will comply with the announcement, circular and independent shareholders' approval requirements under Chapter 14A of the HK Listing Rules if there are any material changes to the terms of the Amgen Collaboration Agreement;
- (b) the Company's independent non-executive directors from time to time will ensure that the transactions in relation to the Amgen Collaboration Agreement are undertaken in accordance with its terms;
- (c) the Senior Vice President, General Counsel of the Company will use his best endeavours to supervise the compliance with the terms of the Amgen Collaboration Agreements and applicable HK Listing Rules requirements to the extent not waived by the HKEx on a regular basis;
- (d) the independent non-executive directors and the auditors of the Company will review the transactions in relation to the Amgen Collaboration Agreement on an annual basis and confirm in the Company's annual reports the matters set out in Rules 14A.55 and 14A.56 of the HK Listing Rules, respectively; and
- (e) in the event of any future amendments to the HK Listing Rules imposing more stringent requirements than those as at the date of the announcement published by the Company on November 1, 2019 via the HKEx, the Company will take immediate steps to ensure compliance with such new requirements.

Under the Amgen Collaboration Agreement, the transaction amounts arising from the costs and revenues of the commercialization of the products and the royalties to be received by the Company shall be determined in accordance with the below formulae:

- (a) Caps in relation to the profits and losses of the commercialization of the Products

The Company and Amgen will share equally in the profits and losses of the commercialization of the Products in China in accordance with the following formula:

Net profit to be received/net loss to be borne by the Company = 50% x (net revenue of the relevant Product – manufacturing actual costs – commercialization and related costs)

CORPORATE GOVERNANCE REPORT

(b) Caps in relation to royalties

- Global Ex-China Royalties

During the applicable Global Pipeline Royalty Term (the period beginning on the first commercial sale of a Pipeline Product in a country (other than China) and expiring on the latest of (i) the expiration of the last valid patent claim, (ii) the expiration of regulatory exclusivity, or (iii) the earlier of (x) eight years after the first commercial sale of the product in the country of sale or (y) 20 years from the date of first commercial sale of the product anywhere in the world), the Company will be eligible to receive tiered mid-single digit royalties on global net sales outside of China on a sliding scale for each Pipeline Product (other than AMG 510) in accordance with the following formula:

Royalties to be received = incremental annual global net revenue of the relevant Pipeline Product outside China x the applicable royalty rate

- China Royalties

During the applicable five-year period beginning on the return of a Product to Amgen, the Company will be eligible to receive tiered mid-single to low-double digit royalties on net sales in China on a sliding scale for each Product returned to Amgen in accordance with the following formula:

Royalties to be received = annual net revenue of the relevant returned Product in China x the applicable royalty rate

Under the Amgen Collaboration Agreement, the Company will receive from Amgen quarterly financial information regarding the royalty calculation and the Company is entitled to specified audit right.

Under the Amgen Collaboration Agreement, the Company's payment obligations, whether in cash or in kind, towards the development of the Pipeline Products shall be subject to an aggregate maximum of US\$1.25 billion. The Company will also share in the costs of developing additional indications for the In-Line products in China, subject to an annual maximum contribution by the Company of US\$12.5 million and an aggregate maximum of US\$37.5 million over the term of the Amgen Collaboration Agreement.

CORPORATE GOVERNANCE REPORT

Confirmation from Our Independent Non-executive Directors

Our independent non-executive Directors have reviewed the continuing connected transactions (the “Continuing Connected Transactions”) contemplated under the Amgen Collaboration Agreement, and confirmed the Continuing Connected Transactions have been entered into: (a) in the ordinary and usual course of business of the Group; (b) on normal commercial terms or better; and (c) the terms of the Continuing Connected Transactions are fair and reasonable and in the interests of our shareholders as a whole.

Confirmation from Auditor

To comply with Rule 14A.56 of the HK Listing Rules, the Company has engaged Ernst & Young (the “Auditor”) to conduct certain procedures in respect of the Continuing Connected Transactions contemplated under the Amgen Collaboration Agreement for the year ended December 31, 2020, in accordance with the Hong Kong Standard on Assurance Engagement 3000 (Revised) Assurance Engagements Other Than Audits or Reviews of Historical Financial Information and with reference to Practice Note 740 Auditor’s Letter on Continuing Connected Transactions under the Hong Kong Listing Rules issued by the HKICPA. The Auditor has confirmed in a letter to the Board that, with respect to the Continuing Connected Transactions contemplated under the Amgen Collaboration Agreement for the year ended December 31, 2020: (a) nothing has come to their attention that causes them to believe that the disclosed continuing connected transactions have not been approved by the Company’s board of directors; (b) for transactions involving the provision of goods or services by the Group, nothing has come to their attention that causes them to believe that the transactions were not, in all material respects, in accordance with the pricing policies of the Group; and (c) nothing has come to their attention that causes them to believe that the transactions were not entered into, in all material respects, in accordance with the relevant agreements governing such transactions.

Direct Purchase Option

On March 17, 2020, the Company and Amgen entered into an Amendment No. 2 (the “Second Amendment”) to the Share Purchase Agreement in order to account for periodic dilution from the issuance of shares by us, which agreement was restated in its entirety on September 24, 2020 (the “Restated Second Amendment”). Pursuant to the Restated Second Amendment, Amgen has an option (the “Direct Purchase Option”) to subscribe for additional ADSs in an amount necessary to enable it to increase (and subsequently maintain) its ownership at approximately 20.6% of our outstanding shares. The Direct Purchase Option is exercisable on a monthly basis, but only if Amgen’s interest in our outstanding shares at the monthly reference date is less than 20.4%. The Direct Purchase Option (i) is exercisable by Amgen solely as a result of dilution arising from issuance of new shares by us under our equity incentive plans from time to time, and (ii) is subject to annual approval by our independent shareholders each year during the term of the Restated Second Amendment. The exercise period of the Direct Purchase Option commenced on December 1, 2020 and will terminate on the earliest of: (a) the date on which Amgen and its affiliates collectively own less than 20% of the outstanding share capital of the Company as a result of Amgen’s sale of shares; (b) at least 60-day advance written notice from either Amgen or the Company that such party wishes to terminate the Direct Purchase Option; or (c) December 1, 2023. The Direct Purchase Option has no vesting period. No share was issued under the Direct Purchase Option as of the date of this annual report.

CORPORATE GOVERNANCE REPORT

Issue of Shares under a General Mandate

On July 15, 2020, the Company allotted and issued 145,838,979 ordinary shares of the Company to eight existing investors for an aggregate cash consideration of approximately US\$2.08 billion at a purchase price of US\$14.2308 per ordinary share of the Company (equivalent to US\$185 per ADS), in accordance with a share purchase agreement dated July 12, 2020 pursuant to the general mandate granted to the Board at the 2020 annual general meeting.

Two of the investors, namely Baker Bros. Advisors LP and Amgen, together with their affiliated entities, were substantial shareholders of the Company, and therefore connected persons of the Company. The issue and allotment of the purchased Shares to these connected persons up to their pro-rata amount of purchased Shares was made pursuant to the Shareholders' approval of ordinary resolutions at the 2020 annual general meeting to authorize the Company in its sole discretion to, in the Company's securities offerings, allocate to Baker Bros. Advisors LP, Hillhouse Capital Management, Ltd. and Amgen and the parties affiliated with each of them, up to a maximum amount of shares in order to maintain the same shareholding percentage of each of them (based on then-outstanding share capital of the Company) before and after the allocation of the corresponding securities issued pursuant to an offering conducted pursuant to the general mandate granted to the Board at the 2020 annual general meeting. For further details, please refer to the announcement of the Company dated July 13, 2020.

Hillhouse Loan

On September 24, 2020, the Company entered into a loan agreement with Zhuhai Hillhouse Zhaohui Equity Investment Partnership for a total loan facility of US\$73,640,000 (RMB500,000,000) (the "Hillhouse Loan"), of which US\$14,728,000 (RMB100,000,000) could be used for general corporate purposes and US\$58,912,000 (RMB400,000,000) can only be applied towards the repayment of a senior loan facility of up to US\$200,000,000 provided by China Minsheng Bank. The provision of the Hillhouse Loan was conducted on normal commercial terms or better and was not secured by the assets of the Group, and was therefore fully exempt from shareholders' approval and all disclosure requirements under Chapter 14A of the HK Listing Rules. For further details, see Note 9 to our consolidated financial statements included in this annual report.

CORPORATE GOVERNANCE REPORT

Consulting Agreement with Dr. Xiaodong Wang

We have also entered into a consulting agreement with Dr. Xiaodong Wang, which is a fully-exempt continuing connected transaction, as disclosed in this annual report.

Except as disclosed hereunder, during the year ended December 31, 2020, the Group has not entered into any connected transaction or continuing connected transaction which should be disclosed pursuant to the requirements of Rule 14A.71 of the HK Listing Rules.

RELATED PARTY TRANSACTIONS

Details of the related party transactions of the Group for the year ended December 31, 2020 are set out in Note 28 to the consolidated financial statements contained herein.

Except as disclosed herein, none of the related party transactions constitutes a connected transaction or continuing connected transaction subject to independent shareholders' approval, annual review and all disclosure requirements in Chapter 14A of the HK Listing Rules.

RISK MANAGEMENT AND INTERNAL CONTROLS

The Board acknowledges its responsibility for overseeing management's review and implementation of risk management and internal control systems. Such systems are designed to manage rather than eliminate the risk of failure to achieve business objectives, and can only provide reasonable and not absolute assurance against material misstatement or loss.

We have devoted ourselves to establishing and maintaining risk management and internal control systems consisting of policies and procedures that we consider to be appropriate for our business operations, and we are dedicated to continuously improving these systems.

We have adopted and implemented comprehensive risk management policies in various aspects.

CORPORATE GOVERNANCE REPORT

Financial Reporting Risk Management

As a public company in the United States, we are subject to the Sarbanes-Oxley Act, together with the rules implemented by the SEC and applicable market regulators. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal control for financial reporting and disclosure controls and procedures. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles. Management is responsible for establishing and maintaining adequate internal control over our financial reporting process, and the Audit Committee oversees our financial reporting process on behalf of the Board. We perform system and process evaluations and testing of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, in order to allow management to report on the effectiveness of our internal control over financial reporting and describe any material weakness in internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The effectiveness of our internal control over financial reporting is also tested by the Auditor.

Information System Risk Management

In the ordinary course of our business, we collect and store sensitive data, including, among other things, legally protected patient health information, identity information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. These applications and data encompass a wide variety of business critical information including research and development information, commercial information, and business and financial information. We have implemented relevant internal procedures and controls to ensure that such sensitive data is protected and that leakage and loss of such data is avoided.

Human Resources Risk Management

We provide regular and specialized training tailored to the needs of our employees in different departments. We regularly organize internal training sessions conducted by senior employees or outside consultants on topics of interest. The human resources team, run by senior leaders and experienced human resource professionals, create, schedule and deliver the training. The long-term goal is to further increase the number of trainings available to all employees as well as measure the success of the trainings.

In China and the U.S., we have in place employee handbooks approved by our management and distributed to all our employees, which contain internal rules and guidelines regarding best commercial practice, work ethics, fraud prevention mechanism, negligence and corruption.

We also have in place an FCPA Policy to safeguard against corruption within our Company. The policy explains potential corruption conducts and our anti-corruption measures. We make our internal reporting channel open and available for our staff to report suspected acts of corruption, and our staff can also make anonymous reports to our compliance department. Our compliance department is responsible for investigating reported incidents and taking appropriate measures.

CORPORATE GOVERNANCE REPORT

Investment Risk Management and Treasury Policy

With our surplus cash on hand, we make short-term investments comprised primarily of U.S. treasury securities, U.S. agency securities and time deposits with original maturities between three and twelve months. The primary objective of short-term investments is to preserve principle, provide liquidity and maximize income without significant increasing risk. Our investment decisions are made on a case-by-case basis and after due and careful consideration of a number of factors, including but not limited to the market conditions, the anticipated investment conditions, the investment costs, the duration of the investment and expected benefit and potential loss of the investment.

Our finance department, under the supervision of our Chief Financial Officer, is responsible for managing our short-term investment activities. Before making a proposal to invest in wealth management products, our financial department must assess our cash flow and operational needs and capital expenditures. We operate under a Board-approved Investment Policy which governs the investment of our funds. The Investment Policy is reviewed annually by the Board and is circulated to the investment advisors to ensure compliance. Our investments to date have been primarily limited to U.S. Treasury securities, U.S. agency securities, and time deposits at reputable banks. Any material deviations from the Investment Policy would require consent by the Board or the Audit Committee. There have been no cases of material deviation from our Investment Policy to date.

In assessing a proposal to invest in wealth management products, a number of criteria must be met, including but not limited to:

- investments in high risk products are prohibited;
- the primary objectives of investment activities are safety, liquidity and reasonable yield;
- the proposed investment must not interfere with our business operation or capital expenditures; and
- the wealth management products should be issued by a reputable bank.

We believe that our internal policies regarding investment in wealth management products and the related risk management mechanism are adequate. We may make investments in wealth management products that meet the above criteria, after consultation and approval by our Board or the Audit Committee, as part of our treasury management where we believe it is prudent to do so.

CORPORATE GOVERNANCE REPORT

Audit Committee Experience and Qualification and Board Oversight

Our Audit Committee reviews the adequacy of our internal control over financial reporting to ensure that our internal control system is effective in identifying, managing and mitigating risks involved in our business operations. We also maintain an internal audit department which is responsible for reviewing the effectiveness of internal control and reporting to the Audit Committee on any issues identified.

Ongoing Measures to Monitor the Implementation of Risk Management Policies

Our Audit Committee, internal audit department and management together monitor the implementation of our risk management policies on an ongoing basis to ensure our policies and implementation are effective and sufficient.

Arrangements are in place to facilitate employees of the Company to raise, in confidence, concerns about possible improprieties in financial reporting, internal control or other matters of the Company.

We have adopted a Code of Conduct that governs, among other things, the handling of confidential information. All current Directors, officers and employees are being supplied a copy of the Code of Conduct. Future Directors, officers and employees will be supplied a copy of the Code of Conduct when beginning service at the Company. All Directors, officers and employees will be expected to review and acknowledge their review and agreement to comply with the Code of Conduct on a periodic basis. Our management, under the supervision of our Board or a committee of our Board takes reasonable steps to (i) monitor compliance with the Code of Conduct, and (ii) when appropriate, impose and enforce appropriate disciplinary measures for violations of the Code of Conduct.

Review on Risk Management and Internal Control Systems

For the year ended December 31, 2020, we have conducted an annual review of the effectiveness of our risk management and internal control systems, which we consider to be effective and adequate.

COMPANY SECRETARY

Ms. Chau Hing Ling, of Vistra Corporate Services (HK) Limited, is our company secretary with respect to Hong Kong matters, and is responsible for advising the Board on corporate governance and company secretarial matters and ensuring that our Group complies with and applicable Hong Kong rules and regulations. Ms. Chau's primary contact person within the Company is Mr. Scott A. Samuels, Senior Vice President, General Counsel of the Company. For the year ended December 31, 2020, Ms. Chau has undertaken not less than 15 hours of relevant professional training respectively in compliance with Rule 3.29 of the HK Listing Rules.

CORPORATE GOVERNANCE REPORT

SHAREHOLDERS' RIGHTS

Convening of Extraordinary General Meetings by Shareholders

Pursuant to articles 61 and 62 of our Articles, an extraordinary general meeting of our Company shall be convened on a members' requisition put forth by our shareholders holding at the date of deposit of the requisition in aggregate not less than one-tenth of the voting rights of such of the issued Shares as at that date of the deposit carries the right of voting at general meetings of our Company. The requisition must state the object of the meeting, set forth a form of any resolutions proposed by the requisitionists for consideration at the meeting and must be signed by the requisitionists and deposited at the registered office of the Company, and may consist of several documents in like form each signed by one or more requisitionists. If the Directors do not within 21 days from the date of the deposit of the requisition duly proceed to convene a general meeting to be held within a further 21 days, the requisitionists, or any of them representing more than one-half of the total voting rights of all of them, may themselves convene a general meeting, but any meeting so convened shall not be held after the expiration of three months after the expiration of 21 days from the date of the deposit of the requisition.

Putting Forward Enquiries to the Board and Contact Details

The Board provides to every shareholder the ability to communicate with the Board, as a whole, and with individual Directors through an established process for shareholder communication. For a shareholder communication directed to the Board as a whole, shareholders may send such communication to the attention of our Secretary via regular mail or expedited delivery service to: BeiGene, Ltd., c/o Mourant Governance Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, Grand Cayman KY1-1108, Cayman Islands, Attn.: Board of Directors c/o Secretary.

For a shareholder communication directed to an individual Director in his or her capacity as a member of the Board, shareholders may send such communication to the attention of the individual Director via regular mail or expedited delivery service to: BeiGene, Ltd., c/o Mourant Governance Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, Grand Cayman KY1-1108, Cayman Islands, Attn.: *[Name of Individual Director]*.

Communications will be distributed to the Board, or to any individual Director or Directors as appropriate, depending on the facts and circumstances outlined in the communications. Items that are unrelated to the duties and responsibilities of the Board may be excluded, such as junk mail and mass mailings, resumes and other forms of job inquiries, surveys and solicitations or advertisements.

COMMUNICATION WITH SHAREHOLDERS AND INVESTOR RELATIONS

The Company considers that effective communication with shareholders is essential for enhancing investor relations and investor understanding of the Group's business performance and strategies. The Company endeavors to maintain an on-going dialogue with shareholders and in particular, through annual general meetings and other general meetings. At the forthcoming 2021 annual general meeting, Directors (or their delegates as appropriate) will be available in person or via teleconference to meet shareholders and answer their enquiries.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

I. ABOUT THE REPORT

This Environmental, Social and Governance (“ESG”) report provides information on the ESG performance of our Company for the period from January 1, 2020 to December 31, 2020. This report is prepared in accordance with the ESG Reporting Guide set out in Appendix 27 to the HK Listing Rules. This report is to be read in conjunction with the Company’s 2020 Annual Report, in particular the Corporate Governance Report.

Our major operations are in the PRC, and we have offices located in Asia-Pacific, North America and Europe. Unless otherwise specified, the scope of this report covers our global operations.

II. ESG STRATEGY AND GOVERNANCE

i. ESG Strategy

We are a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our vision, mission, values, and behavior guidelines demonstrate our core ESG strategy.

- **Our Vision**

Transform the biopharmaceutical industry, creating impactful medicines that will be affordable and accessible to far more cancer patients around the world.

- **Our Mission**

Build the first next-generation biopharmaceutical company – one that expands the highest quality therapies to billions more people – through courage, persistent innovation, and challenging the status quo.

- **Our Passion**

At BeiGene, we are passionate about our people, science, and creating a lasting impact. These priorities are of utmost importance to our organization. We strive to build a global organization recognized for its impact in cancer research and drug development, talented people, and integrity.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

- **Our Values**
 - **All Patients First.** Striving to improve the health and well-being of all patients, regardless of location or income.
 - **Transformational Mindset – Challenging the Status Quo.** Embracing innovative ways of doing things at all levels, and stretching our minds to accomplish things that others thought were impossible.
 - **Sense of Urgency, With Commitment to Quality and Compliance.** Maintaining our sense of urgency and agility with a relentless dedication to quality and compliance, with a commitment to continuous improvement.
 - **Regional and Functional Teamwork.** Creating superior teamwork through open, authentic communication and respect for individual differences to enable excellence cross-functionally and around the world.
 - **Global Capabilities, Local Expertise.** Operating at the highest global standards, while understanding and respecting the value and importance of local expertise.
 - **Effective Non-Hierarchical Decision-Making.** Involving inclusively the appropriate people; communicating openly and transparently, listening actively, considering all options; articulating a scientific/logic-based decision, and aligning to support decisions made.
 - **Individual Growth.** Creating an environment, built on diversity and inclusion, in which all employees have an opportunity to grow professionally, affect the world meaningfully, and build lifelong friendships with exceptional people.

- **Our Behavior Guidelines**

How we get things done is just as important as what we accomplish – we operate with an unwavering commitment to compliance, ethics, and integrity, and always treat fellow colleagues with respect and dignity.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

ii. ESG Governance and Management

We pursue our business objectives with integrity, trust, and respect, and in compliance with applicable laws and regulations. We have integrated ESG considerations into our operations. Also, we established the ESG organizational and management systems based on the characteristics of our business.

Our Board oversees and reviews the Company's ESG matters, including:

- reviewing and discussing periodically the Company's ESG management approach and strategy, and promoting ESG considerations to be part of the business decision-making process;
- reviewing and discussing periodically the process and result of the Company's ESG materiality assessment;
- reviewing and discussing periodically the ESG goals and targets and the progress made against the goals and targets;
- reviewing and discussing the annual ESG report and other ESG-related information disclosure; and
- reviewing and discussing the Company's major ESG risk exposures, and the actions that the management makes to monitor and control such risks.

Relevant departments are responsible for the implementation of ESG-related work.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

iii. BeiGene and Sustainable Development Goals

The United Nations Sustainable Development Goals (“SDGs”) are the blueprint to achieve a better and more sustainable future for all. At BeiGene, we have also identified our SDG priorities, and have taken actions to contribute to the advancement of the SDGs.



It is our vision to create impactful medicines that will be affordable and accessible to far more cancer patients around the world. We strive to build a global organization recognized for its impact in cancer research and drug development. The sections headed “Product Quality Control” and “Community Investment” illustrate our commitment and actions to promote people’s health and well-being.



We strive to create a comfortable and harmonious workplace while building an inclusive culture where everyone can contribute their best work. See the section headed “Workplace” for more information.



One of our values is that we embrace innovative ways of doing things at all levels, and stretch our minds to accomplish things that others thought were impossible. Since the Company was founded, we have made great achievements in medical innovation. See the section headed “Product Responsibility” for more information.



We have established an environmental management system for energy conservation and emission reduction. The section headed “Environment” describes how we reduce our environmental impact.



We promote a culture of compliance and ethical operations and set up comprehensive risk-based monitoring programs. Sections headed “Anti-Corruption” and “Supply Chain Management” provide more information on our anti-bribery and anti-corruption efforts.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

iv. Stakeholder Engagement

We have maintained close communication with our stakeholders and established channels to understand their opinions on the Company's ESG performance and future development strategy. According to our business characteristics, we identified the main stakeholders and their main ESG concerns as follows:

Main Stakeholders	Main ESG Concerns	Main Communication Channels
Shareholders	<ul style="list-style-type: none"> Product responsibility such as product R&D innovation, client satisfaction, products quality control, and patents and intellectual property protection Supply chain management Anti-corruption 	<ul style="list-style-type: none"> Shareholder meeting Annual report Regular announcements Official website Face-to-face communication Investor relations
Government and regulators	<ul style="list-style-type: none"> Product responsibility such as pharmaceutical advertising compliance, products quality control, and privacy and data protection Medical waste management Anti-corruption 	<ul style="list-style-type: none"> Policy consultation Incident reporting Information disclosure
Employees	<ul style="list-style-type: none"> Diversity, equity and inclusion Employee benefits Talent attraction and retention Employee training and development Employee health and safety 	<ul style="list-style-type: none"> Communication meetings Employee satisfaction survey Employee activities Social media Face-to-face communication Whistleblower Emails Intranet
Customers and patients	<ul style="list-style-type: none"> Product responsibility such as product R&D innovation, client satisfaction, products quality control, and privacy and data protection Anti-corruption 	<ul style="list-style-type: none"> Quality management system Information disclosure Whistleblower
Suppliers	<ul style="list-style-type: none"> Supply chain management Anti-corruption 	<ul style="list-style-type: none"> Supplier assessment Conferences Telephone calls Emails Whistleblower

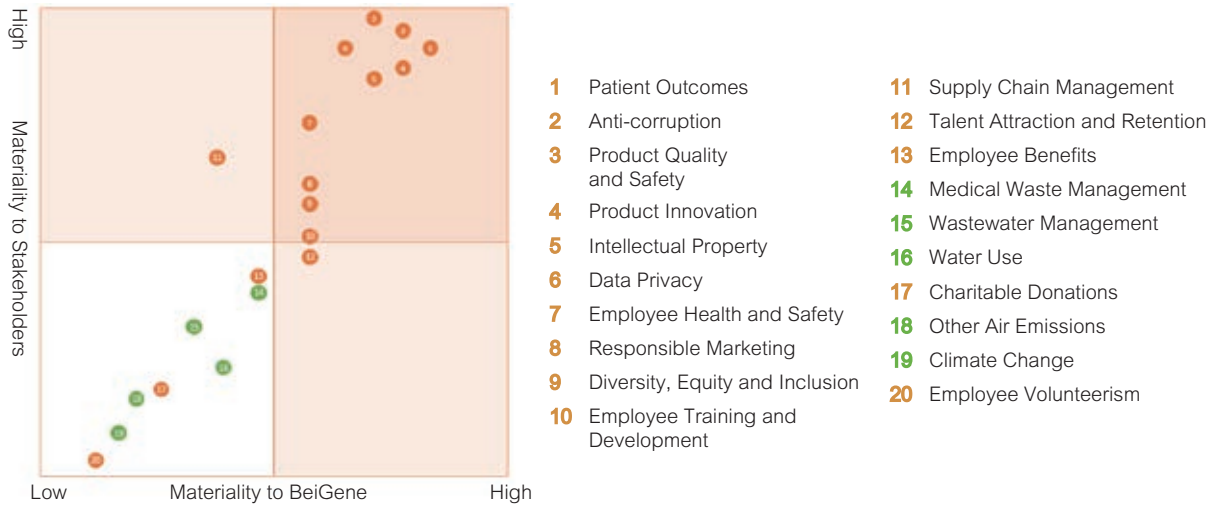
ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

Main Stakeholders	Main ESG Concerns	Main Communication Channels
Distributors	<ul style="list-style-type: none"> • Product responsibility such as client satisfaction and products quality control • Supply chain management • Anti-corruption 	<ul style="list-style-type: none"> • Conferences • Telephone calls • Emails • Whistleblower
Media and non-governmental organizations	<ul style="list-style-type: none"> • Climate change • Energy management • Reduce pollution to water and air • Medical waste management • Water use • Product responsibility such as product R&D innovation, pharmaceutical advertising compliance, products quality control, and privacy and data protection • Diversity, equity and inclusion 	<ul style="list-style-type: none"> • Social media • Official website
Community	<ul style="list-style-type: none"> • Climate change • Energy management • Reduce pollution to water and air • Medical waste management • Water use • Charitable donations • Volunteering activities 	<ul style="list-style-type: none"> • Community interaction • Public welfare activities • Social media

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

v. Materiality Assessment

Based on the communication with the main stakeholders and the operating characteristics of the Company, we conducted an online survey to understand ESG topics that our stakeholders believe to be material to BeiGene and themselves. The result of the materiality assessment is summarized below. These topics are discussed in detail in this ESG report.



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III. PRODUCT RESPONSIBILITY

We have grown into a fully-integrated global biotechnology company with a broad portfolio of medicines and drug candidates. We are committed to the development of a diverse pipeline of novel therapeutics for cancer. We currently market two internally-discovered oncology medicines: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China.

In 2020, we made significant progress and more recently with our collaboration agreement with Novartis and Amgen respectively to develop and commercialize tislelizumab and XGEVA® across multi-countries, and the expansion of our commercial portfolio, including the most recent approval from the NMPA for tislelizumab for use in combination with two chemotherapy regimens as a first-line treatment for patients with advanced squamous NSCLC.

We market REVLIMID®, and VIDAZA® under a license from Celgene Logistics Sàrl, now a BMS company, since 2017, and also market or plan to market additional oncology in-licensed products in China from our collaborations such as with Amgen Inc. and EUSA Pharma.

We announced that three innovative oncology products have been included in the updated NRDL by the NHSA, including BRUKINSA® (zanubrutinib), tislelizumab, and XGEVA® (120-mg denosumab). The NRDL inclusion of tislelizumab, BRUKINSA®, and XGEVA® will help expand access to these high-quality oncology treatments across China and alleviate some of the financial burden for many cancer patients and their families. We believe that it would make a profound impact on local patients who are roughly one-quarter of the world's new cancer patients every year.

We have entered into an exclusive license agreement with Singlomics Biopharmaceuticals Co., Ltd, for developing, manufacturing, and commercializing Singlomics' investigational anti-COVID-19 antibodies, including DXP-593 and DXP-604. We plan to develop one or more of these antibodies globally outside of greater China, while Singlomics would retain rights in greater China, to help support the prevention and control of the epidemic.

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i. Product Quality Control

BeiGene strives to never compromise on the safety, compliance, and quality of our products, our research, or our services. BeiGene maintains a quality-focused culture to ensure the highest priority is placed on the quality of our products, the safety of our patients and consumers, the integrity of data supporting our products such as in regulatory submissions, and interactions with our stakeholders.

We have developed a comprehensive quality assurance and control program to generate awareness, foster a culture of quality, and support our compliance with applicable laws and regulations and internationally recognized standards. We earn and preserve stakeholders' trust by adhering to strict quality control standards in testing, manufacturing, packaging, storage, and distribution of our medicines. We are committed to high standards on safety, standardization, product quality, research, and service quality. Our internal standards are often stricter than those required by national and industry practice, and are optimized and enhanced on an ongoing basis. We also expect our external business partners, such as vendors, contract manufacturers, contract research organizations, specialty service providers, contractors, and distributors to demonstrate their alignment with our quality control requirements to achieve patient safety and compliance.

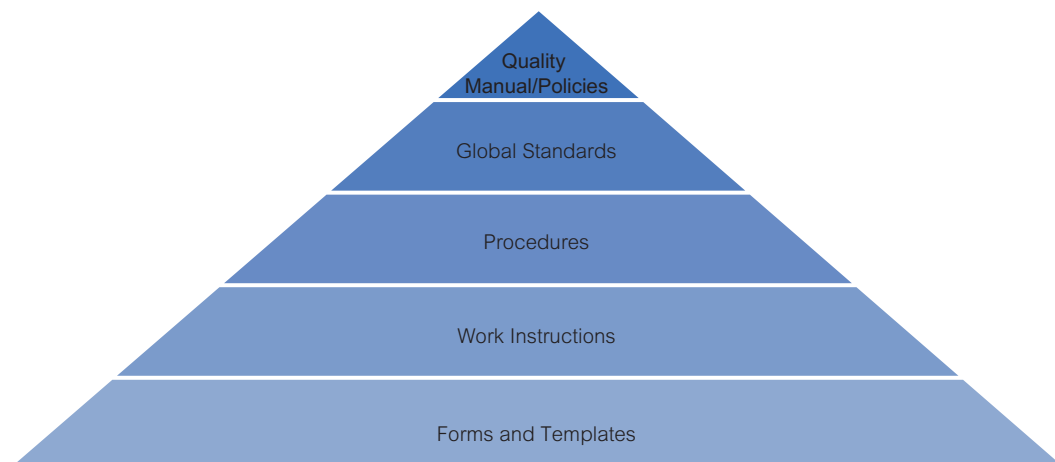
Our clinical studies are conducted in compliance with Good Clinical Practice ("GCP") and Good Pharmacovigilance Practice ("GVP"). Our investigational new drug enabling nonclinical studies are conducted in compliance with principles of Good Laboratory Practice ("GLP"). Our manufacturing sites follow requirements of the FDA, NMPA and EMA, such as Good Manufacturing Practice ("GMP"), and the ICH Q10 Drug Quality Control System. In 2020, we completed GMP qualification for the second phase of biologics manufacturing facility in Guangzhou, China, with a total capacity of 24,000 liters for the completed first and second phases.

1. *Quality Management*

BeiGene commits to serving patients first by delivering safe, effective, high quality medicines that consistently meet or exceed customer and regulatory requirements. We have established a comprehensive and full life-cycle Quality Management System to set quality objectives, conduct quality related risk assessments, and promote continuous improvement. The system covers drug discovery, research and development, manufacturing facilities, production, and inspection. We have formulated detailed guidelines for our quality control processes. All subsidiaries within the BeiGene network operate under this global quality system for the management, monitoring and control of our product quality based on their business characteristics.

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Our quality system is illustrated below and includes quality manual/policies, global standards, standard operating procedures, work instructions, and forms and templates. In the pyramidal structure, each level interlocks with and supports the next higher level. We periodically review and enhance our quality management system to ensure its robustness and effectiveness.



We have an independent and autonomous group tasked with establishing and maintaining procedures, tools, and the organizational structures required to support an effective quality system. It consists of four areas under the Global Head, Quality & Compliance, including GMP Quality, Medical Quality Assurance, Computer Systems Validation Quality Assurance, and Quality Management Systems.

In addition, we have established a global patient safety group headed by a Chief Safety Officer to manage overall responsibilities for product and service safety. Safety management review for senior leadership is conducted periodically. In addition, our clinical scientists are responsible for identifying and monitoring safety issues in our operation to ensure the safety of our medicines.

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2. *Monitoring*

At BeiGene, a quality management risk process is in place to support all GxP (including GMP, GCP, GLP, etc.) operations in identifying, analyzing, and devising controls for managing potential risks observed with internal manufacturing, CMOs and in the quality system. We believe that it is our responsibility to monitor the whole process and evaluate potential risks to ensure product safety and quality.

We have set up comprehensive, risk-based monitoring programs to ensure the robustness and effectiveness of our quality system. We carry out management reviews periodically. Performance measures including key quality indicators are reviewed, analyzed and summarized in periodic reports. Based on these periodic reviews, we implement continuous enhancements as needed to maintain an effective quality system, including training, additional resources, modifications of roles and responsibilities and/or procedural changes.

We also maintain internal and external audit programs to ensure our functional business units, vendors, and clinical trial sites comply with relevant procedures, written agreements, and applicable regulations. Procedures are in place for scheduling, performing, and documenting audits, and for tracking and resolving audit observations in a timely manner. Annually, internal compliance audits of each manufacturing site for cGMP compliance, clinical operations for GCP and GPV compliance, external audits of suppliers of services and products are conducted on a risk-based approach.

3. *Training*

BeiGene fosters a quality culture by developing quality awareness throughout the organization. Role-based training on GxP regulations and standards is provided on a regular basis to ensure that all BeiGene personnel are qualified to perform job functions and remain proficient in their understanding of GxP regulations and operational procedures. We maintain training records for all personnel and conduct periodic and systematic reviews of these records to ensure personnel are receiving the training required by their job function.

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4. *Promoting Industry Development*

We actively participate in industry events to promote industry development. Our quality leadership team participates as experts in industrial workshops and conferences on quality issues jointly with local provincial authorities. For example, we are an active member of many non-profit associations and industry communities such as Biotechnology Innovation Organization, European Confederation of Pharmaceutical Entrepreneurs, Parenteral Drug Association and International Society for Pharmaceutical Engineering, to connect and collaborate with more key industry leaders and actively promote industry development. In China, we share our experiences with various biotechnology companies sharing international standards in safety management and biologics production.

ii. **Complaints and Recall Procedures**

Timely reporting of potential product complaints or quality concerns is critical to ensure the integrity of our medicines. We have issued a global standard relating to complaint handling to define the process and ensure that product complaints related to clinical and commercial products are documented, evaluated, investigated, monitored, reported, and trended in accordance with regulatory requirements.

Our channels for receiving complaints include a web portal, telephone hotline, and email. All employees and representatives are responsible for reporting product complaints for any products owned or marketed by BeiGene. Our Quality Assurance Department monitors these channels daily for product complaints. All complaints are documented, tracked, and rigorously investigated. Based upon the findings, the Quality Assurance Department investigation determines whether more stringent preventive measures are required and implements them accordingly.

In 2020, we amended our global standard, stipulating that all product complaints for any BeiGene owned or marketed product should be reported by our employees, representatives and product customers/patients within 24 hours of awareness, which shortened the reporting timeline and further helped us in our efforts to prevent subsequent adverse events from occurring.

Should a serious product quality issue be identified, customers would be advised to stop using the product immediately, and a recall may be initiated. We have established a global standard product recall procedure for our products. If a stock recovery/recall is warranted, our Stock Recovery/Recall Committee consisting of representatives from Regulatory Affairs, Quality, Clinical Development, and Supply Chain, will determine the extent of such a recovery/recall. Further investigation will be conducted to identify the root cause so as to implement corrective actions and propose any preventive actions needed to ensure that the quality issue shall not reoccur.

We were not aware of any significant adverse events based upon complaints due to quality in BeiGene products in 2020. On March 25, 2020, the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to us by BMS. This suspension is based on inspection findings at BMS's contract manufacturing facility in the United States. Following additional meetings with the health authorities, BMS initiated a voluntary recall of all existing stock of ABRAXANE® in China. We cooperated with our partners and related authorities on their investigation and efforts to trace product to support the recall procedures.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

iii. Intellectual Property Rights

Our commercial success depends to a large extent on our ability to develop and protect our proprietary technology and knowledge by obtaining, maintaining and pursuing enforcement of our intellectual property rights.

We strictly abide by and keep abreast of the requirements of relevant laws and regulations in countries and regions in which we operate. In 2020, the Patent Law of the People's Republic of China was amended to be effective as of June 1, 2021, and the amendment expects to serve as an incentive to the innovation of the pharmaceutical industry.

We have filed patent applications and obtained patents in China, the United States and other countries and regions, relating to our medicines and drug candidates, and are pursuing additional patent protection for our medicines, drug candidates and technologies. We rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection, including our manufacturing processes.

We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with employees, consultants, scientific advisors and contractors and invention assignment agreements with our employees. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

In addition, we also comply with all applicable laws and regulations regarding inventor remuneration and establish the employed inventor policy to encourage drug innovation and new drug development. We provide training to employees to raise their awareness on intellectual property protection.

We avoid infringing the valid patents and other intellectual property rights of third parties. We conduct Freedom to Operate ("FTO") analysis to make sure that the development and commercialization of our medicines does not infringe others' valid patent rights. We rely not only on our know-how and continuing technological innovation, but also on in-licensing opportunities to develop, strengthen and support our development programs. Intellectual property due diligence is conducted for in-license and out-license projects to minimize intellectual property risks.

As of December 31, 2020, we owned 14 issued China patents, 28 issued the United States patents, a number of pending China and the United States patent applications, and corresponding patents and patent applications in other jurisdictions. In addition, we own pending international patent applications under the Patent Cooperation Treaty ("PCT"), which we plan to file in the United States and other jurisdictions, as well as additional priority PCT applications. We also own a number of registered trademarks and pending trademark applications. We currently have registered trademarks for BeiGene, our corporate brand and product names and logos in the United States, China, the EU and other jurisdictions, and we are seeking further trademark protection for BeiGene, our corporate brand, product names and logos, and other trademarks in jurisdictions where applicable and appropriate.

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iv. Privacy and Data Protection

As indicated in our Code of Conduct, BeiGene is committed to protecting the privacy and security of personal data.

A number of privacy and data protection laws and regulations apply to our business operations, including but not limited to the GDPR, the California Consumer Privacy Act, the Regulation on the Administration of Human Genetic Resources, and the Cybersecurity Law of the People's Republic of China.

Our global Privacy and Data Protection Policy establishes core requirements for personal data BeiGene receives, uses, stores, transmits or otherwise processes. Violations of that Policy may result in discipline, up to and including termination, or referral to regulatory authorities and potential civil and criminal liability, where appropriate.

Designated employees oversee BeiGene's compliance with data protection laws and regulations. We provide training to all employees on privacy protection, and specifically data protection training to individuals in departments that process sensitive personal data.

We are committed to processing personal data lawfully, fairly, and in a transparent manner. We collect personal data only for legitimate and justifiable purposes, and that are relevant, adequate and limited to what is necessary to achieve legitimate purposes. We maintain data only for as long as necessary for the purposes for which it is processed, or as otherwise permitted under applicable laws and regulations. We also secure personal data to help protect against unauthorized or unlawful processing and against accidental loss, destruction or damage.

Protection for the data of patients who are participating in BeiGene clinical trials include the following:

1. *Contractual Protections*

Our agreements with trial centers, principal investigators and clinical trial vendors require compliance with applicable laws, which include privacy and security laws, and strict confidentiality.

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2. *Informed Consent*

We and our clinical trial collaborators are all legally and contractually required, in accordance with the China GCP to obtain clinical trial subjects' permission to collect personal data, share personal data with us, and if applicable, transfer personal data outside of China. This is conducted through the informed consent process, which includes written, documented consent from the parties involved.

We have policies governing the preparation, review, approval and use of the informed consent form ("ICF"). ICF templates must be approved by the ethics committee of each clinical trial site in every trial. Under these policies, clinical trial subjects, prior to being enrolled in a clinical trial, would be informed in writing of the scope of the information to be collected from them as well as how, and to what extent, such information will be used, processed, transferred, and stored, and requested to give their consent in writing. Our use of personal data obtained from clinical trial subjects complies with the terms of such consent.

3. *Regulatory Approvals*

We obtain approval from the Ministry of Science and Technology of the People's Republic of China before the commencement of clinical trials in which we, and clinical trial centers in China, obtain human genetic resources ("HGR"), and before exporting the HGR samples or associated data outside of China.

4. *Security Measures*

We employ security measures that protect the confidentiality and security of data that we collect, store and otherwise process. Most clinical trial data maintained by us resides in validated quality systems that include additional security protections such as limited role-based access and firewall protection. Our employees must explicitly agree to comply with applicable security measures as outlined in our Acceptable Use Policy and attend mandatory information security training sessions.

5. *Others*

Our Code of Conduct mandates that all employees comply with applicable laws and protect confidential information, including personal data. Confidentiality obligations are further detailed in the employment documents with all employees. These compliance and confidentiality obligations extend to the protection of all personal data collected and processed by us, including the personal data of clinical trial subjects.

Our employees are obliged to report any data incident immediately upon learning, so that the Legal and Compliance and IT Departments can take appropriate action, including assessing any potential disclosures, and notification requirements to data protection authorities or affected individuals, as appropriate.

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v. Advertising and Labelling

The FDA, NMPA, EMA and other regulatory authorities strictly regulate the marketing, labeling, advertising, and promotion of drugs. Our medicines may be promoted only for their approved indications and for use in accordance with the provisions of the approved label.

At BeiGene, we strictly abide by advertising and labelling laws and regulations, such as the Advertisement Law of People's Republic of China, the Pharmaceutical Administration Law of the People's Republic of China, Classification Management Measures of Prescription Drugs and Non-Prescription Drugs, the Provisions for Drug Advertisement Examination, the Drug Instructions and Label Management Regulation and the United States Food, Drug and Cosmetic Act, so that regulators, medical professionals and patients may receive authentic and rigorous product and academic information.

In China, prescription drugs are strictly forbidden from being advertised to the general public and are only permitted to be advertised in professional medical journals. We manage publicity work strictly according to the regulations and do not advertise our products to the general public in China. We also require that all materials used in external communications shall be approved by our Material Review Committee consisting of the Functional Reviewer, Medical Affairs and Legal department to ensure appropriateness compliance and accuracy. All promotion and advertising-related interactions with healthcare professionals, including physicians, nurses, nurse practitioners, physician assistants, pharmacists, or health plan administrators, must be consistent with the prescribing information approved by relevant regulatory authorities.

We have developed global standard operating procedures ("SOPs") for regulatory labeling processes for the development, review, approval, update, and distribution of labeling documents for all marketed and development products for which BeiGene holds core labeling document responsibilities. We have an Executive Labeling Committee and a Labeling Committee to ensure all core labeling content receive the appropriate level of internal review prior to release for submission to a regulatory agency and/or before releasing for product commercialization. Our Executive Labeling Committee, comprised of key senior representatives from specific functions and product units, is accountable for making decisions, advising the Labeling Committee on labeling documents as appropriate, and providing the final approval of any significant labeling.

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IV. WORKPLACE

BeiGene values the growth of employees as we believe that our people are critical to the success of the Company. We strive to create a comfortable and harmonious workplace while building an inclusive culture where everyone can contribute their best work. One of our core values is *creating an environment, built on diversity and inclusion, in which all employees have an opportunity to grow professionally, affect the world meaningfully, and build lifelong friendships with exceptional people*. We are committed to taking care of our employees' wellbeing and creating a safe, healthy, innovative, and diverse work environment for our staff. We have adopted policies to protect our employees' health and safety, keep a work-life balance, and foster their career development.

From January 1, 2020 to December 31, 2020, we were not aware of any incidents of material non-compliance with applicable laws and regulations in the People's Republic of China relating to employment, occupational health and safety, and labor standards.

i. Employment and Labor Practices

We strictly comply with PRC laws and regulations relating to employment, such as the Labor Law of the People's Republic of China, the Labor Contract Law of the People's Republic of China, the Law of the People's Republic of China on the Protection of Women's Rights and Interests, the Social Insurance Law of the People's Republic of China, and the Provision on Minimum Wage of the People's Republic of China.

We have developed an employee handbook in China, specifying the policies for recruitment, promotion, working hours, leave entitlements, compensation, dismissal, welfare and other benefits, anti-discrimination, diversity and equal opportunity. In 2020, we focused on making standards and policies clearer, optimizing the processes, and managing employees effectively through the employee handbooks.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

1. *Diversity and Equal Opportunity*

BeiGene promotes diversity, inclusion, and equal opportunity through recruiting and employees' work life as we understand that international talents are strongly needed for every organization. Currently, we have offices located in Asia-Pacific, North America, and Europe. Our employees are from diverse backgrounds and we are committed to creating a diverse and inclusive environment.

We comply with the relevant PRC national and local employment laws and regulations, and prohibit any discrimination on the grounds of gender, ethnicity, race, disability, age, religious belief, sexual orientation, nationality, or family status. We clearly state in our employee handbook that the basic principle of employee management at BeiGene is that we are firmly committed to giving all employees equal treatment and opportunities regardless of their nationality, ethnicity, race, gender, religion, etc. In terms of other corporate initiatives, we have created many collaboration opportunities across the division to enhance inclusion and improve employees' capabilities.

We do not tolerate discrimination or harassment in the workplace, including any form of abusive conduct or action, such as verbal, non-verbal, written, electronic, or physical conduct that creates an intimidating, hostile or offensive work environment; unreasonably interferes with an individual's work performance; or demeans or shows hostility toward an individual. Employees are required to report any discrimination or harassment they may witness or experience in the workplace through our complaint and whistle-blowing mechanism.

2. *Recruitment and Dismissal*

In strict accordance with relevant laws and regulations such as the Provisions on Prohibition of Child Labor, we strictly forbid the employment of child labor and incidents of forced labor. We have recruitment guidelines in place. Every job applicant is required to provide information such as ID card, educational background and work experience, which is reviewed by us and verified by a professional background checking agency as needed, to avoid related risks. During the reporting period, BeiGene did not have any cases of child labor or forced labor.

We primarily recruit employees through recruitment agencies, employee referrals, on-campus job fairs and online channels including our corporate website, social networking platforms and industry referrals. Recruitment interviews are conducted at three levels in sequence, including the human resources department, line manager and senior manager. These procedures are designed to recruit suitably talented employees who fit the job descriptions under the principle of equal employment opportunity. In 2020, we focused on making position competency requirements clearer and more specific based on qualifications of different level of jobs to increase recruiting efficiency. Besides, we switched the face-to-face handwriting contract signing process to the online contract signing process, which provided more convenience for remote employees, improved our productivity, and helped maintain the social distancing policy during COVID-19.

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As of December 31, 2020, BeiGene had a total of approximately 5,100 employees across all our global operations. Dismissal of employees is strictly compliant with applicable PRC laws and regulations, and contractual terms and clauses as stipulated in our labor contracts.

3. *Working Hours and Leave Entitlements*

We adopt two working hour systems in China. In 2020, we have set up special allowances for remote employees and added “home office” applications to the attendance system to provide employees with flexible options during the COVID-19 pandemic. According to our China leave policy, our employees are entitled to annual leave, fully-paid sick leave, and other statutory leave. Additionally, our female employees are entitled to take fully-paid maternity leave and other associated leave benefits, while male employees are entitled to take fully-paid paternity leave.

4. *Compensation and Promotion*

We promote a high performance and high appreciation global culture. We refer to the salary and welfare standard of the pharmaceutical and other industries to offer competitive salary and benefits to attract talent and retain our employees. The financial benefits we offer to employees include base pay, cash bonuses and equity compensation.

Every employee receives a performance evaluation annually. The results of employee performance evaluations are an important factor affecting employees’ annual performance bonuses, promotion or demotion, rewards and disciplinary action. Promotion is reviewed and determined by different internal business units according to preset criteria on candidates’ performance, job requirements and business performance. In 2020, we improved our talent management policies and there were more layers of rewards designed for promoting collaboration and praising employees’ good performance. For example, the criteria for salesperson became more specific. Employees had more opportunities to get promotions compared to the past.

5. *Welfare and Benefits*

We provide benefits related to health, wellness, retirement and leaves of absence to help attract, cultivate and retain the industry’s most talented workforce. In China, we provide a range of insurances including medical insurance, pension insurance and unemployment insurance as required by local rules and regulations. To demonstrate our commitment to the health of our employees, we also provide commercial insurances to all employees and premium plan insurance packages to executive-level employees and organize health lectures periodically to share health knowledge. Transportation and meal subsidies are also available to our employees.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

6. *Communication*

Employees' suggestions and opinions are important to BeiGene. We have established a variety of internal communication channels such as company website, president email, business WeChat account, CEO communication letter, townhalls and all-hands meeting to collect employees' suggestions, opinions and complaints. In 2020, BeiGene conducted an Engagement Survey to understand employees' needs and recommendations for the Company. The employee satisfaction rate reported in the survey was approximately 80% globally and 84% in China.

7. *Employee activities*

We promote efficient work and encourage employees to maintain a positive work-life balance. We hold a "Healthy Running" event every year to promote the concept of healthy living. In 2020, to enhance COVID-19 prevention and control and comply with the requirements of national and local governments, we did not hold company-level off-site activities that enrolled each employee. However, we organized a series of functional level activities within each department for team building to help employees stay engaged and involved. We also held volunteer programs that encouraged employees to attend including charitable donations to help low-income families.

ii. **Occupational Health and Safety**

We are committed to maintaining safe workplaces. We strictly comply with the applicable laws related to occupational health and safety, such as the Law of the People's Republic of China on Prevention and Control of Occupational Diseases, the Technical Specification for Occupational Health Surveillance, the Law of the People's Republic of China on the Prevention and Treatment of Infectious Diseases, the Provisions of the State Council on the Investigation of Administrative Responsibility for Major Safety Accidents, and the Notice of the State Administration of Work Safety on the Adjustment of the Statistical Report on the Dispatch of Work Safety Accidents.

In 2020, We engaged a professional third-party vendor to help establish a database of applicable EHS laws and regulations to facilitate a more effective management of our compliance with these laws and regulations. We stay up-to-date on the latest changes in EHS laws and regulations by obtaining periodic research reports from third-party experts and monitoring by our dedicated EHS team. We take immediate measures to respond to these changes when necessary. In 2020, there were no significant changes in occupational health and safety laws and regulations that may have a significant impact on BeiGene, and we did not have any material violations of PRC laws and regulations relating to occupational health and safety.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

1. *Environmental, Health and Safety Management Structure and Policy*

Our EHS management mechanism is set up based on the ISO14001 framework. We have a comprehensive EHS management framework consisting of senior management, EHS department and EHS coordinators responsible for the effective implementation of EHS management policies. Our Senior Vice President, Head of Biologics is responsible for overseeing and directing overall EHS management.

We have formulated EHS policies to guide EHS management in our manufacturing sites and other facilities. We are committed to achieving the following EHS objectives:

- **Employee Health and Safety:** Fostering a safe work environment that prevents injuries and diseases and promotes employee health and productivity; We also ensure that our employees have the awareness, skills, and knowledge to carry out this policy;
- **Sustainability:** We strive to conserve natural resources and eliminate or minimize adverse EHS aspects and hazards that may be associated with our products, services, and operations, with a focus on creating value for internal and external stakeholders;
- **Suppliers and Contractors:** We work with our suppliers and contractors to enhance EHS and sustainability performance;
- **Compliance:** We comply with all applicable EHS laws and regulations and continue to integrate sound EHS practices consistent with our EHS management system into all aspects of the business;
- **Business Integration:** We integrate EHS and sustainability considerations into our business activities;
- **Customer:** We work with our customers to help them address their EHS and sustainability needs; and
- **Community and Government:** We participate in community and government EHS and sustainability initiatives.

To support implementation of the EHS policies, we have established procedures and standards, such as an EHS Management System Manual, EHS Specifications, Restricted Space Management Procedure, Emergency Preparedness and Procedures, Emergency Rescue Management, Procedure for Explosive Chemicals Management, Procedure for Precursor Chemicals Management, Health Examination Procedure, and Occupational Health Management Procedure, to manage and control occupational health and safety risks. We regularly review and update relevant procedures and standards to ensure their applicability to the latest situation.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

We evaluate, identify, and monitor the occupational disease hazard factors and safety risks in our workplace, and take necessary measures to remove or reduce occupational hazards and safety risks.

We conduct occupational physical examinations for employees before employment, during the term of employment, and before departure. Appropriate Personal Protective Equipment (“PPE”) is provided to employees in positions with potential exposure to occupational health risk to prevent occupational diseases. If an employee suffers from occupational health issues, his or her posts and responsibilities will be adjusted with necessary remediations actions. In 2020, the occupational health physical examination coverage rate was 100%.

Our employees who engage in higher risk work activities are required to receive relevant training and obtain corresponding qualifications. We have put in place various policies and procedures including our Chemical Management Procedure, Procedure for Explosive Chemicals Management, and Procedure for Precursor Chemicals Management in managing hazardous safety risk of our employees. Our chemical warehouses and manufacturing facilities are well tested for safety in compliance with applicable PRC laws and regulations.

2. Education and Training

We integrate safety awareness into our business processes and our corporate culture. We conduct occupational health and safety trainings for all our employees and third parties on a regular basis to enhance occupational health and safety awareness and improve their capabilities to cope with safety emergencies, such as training on PPE use, first aid, and confined space operation.

3. Monitoring and Inspection

In our Suzhou and Guangzhou manufacturing facilities, we conduct internal EHS audit activities regularly. The management team and EHS coordinators conduct monthly safety inspections, whereas relevant departments conduct daily and monthly reviews.

4. Emergency Response

We have established an emergency response system and developed emergency response plans to deal with natural disasters, medical emergencies, fire and explosion emergencies, chemical spills, sewage treatment system emergencies, occupational disease hazard accidents, and special equipment related emergencies.

We also carry out relevant emergency drills regularly, including fire drills and emergency drills for chemical leaks, confined space rescue, and special equipment accidents. All sites are equipped with first-aid kits, and automated external defibrillators (“AEDs”) are set up in the public areas of the Suzhou plant. All first-aid specialists in the plants have received professional training delivered by the local Red Cross.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

5. *Response to COVID-19*

During the worldwide COVID-19 health crisis, our primary focus has been on keeping BeiGene colleagues and their families safe, upholding our commitments to patients, and providing assistance and materials to doctors and hospitals on the frontline.

For the safety of our employees, we were early in closing our offices in China and then in the United States and Europe as the COVID-19 pandemic spread. We were also early in suspending domestic and international travel, changing all in-person meetings to virtual meetings, and temporarily suspending all in-person field activities. Our employees in China have returned to the office, following required and recommended precautions such as wearing masks, temperature screening and social distancing, and we are monitoring the situation closely in the United States and Europe as we make plans for our employees to return to the office when it is deemed safe.

During the COVID-19 outbreak, we immediately acted upon the National Health Commission of China, World Health Organization, Center for Disease Control and local government requirements and developed an action plan for pandemic prevention and control. We set up a dedicated Emergency Response Team in China comprising personnel from our EHS, HR and Administration departments and in the United States created a global COVID team from Workplace Services, Legal, Human Resources, IT, Travel and Security with clearly defined roles and responsibilities. The action plan includes various management measures and procedures with respect to monitoring risks and impacts of the pandemic, managing internal and external communication, collecting and tracking health information and wellbeing of our employees for necessary care and assistance, and reporting and emergency response procedures. COVID testing and PPE was provided in the United States for those interacting with medical facilities. Leaders are monthly informed of any changes on all aspects related to each region. Outside of China employees are working from home and were given the necessary IT equipment and a monthly stipend for internet and miscellaneous expenses. As vaccines become available in 2021, offices outside of mainland China are expected to open.

We continue to closely monitor the pandemic situation and maintain continuous communication with our employees on the latest developments with the pandemic and have issued specific guidance on infection prevention and personal safety and health protection.

We continue to take vigorous disinfection measures in our offices and plants, provide our employees with adequate protective equipment and necessary facilities to ensure a safe environment for our operations and production, conduct safety inspection, and train all employees and third parties' personnel online on the requirements and cautions.

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In addition, we launched a charitable initiative, called BeGenerous, coordinated by our COVID-19 task force, to procure and donate PPE to hospitals around the world and provide other charitable support. Initially, our team in China, with the assistance of our global team, secured and delivered much-needed PPE and supplies to doctors and hospitals on the frontlines in the city of Wuhan and Hubei Province. We were among the first companies to do this. We have also helped to secure PPE for distribution to hospitals in the United States, while our employees globally, including in Europe and Australia, have engaged in active donations of medical supplies and other support in their communities.

iii. Training and Development

We are committed to fostering a culture of continuous learning and providing training tailored to the needs of different positions. Our employees make their own personal development plans annually and propose training needs, based on which we design the annual training program. There are generally three types of training: new employee orientation, annual mandatory training on compliance/intellectual property/quality/EHS, and training on general professional skills, management skills and job-specific technical skills. We help new employees quickly fit into the Company by offering induction training and on-the-job training from their entry. By coaching new employees using the onboarding performance management system, we aim at helping everyone achieve their goals proactively. All of these training courses are organized by the responsible functions including quality, legal, compliance, EHS and human resources. Additionally, we have a dedicated sales training team to provide tailored training to our sales representatives.

We are committed to continuously optimizing our training system and courses. In 2020, additional new training courses for general professional skill training and new employee training were provided and the participation percentage of employees reached 100%. With frequent communication with our business departments to understand training needs, we provide customized training courses, mentorship programs, and workshops to our employees.

Training courses are regularly provided to employees by internal trainers or external consultants. Our employees may also attend external training courses upon their supervisors' approval. Moreover, we have set up an online learning platform – e-Learning Management System (“eLMS”) so that employees can learn anytime and anywhere. “BeiGene ELIVE LIVE” sessions were held entirely online to provide employees training with a wide range of topics such as time management and communication skills. To better support on-the-job education for our employees, we have set up a talent review project based on the results and feedback of talent mapping. Human capital internal assessment and change management are conducted periodically based on organizational growth and future strategy.

Furthermore, we are working on a special program designed for directors and above employees called Talent Acceleration Program, expected to be launched in the middle of 2021. By utilizing a “square nine box” mapping method, the program is aimed at helping top talents reach their career goals and support BeiGene in retaining talent.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

V. ANTI-CORRUPTION

BeiGene values a clean and honest corporate environment and is committed to preventing corruption in any form. BeiGene adopts a zero-tolerance attitude towards bribery and corruption. We implement anti-corruption control measures and strictly follow relevant laws and regulations against corruption, extortion, fraud, bribery and unfair competition, such as the Law of the People's Republic of China against Unfair Competition, Sarbanes-Oxley (SOX) Act, the federal Anti-Kickback Statute, and the Foreign Corrupt Practices Act. In 2020, we continue to improve our management policies and control measures related to bribery, extortion, fraud and money laundering in accordance with updated laws and regulations.

The compliance management, under the Audit Committee's supervision, ensures the implementation of relevant regulations. It consists of senior managers from the Commercial Department, the Finance Department, and the HR Department to oversee and review the work related to professional and business ethics.

At BeiGene, a comprehensive and robust compliance management system has been built, consisting of the following key components:

- Designated compliance officer;
- Internal policies and procedures;
- Education and training programs;
- Online compliance management system;
- Platform/Lines of communications between employees and leadership;
- Effective due diligence programs; and
- Remedial actions.

Our Code of Conduct outlines the ethical and compliance principles that guide our daily operations and embody our commitment to ethical business practices in all of our interactions with the healthcare community, patients, suppliers, business partners, government regulators, shareholders, and each other. In addition to the Code of Conduct, BeiGene developed a series of global policies, including the Anti-corruption Policy, the Global Healthcare Compliance Policy, the Global Vendor Code of Conduct, and the IT Security Policy.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

i. Compliance Education and Training

At BeiGene, we are committed to promoting a culture of compliance and ethical operations. We develop education and training programs for our employees to fully understand the requirements of our compliance policies and relevant laws and regulations.

We conduct both online and offline training programs. Through our eLMS, we provide tailored training programs for different employees based on their roles and responsibilities. Every new employee receives training on company policies related to anti-bribery, extortion, fraud and money laundering. Online training is provided to all employees every quarter. We have ethical marketing training programs and quarterly tests for sales personnel to ensure they understand relevant policies and procedures. Classroom training is also provided. For example, in 2020, an anti-corruption training was provided to the BeiGene China Leadership Team including the heads of each business unit.

ii. Monitoring and Reporting

We have set up comprehensive, risk-based internal monitoring programs to review high-risk processes and transactions, including forensic data analytics, monthly travel and entertainment (“T&E”) transaction testing. These programs help us identify risks, gaps, and potential misconduct in a timely manner, so that we can take prompt remediation actions. We also employ independent reviews by third parties on a quarterly basis. Reports are sent to the Audit Committee for quarterly review. In 2020, we carried out a program to enhance vendor due diligence, and launched unannounced audits for online meeting.

At BeiGene, we value feedback and promote an open-door policy. We encourage our employees to ask questions or raise concerns with no hesitation or fear of retaliation. If individuals are not comfortable reporting issues of concern directly to management, they may file complaints via our compliance hotline or web portal, available 24 hours a day, 365 days a year. We process these reports in accordance with the law and regulations. All reports are investigated thoroughly and independently by designated compliance personnel. In response to any findings identified in monitoring programs and investigations, we take appropriate preventative actions, such as disciplinary action or enhancement to policies, procedures, and controls.

Complaints, and investigation procedures, conclusions and remedial actions are recorded in our report and investigation system, and automatically notified to BeiGene’s Chief Compliance Officer, General Counsel and Audit Committee Chair.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

VI. SUPPLY CHAIN MANAGEMENT

We are committed to conducting business activities with integrity, quality, respect, and responsibility. We have established a sound supplier management system and strive to build a long-term and stable relationship with suppliers to ensure that our products are consistently produced and controlled according to quality standards such as GMP. We have developed a procurement policy and a global contract policy.

In 2020, we developed the Supplier Code of Conduct to regulate the behaviors of our suppliers globally, covering commitment to an ethical workplace, adherence to laws, regulations and guidance, anti-bribery and anti-corruption, fair competition, marketing and promotional practices, conflicts of interest, trade, privacy, security, confidential and proprietary information, commitment to quality, accuracy of books and records, management systems, non-discrimination and fair treatment, wages, benefits and working hours, freedom of association, prohibition of slavery, human trafficking and child labor, workplace health and safety, diversity in employment, emergency preparedness and response, animal welfare, and environmental safety.

i. Supplier Access Management

Our suppliers mainly include production suppliers and non-production suppliers, including research service organizations, fixed asset suppliers, reagents/consumables suppliers and contract research organizations. All suppliers are required to be pre-assessed before they are selected or qualified for procurement. We also have developed evaluation standards for new suppliers which consider factors like business legitimacy and technical professional reputation. For production suppliers, there are additional quality assurance standards and other stringent evaluation criteria such as specific recognized technical qualification requirements.

ii. Supplier Selection and Assessment

During the supplier selection and assessment stage, we constantly monitor and supervise suppliers before and after we agree to cooperate. Supplier assessments and evaluations including supplier selection, routine competitive bidding, and annual performance assessments are conducted throughout the process of supplier management.

Our procurement department, assisted by business line managers, is responsible for sourcing potential supplier candidates and the final selection. Supplier assessments are conducted by suppliers' business natures, based on established internal selection criteria and standards, including quotation, quality of performance, deliverables, services, etc. Line managers may jointly participate in the evaluation and selection of suppliers and provide professional recommendations as necessary. In addition, phased and continuous performance evaluations are conducted. The results are considered when evaluating future collaboration opportunities.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

iii. Supplier Environmental and Social Requirements

Our supply chain management program focuses not only on the quality, cost and reliability of the products and services, but also on a wide range of environmental and social responsibility considerations, such as employees' health and safety and environmental impacts.

We stress business ethics risk management in procurement. We have incorporated anti-corruption rules and requirements into our contracts, and integrity commitment letters that require our suppliers to operate with honesty and integrity. Due diligence is conducted periodically for selected suppliers.

We expect suppliers to abide by all laws, regulations, and standards not only related to healthcare, but also those that address financial, labor, health, safety, transparency, and environmental practices. We may seek to verify a supplier's compliance with our Supplier Code of Conduct. If we are aware of any actions or conditions not in compliance with our standards, we will seek to work with our suppliers to take corrective or remedial actions. We also established a program to monitor our suppliers, which includes surveying and auditing supplier adherence to the BeiGene Supplier Code of Conduct.

For suppliers with higher environmental and social risks, such as engineering and construction suppliers, we have additional stringent requirements on their management of environmental and social risks. For example, our contracts with engineering suppliers specify that they are obliged to minimize the adverse impacts of their operations on the environment. In addition, we give preference to environmentally friendly suppliers during the selection process in order to encourage them to use more eco-friendly production, packaging and logistics.

During the COVID-19 pandemic, we strived to maintain a healthy and safe work environment for suppliers and established backup systems in case deliveries of raw materials and equipment provided by overseas suppliers were delayed. By setting up backup mechanisms such as utilizing more local suppliers and domestic factories, the pandemic did not have a material impact on our local production in 2020.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

VII. ENVIRONMENT

We value the importance of living in harmony with the environment and are committed to responsible production. Our main impacts on the environment and natural resources are emissions generated and the use of natural resources in the process of research and development, manufacturing, and daily office work. We have adopted emission reduction and resource conservation measures to minimize these impacts. For example, towards a sustainable future, we aim to have 100% of the office paper procured and used in the Suzhou factory be certified by the Forest Stewardship Council (“FSC”) by the end of 2021.

i. Environmental Management

With our manufacturing currently in China, we strictly abide by the country’s environmental laws and regulations, such as the Environmental Protection Law of the People’s Republic of China, the Environmental Noise Pollution Prevention and the Control Law of the People’s Republic of China, the Water Pollution Prevention Law of the People’s Republic of China, the Law of the People’s Republic of China on the Prevention and Control of Environmental Pollution by Solid Waste, and Regulations on the Administration of Construction Project Environmental Protection. In 2020, we did not have any material violations of PRC environmental laws and regulations.

Within the framework of our EHS management system, we have developed a series of management procedures, such as the Management Procedure for Wastewater, Gas Emissions, Noise and Solid Waste, and the Leak Prevention Procedures.

We have established environmental emergency response plans for our plants and R&D centers in coordination with the local government, the local Ecological Environment Bureau, Environmental Monitoring Stations, the Public Security and Fire Detachment and the industrial parks to quickly respond to environmental emergencies.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

ii. Emissions and Waste Management

At BeiGene, we are working towards a low-carbon future. Our greenhouse gas emissions mainly come from the use of electricity, natural gas, and steam. We reduce carbon emissions by saving energy and improving energy efficiency.

Apart from greenhouse gas emissions, our major air emissions include SO₂ and NO_x generated from natural gas consumption during production, and a small volume of waste gas generated during laboratory operations. SO₂ and NO_x emissions are discharged after being processed by waste gas treatment facilities to ensure that SO₂ and NO_x concentrations meet the emission standards set by the local authority. Waste gas from the laboratories is discharged through a fume hood, and a treatment device has been installed at the end of the ventilation system in each laboratory to ensure we meet emissions standards.

Wastewater produced by the Company includes industrial wastewater and sanitary sewage. Our R&D centers and plants are equipped with wastewater treatment facilities, and we conduct monitoring to ensure that the treated water meets national and local standards. The industrial wastewater from the Suzhou plant is 100% recycled after being treated. The sanitary sewage from our plants is discharged into the municipal pipelines in accordance with the local standards.

We engage qualified testing institutions to conduct regular air emissions and wastewater discharge testing. In 2020, we did not find any cases in which emissions or wastewater exceeded the local standards.

Our non-hazardous waste includes domestic waste produced in office operations and non-hazardous waste from production. Non-hazardous waste produced in manufacturing is disposed of by municipal sanitary stations. Domestic waste produced in office operations is handled by property management companies, with whom we collaborate to recycle items such as cardboard boxes, glass, plastic, and paper. Our operation sites follow waste sorting standards and abide by local laws and regulations.

Hazardous waste produced in manufacturing and the laboratories is collected and stored in compliance with applicable PRC laws and regulations and transported to qualified third-party vendors for disposal. Through strict daily management and optimization of production processes, we strive to reduce the generation of hazardous waste.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

iii. Use of Resources

We strive to conserve energy and water in our operations.

We use energy-saving technologies in our plants. In the Guangzhou plant, we use frequency conversion energy-saving chillers, and the backup boiler is equipped with low NOx burners and a heating recovery device, which greatly increases energy recovery. We also implement energy efficiency improvements in our plants to save energy. In 2020, we relocated the light switches in our warehouse to centralize control and ensure power is turned off during non-working periods.

We have also launched water-saving initiatives. In 2020, we retrofitted the cooling system of the steam condensate water tank in the Suzhou plant. Now, instead of using tap water for cooling, the system uses reverse osmosis drainage from purifying water process, saving two tons of tap water per hour, or 17,280 tons per year, while creating less wastewater.

Other measures to reduce our environmental footprint include encouraging employees to use public transportation for commuting, using LED lights and motion sensors in our offices, turning off lights after meetings, and posting energy and water saving signs and posters in the office areas.

iv. Environmental Key Performance Indicators

Unless otherwise specified, the environmental data below covers the major operations of BeiGene, including our Beijing and Shanghai R&D centers, Suzhou and Guangzhou manufacturing facilities, all office buildings located in China and the Cambridge office in the United States for the period from January 1, 2020 to December 31, 2020. Our Shanghai R&D center was put into service on November 20, 2020, so its data only covers the period from November to December, 2020. Our operations in relation to our offices in other countries are not included due to their relatively small environmental footprint.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

1. Emissions

KPIs	2020
Total GHG emissions (Scope 1 and 2) (tonnes)	27,622.91
Direct GHG emissions (Scope 1) (tonnes)	493.08
Including: Natural gas (tonnes)	493.08
Indirect GHG emissions (Scope 2) (tonnes)	27,129.83
Including: Electricity (tonnes)	17,582.68
Steam (tonnes)	9,547.15
Total GHG emissions per unit of operating income (tonnes/US\$10,000)	0.89
Total SO ₂ emissions (tonnes)	0.08
Total NO _x emissions (tonnes)	1.23
Total VOC emission (tonnes)	0.17
Total hazardous waste (tonnes)	210.44
Hazardous waste per unit of operating income (tonnes/US\$10,000)	0.007
Total non-hazardous waste (tonnes)	672.38
Non-hazardous waste per unit of operating income (tonnes/US\$10,000)	0.022
Wastewater (tonnes)	52,481.01
COD (tonnes)	5.57
Ammonia nitrogen (tonnes)	0.42
Wastewater per unit of operating income (tonnes/US\$10,000)	1.70

Note:

- BeiGene's GHG emissions inventory includes CO₂, CH₄ and N₂O. GHG emissions data is presented in carbon dioxide equivalents and is based on the 2019 Baseline Emission Factors for Regional Power Grids in China for Clean Development Mechanism(CDM) and Chinese Certified Emission Reduction (CCER) issued by the Ministry of Ecology and Environment, the Emissions & Generation Resource Integrated Database (eGRID) 2019 provided by the United States Environmental Protection Agency and the 2006 IPCC Guidelines for National Greenhouse Gas Inventories of the Intergovernmental Panel on Climate Change (2019 revised).
- NO_x emissions and SO₂ emissions are generated by natural gas consumption in the Beijing R&D center, and the Suzhou and Guangzhou plants. VOC emissions mainly include non-methane hydrocarbons generated by VOC solvents used in the Beijing and Shanghai R&D centers, and the Suzhou and Guangzhou plants.
- Hazardous waste mainly includes pharmaceutical waste, organic solvents, etc.
- Non-hazardous waste and the volume of wastewater from the office buildings located in China are estimated based on the Emission Factors Manual of the First National Pollution Source Survey of Urban Pollution. Data from Cambridge office is not included.
- The wastewater generated in construction is not included.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

2. Use of Resources

KPIs	2020
Total energy consumption (MWh)	63,392.08
Direct energy consumption (MWh)	2,439.21
Including: Natural gas (MWh)	2,439.21
Indirect energy consumption (MWh)	60,952.87
Including: Electricity (MWh)	31,286.73
Steam (MWh)	29,666.14
Total energy consumption per unit of operating income (MWh/US\$10,000)	2.05
Total water consumption (tonnes)	319,979.00
Production water consumption (tonnes)	295,957.75
Office water consumption (tonnes)	24,021.25
Water consumption per unit of operating income (tonnes/US\$10,000)	10.36
Recycled water (tonnes)	2,912.00
Total packaging material used for finished products (tonnes)	2.55
Packaging material used per unit of product (tonnes/1,000,000 capsules)	0.27

Note:

- Total energy consumption is calculated based on the total electricity, natural gas and steam consumption and the conversion factors in the PRC National Standards General Principles for Calculation of the Comprehensive Energy Consumption (GB/T 2589-2008).
- Water resources used by the Company come from municipal water supplies. There is no issue in sourcing water. Water consumption of the offices located in China is estimated base on the Design Standard for Water Supply and Drainage of Buildings (GB 50015-2019). The data of the Cambridge office is not included.
- The data of electricity and production water consumption has greatly increased due to the construction of the Guangzhou plant.
- The packaging data solely includes that of the Suzhou plant as our Guangzhou plant has not commenced commercial production in 2020.

ENVIRONMENTAL, SOCIAL AND GOVERNANCE REPORT

VIII. COMMUNITY INVESTMENT

We offer various patient support programs; provide charitable donations to patient advocacy organizations, charitable foundations, industry associations and hospitals; and actively participate in and sponsor academic conferences or seminars to further advances in medicine and healthcare.

i. Patient Support Programs

We provide patient support programs in China and the United States.

In China, we collaborated with charitable foundations to set up the Patient Assistance Programs (“PAP”) to provide eligible low-income patients with access to advanced medical treatment. For example, we have collaborated with China Primary Health Care Foundation and Beijing Health Alliance Charitable Foundation to provide free tislelizumab since March 2020. We also worked with VLove Foundation (“Micro-found”) to provide free zanubrutinib to eligible patients since July 2020.

In the United States, we established a comprehensive patient support program called myBeiGene®, which provides reimbursement and coverage support, copay assistance, and free drug for eligible patients to support access to BRUKINSA®.

ii. Donations and Sponsorship

In 2020, we provided donations to numerous organizations in support of initiatives to improve the lives of patients around the world. There were approximately RMB 2 million in cash donations to non-profit organizations in China, and over US\$450,000 in cash donations to non-profit organizations and foundations in the United States.

We also participate in, and sponsor, many pharmaceutical academic conferences or forums to support scientific exchanges. We have joined the Conquer Cancer Coalition, and donated laptops with a total value of US\$3,150 to the Life Science Cares (LSC), a non-profit organization.

Since the outbreak of the worldwide COVID-19 epidemic, BeiGene has proactively initiated various supporting activities and projects in our community. In January 2020, BeiGene donated medical supplies in the amount of approximately RMB1,000,000 to Wuhan city to support front-line medical workers. We donated more than 73,000 medical masks, more than 16,000 N95 masks, 5,000 sets of protective clothing and approximate 150,000 pairs of medical gloves to support various hospitals in Hubei. In the U.S., BeiGene donated PPE valued at US\$120,000 for hospitals, employees and front-line workers, and in Australia over US\$7,000 worth of donations were made to the Red Cross COVID initiative.

INDEPENDENT AUDITOR'S REPORT

To the shareholders of BeiGene, Ltd.

(Incorporated in the Cayman Islands with limited liability)

Opinion

We have audited the consolidated financial statements of BeiGene, Ltd. (the "Company") and its subsidiaries (the "Group") set out on pages 297 to 392, which comprise the consolidated balance sheets as at December 31, 2020, and the consolidated statements of operations, the consolidated statements of comprehensive loss, the consolidated statements of shareholder's equity and the consolidated statements of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the consolidated financial statements give a true and fair view of the consolidated financial position of the Group as at December 31, 2020, and of its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with U.S. generally accepted accounting principles ("US GAAP") and have been properly prepared in compliance with the disclosure requirements of the Hong Kong Companies Ordinance.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing ("ISAs") issued by the International Auditing and Assurance Standards Board ("IAASB"). Our responsibilities under those standards are further described in the *Auditor's responsibilities for the audit of the consolidated financial statements* section of our report. We are independent of the Group in accordance with the International Ethics Standards Board for Accountants' *Code of Ethics for Professional Accountants* (the "Code"), and we have fulfilled our other ethical responsibilities in accordance with the Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. For each matter below, our description of how our audit addressed the matter is provided in that context.

We have fulfilled the responsibilities described in the *Auditor's responsibilities for the audit of the consolidated financial statements* section of our report, including in relation to these matters. Accordingly, our audit included the performance of procedures designed to respond to our assessment of the risks of material misstatement of the consolidated financial statements. The results of our audit procedures, including the procedures performed to address the matters below, provide the basis for our audit opinion on the accompanying consolidated financial statements.

INDEPENDENT AUDITOR'S REPORT

Key audit matters (Continued)

Key audit matter	How our audit addressed the key audit matter
<i>Accrual of research and development expenses</i>	
<p>During the year ended December 31, 2020, the Company recognized US\$1,294.9 million in research and development (“R&D”) expenses. The balance of accrued external R&D activities related expenses as of December 31, 2020 amounted to approximately US\$143.3 million. As described in Note 2 to the consolidated financial statements, R&D expenses include costs related to clinical trials paid to third-party contract research organizations and contract manufacturing organizations (collectively referred as “Outsourced Service Providers”).</p> <p>Auditing the accrual of R&D expenses related to Outsourced Service Providers is complex because the clinical trial activities with the Outsourced Service Providers are typically performed over an extended period with several milestones for the services in each agreement. As a result, R&D expenses are allocated to each financial reporting period based upon the progress of the clinical trial activities. Determining the progress of the clinical trial activities requires significant estimates and judgment. These estimates are based on several factors, including management’s knowledge of the clinical trial activities associated with timelines, invoicing to date and the provisions in the contracts. Changes in these estimates can have a material effect on the amount of R&D expenses recognized during the reporting period.</p>	<p>We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the accrual of the R&D expenses. For example, we tested controls over management’s review of the R&D accrual method and the estimates of the actual services performed by the Outsourced Service Providers.</p> <p>To test the accrual of R&D expenses, our audit procedures included, among others, reading the contracts with Outsourced Service Providers on a sample basis and understanding and testing the estimates on the progress of clinical trial activities developed by management. Testing management’s estimates involved evaluating management’s assumptions used in the calculation related to the clinical trial activities and associated timelines, invoicing to date and the provisions in the contracts. We then evaluated the accrual of R&D expenses by comparing it to the subsequent progress billings issued by the Outsourced Service Providers. We also assessed the accrual methodology used by the Company, including the adequacy of related disclosures in the consolidated financial statements.</p>

INDEPENDENT AUDITOR'S REPORT

Key audit matters *(Continued)*

Key audit matter	How our audit addressed the key audit matter
<i>Allocation of proceeds received in relation to the Amgen Collaboration and Share Purchase Agreements</i>	
<p>As discussed in Notes 3 and 22 to the consolidated financial statements, the Company entered into a collaboration arrangement and a share purchase agreement with Amgen Inc. (collectively, the “Amgen Agreements”) and pursuant to which, the Company received cash proceeds of US\$2,779.2 million for a 20.5% ownership stake in the Company. The Company determined that the proceeds paid by Amgen also represents a cost share liability due to the Company’s co-development obligations (“R&D cost share liability”) in accordance with ASC 808 – Collaborative Arrangements (“ASC 808”), as the Company and Amgen are both active participants and are exposed to the risks and rewards dependent on the commercial success of the activities performed under the collaboration agreement. The Company allocated the cash proceeds between the equity issued and the R&D cost share liability based on a relative fair value method. On January 2, 2020, the closing date of the Amgen Agreements, the Company recognized US\$2,162.4 million in equity and US\$616.8 million in R&D cost share liability based on the allocation.</p> <p>Auditing the allocation of cash proceeds received in relation to the Amgen Agreements is complex due to the significant estimates and judgments involved in determining the fair values of the equity component and liability component, including assessing the lack of marketability discount and the estimated future cashflows related to R&D activities, respectively. The estimate of future cashflows related to R&D activities involved key assumptions such as revenue growth rates and probability of technical and regulatory success. These significant assumptions are forward looking and could be affected by future economic, regulatory, and market conditions, which in turn led to significant auditor judgment, subjectivity and effort in performing procedures to evaluate audit evidence for these estimates.</p>	<p>We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the allocation of cash proceeds received in relation to the Amgen Agreements. For example, we tested controls over management’s review of the significant assumptions used in determining estimated future cashflows and the fair values of the equity issued and the R&D cost share liability.</p> <p>To test the allocation of the cash proceeds received in relation to the Amgen Agreements, our audit procedures included, among others, evaluating the valuation methodologies, comparable companies and discount rate used by management to determine the fair values of equity issued and the R&D cost share liability, with the assistance of our internal valuation specialist. We tested the significant underlying assumptions and the completeness and accuracy of the underlying data used by the Company in developing its estimated future cashflows, including revenue growth rates and probability of technical and regulatory success. We compared these significant assumptions to current market trends, industry data, and current clinical stages of the pipeline assets. We also performed sensitivity analysis by assessing the changes to the fair value of the equity and liability components resulting from changes in the lack of marketability discount and probability of technical and regulatory success. In addition, we assessed the related disclosures in the consolidated financial statements.</p>

INDEPENDENT AUDITOR'S REPORT

Other information included in the Annual Report

The directors of the Company are responsible for the other information. The other information comprises the information included in the Annual Report, other than the consolidated financial statements and our auditor's report thereon.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the directors for the consolidated financial statements

The directors of the Company are responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with US GAAP and the disclosure requirements of the Hong Kong Companies Ordinance, and for such internal control as the directors determine is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the directors of the Company are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors of the Company either intend to liquidate the Group or to cease operations or have no realistic alternative but to do so.

The directors of the Company are assisted by the Audit Committee in discharging their responsibilities for overseeing the Group's financial reporting process.

Auditor's responsibilities for the audit of the consolidated financial statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Our report is made solely to you, as a body, and for no other purpose. We do not assume responsibility towards or accept liability to any other person for the contents of this report.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

INDEPENDENT AUDITOR'S REPORT

Auditor's responsibilities for the audit of the consolidated financial statements *(Continued)*

As part of an audit in accordance with ISAs, we exercise professional judgement and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the directors.
- Conclude on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the Audit Committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Audit Committee with a statement that we have complied with relevant ethical requirements regarding independence and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

INDEPENDENT AUDITOR'S REPORT

Auditor's responsibilities for the audit of the consolidated financial statements *(Continued)*

From the matters communicated with the Audit Committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

The engagement partner on the audit resulting in this independent auditor's report is Denis Ming Kui Cheng.

Ernst & Young

Certified Public Accountants

Hong Kong

March 30, 2021

CONSOLIDATED BALANCE SHEETS

	Note	As of December 31,	
		2020	2019
		US\$'000	US\$'000
Assets			
Current assets:			
Cash and cash equivalents		1,381,950	618,011
Short-term restricted cash	5	307	288
Short-term investments	6	3,268,725	364,728
Accounts receivable, net	7	60,403	70,878
Inventories	8	89,293	28,553
Prepaid expenses and other current assets	14	<u>160,012</u>	<u>90,238</u>
Total current assets		<u>4,960,690</u>	<u>1,172,696</u>
Non-current assets:			
Long-term restricted cash	5	7,748	2,476
Property, plant and equipment, net	11	357,686	242,402
Operating lease right-of-use assets	10	90,581	82,520
Intangible assets, net	12	5,000	5,846
Deferred tax assets	13	65,962	37,894
Other non-current assets	14	<u>113,090</u>	<u>68,455</u>
Total non-current assets		<u>640,067</u>	<u>439,593</u>
Total assets		<u>5,600,757</u>	<u>1,612,289</u>
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable	15	231,957	122,488
Accrued expenses and other payables	14	346,144	163,556
Tax payable	13	20,380	13,454
Operating lease liabilities, current portion	10	13,895	10,814
Research and development cost share liability, current portion	3	127,808	–
Short-term debt	16	<u>335,015</u>	<u>–</u>
Total current liabilities		<u>1,075,199</u>	<u>310,312</u>

CONSOLIDATED BALANCE SHEETS *(Continued)*

		As of December 31,	
	Note	2020	2019
		US\$' 000	US\$' 000
Non-current liabilities:			
Long-term bank loans	16	183,637	83,311
Shareholder loan	16	–	157,384
Operating lease liabilities, non-current portion	10	29,417	25,833
Deferred tax liabilities	13	10,792	10,532
Research and development cost share liability, non-current portion	3	375,040	–
Other long-term liabilities	14	57,429	46,562
		<u>656,315</u>	<u>323,622</u>
Total non-current liabilities			
		<u>656,315</u>	<u>323,622</u>
Total liabilities		<u>1,731,514</u>	<u>633,934</u>
Commitments and contingencies	25		
Equity:			
Ordinary shares, US\$0.0001 par value per share; 9,500,000,000 shares authorized; 1,190,821,941 and 801,340,698 shares issued and outstanding as of December 31, 2020 and 2019, respectively		118	79
Additional paid-in capital		7,414,932	2,925,970
Accumulated other comprehensive income (loss)	21	6,942	(8,001)
Accumulated deficit		<u>(3,552,749)</u>	<u>(1,955,843)</u>
Total BeiGene, Ltd. shareholders' equity		<u>3,869,243</u>	<u>962,205</u>
Noncontrolling interest	9	–	16,150
		<u>–</u>	<u>16,150</u>
Total equity		<u>3,869,243</u>	<u>978,355</u>
Total liabilities and equity		<u>5,600,757</u>	<u>1,612,289</u>

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF OPERATIONS

		Year Ended December 31,	
	Note	2020 US\$' 000	2019 US\$' 000
Revenues			
Product revenue, net	17	308,874	222,596
Collaboration revenue	3	—	205,616
Total revenues		308,874	428,212
Expenses			
Cost of sales – product		70,657	71,190
Research and development		1,294,877	927,338
Selling, general and administrative		600,176	388,249
Amortization of intangible assets	12	846	1,326
Total expenses		1,966,556	1,388,103
Loss from operations		(1,657,682)	(959,891)
Interest income, net		1,998	9,131
Other income, net	6	37,490	7,174
Loss before income taxes		(1,618,194)	(943,586)
Income tax (benefit) expense	13	(17,671)	6,992
Net loss		(1,600,523)	(950,578)
Less: net loss attributable to noncontrolling interests		(3,617)	(1,950)
Net loss attributable to BeiGene, Ltd.		(1,596,906)	(948,628)
Net loss per share attributable to BeiGene, Ltd.,			
basic and diluted (in US\$)	19	(1.47)	(1.22)
Weighted-average shares outstanding, basic and diluted	19	1,085,131,783	780,701,283
Net loss per American Depositary Share (“ADS”),			
basic and diluted (in US\$)		(19.13)	(15.80)
Weighted-average ADSs outstanding, basic and diluted		83,471,676	60,053,945

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year Ended December 31,	
		2020 US\$' 000	2019 US\$' 000
Net loss		(1,600,523)	(950,578)
Other comprehensive income (loss), net of tax of nil:			
Foreign currency translation adjustments	21	23,603	(9,424)
Pension liability adjustments	24	(8,113)	–
Unrealized holding loss, net	21	<u>(419)</u>	<u>(448)</u>
Comprehensive loss		<u>(1,585,452)</u>	<u>(960,450)</u>
Less: comprehensive loss attributable to noncontrolling interests		<u>(3,489)</u>	<u>(2,295)</u>
Comprehensive loss attributable to BeiGene, Ltd.		<u><u>(1,581,963)</u></u>	<u><u>(958,155)</u></u>

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Note	Year Ended December 31,	
		2020	2019
		US\$' 000	US\$' 000
Cash flows from operating activities:			
Net loss		(1,600,523)	(950,578)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense		31,789	18,617
Share-based compensation expense	20	183,481	134,154
Acquired in-process research and development		109,500	69,000
Amortization of research and development cost share liability	3	(113,986)	–
Unrealized gains on equity investments	6	(11,826)	–
Gain on deconsolidation of a subsidiary	6	(11,307)	–
Deferred income tax benefits		(27,807)	(9,232)
Other items, net		6,634	(1,397)
Changes in operating assets and liabilities:			
Accounts receivable		10,363	(29,822)
Inventories		(58,906)	(12,311)
Prepaid expenses and other current assets		(65,528)	45
Other non-current assets		9,311	(20,782)
Accounts payable		95,835	2,224
Accrued expenses and other payables		182,693	64,030
Tax payable		2,319	7,566
Deferred revenue		–	(27,982)
Operating lease liabilities		(102)	(2,283)
Other long-term liabilities		(25,401)	8,482
		<u>(1,283,461)</u>	<u>(750,269)</u>
Net cash used in operating activities		<u>(1,283,461)</u>	<u>(750,269)</u>
Cash flows from investing activities:			
Purchases of property and equipment		(117,508)	(89,612)
Deconsolidation of a subsidiary		(2,025)	–
Purchases of investments		(5,690,408)	(1,169,300)
Proceeds from sale or maturity of investments		2,751,075	1,882,075
Purchase of in-process research and development		(109,500)	(69,000)
		<u>(3,168,366)</u>	<u>554,163</u>
Net cash (used in) provided by investing activities		<u>(3,168,366)</u>	<u>554,163</u>

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF CASH FLOWS *(Continued)*

	Note	Year Ended December 31,	
		2020 US\$' 000	2019 US\$' 000
Cash flows from financing activities:			
Proceeds from sale of ordinary shares, net of cost	22	4,232,017	–
Proceeds from research and development cost share liability	3	616,834	–
Payment to acquire joint venture (“JV”) minority interest	9	(28,723)	–
Proceeds from loans	16	433,905	67,489
Repayment of loans	16	(144,308)	(32,813)
Capital contribution from noncontrolling interest		–	4,000
Proceeds from option exercises and employee share purchase plan		<u>93,101</u>	<u>47,004</u>
Net cash provided by financing activities		<u>5,202,826</u>	<u>85,680</u>
Effect of foreign exchange rate changes, net		<u>18,231</u>	<u>(9,512)</u>
Net increase (decrease) in cash, cash equivalents, and restricted cash		769,230	(119,938)
Cash, cash equivalents, and restricted cash, beginning of year		<u>620,775</u>	<u>740,713</u>
Cash, cash equivalents, and restricted cash, end of year		<u><u>1,390,005</u></u>	<u><u>620,775</u></u>
Supplemental cash flow disclosures:			
Cash and cash equivalents		1,381,950	618,011
Short-term restricted cash		307	288
Long-term restricted cash		7,748	2,476
Income taxes paid		10,596	8,984
Interest paid		44,130	4,315
Supplemental non-cash activities:			
Acquisitions of equipment included in accounts payable		42,762	29,086

The accompanying notes are an integral part of these consolidated financial statements.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

	Attributable to BeiGene, Ltd.							
	Ordinary Shares		Accumulated			Non-Controlling Interests		Total
			Additional Paid-In Capital	Other Comprehensive Income/(Loss)	Accumulated Deficit			
	Shares	Amount	Capital	Income/(Loss)	Deficit	US\$' 000	US\$' 000	US\$' 000
		US\$' 000	US\$' 000	US\$' 000	US\$' 000	US\$' 000	US\$' 000	US\$' 000
Balance at December 31, 2018	776,263,184	77	2,744,814	1,526	(1,007,215)	1,739,202	14,445	1,753,647
Contributions from shareholders	-	-	-	-	-	-	4,000	4,000
Exercise of options, ESPP and release of RSUs	20,571,675	2	47,002	-	-	47,004	-	47,004
Issuance of shares reserved for share option exercises	4,505,839	-	-	-	-	-	-	-
Share-based compensation	-	-	134,154	-	-	134,154	-	134,154
Other comprehensive loss	-	-	-	(9,527)	-	(9,527)	(345)	(9,872)
Net loss	-	-	-	-	(948,628)	(948,628)	(1,950)	(950,578)
Balance at December 31, 2019	801,340,698	79	2,925,970	(8,001)	(1,955,843)	962,205	16,150	978,355
Proceeds from issuance of ordinary shares, net of cost	145,838,979	14	2,069,596	-	-	2,069,610	-	2,069,610
Issuance of ordinary shares in connection with collaboration	206,635,013	21	2,162,386	-	-	2,162,407	-	2,162,407
Exercise of options, ESPP and release of RSUs	38,020,892	3	93,098	-	-	93,101	-	93,101
Use of shares reserved for share option exercises and RSU releases	(1,013,641)	1	-	-	-	1	-	1
Share-based compensation	-	-	183,481	-	-	183,481	-	183,481
Deconsolidation of a subsidiary	-	-	-	-	-	-	(3,545)	(3,545)
Acquisition of joint venture ("JV") minority interest	-	-	(19,599)	-	-	(19,599)	(9,116)	(28,715)
Other comprehensive income	-	-	-	14,943	-	14,943	128	15,071
Net loss	-	-	-	-	(1,596,906)	(1,596,906)	(3,617)	(1,600,523)
Balance at December 31, 2020	1,190,821,941	118	7,414,932	6,942	(3,552,749)	3,869,243	-	3,869,243

The accompanying notes are an integral part of these consolidated financial statements.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION

BeiGene, Ltd. (the “Company”, “BeiGene”, “it”, “its”) is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and expand access for patients worldwide.

The Company has delivered ten molecules into the clinic in its first ten years, including its two lead commercial medicines, BRUKINSA[®], a small molecule inhibitor of BTK for the treatment of various blood cancers, and tislelizumab, an anti-PD-1 antibody immunotherapy for the treatment of various solid tumor and blood cancers. The Company is marketing BRUKINSA[®] in the world’s two largest pharmaceutical markets, the United States (“U.S.” or “US”) and The People’s Republic of China (the “PRC” or “China”), and tislelizumab in China, with an established, science-based commercial organization. The Company has built state-of-the-art biologic and small molecule manufacturing facilities in China to support the potential future demand of its products, and it also works with high quality CMOs to manufacture its internally developed clinical and commercial products.

The Company is a leader in China-inclusive global clinical development, which it believes can facilitate faster and more cost-effective development of innovative medicines. Its internal clinical development capabilities are deep, including a more than 1,600-person global clinical development team that is running more than 60 ongoing or planned clinical trials. This includes more than 25 pivotal or registration-enabling trials for three product candidates that have enrolled more than 12,000 patients and healthy volunteers, of which approximately one-half have been outside of China, as of January 2021. The Company has over 45 products and product candidates in commercial stage or clinical development, including 7 approved medicines, 5 pending approval, and over 30 in clinical development.

Supported by its development and commercial capabilities, the Company has entered into collaborations with world-leading biopharmaceutical companies such as Amgen Inc. (“Amgen”) and Novartis Pharma AG (“Novartis”) to develop, manufacture and commercialize innovative medicines globally. Since its inception in 2010 in Beijing, the Company has become a fully integrated global organization of approximately 5,300 employees in 14 countries and regions, including China, the U.S., Europe and Australia.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION *(Continued)*

As of December 31, 2020, the Company's subsidiaries are as follows:

Name of Company	Place of Incorporation	Particulars of issued/paid-in capital	Percentage of Ownership by the Company	Principal Activities and Place of Operation
BeiGene 101	Cayman Islands	nil	100%	Inactive
BeiGene Aus Pty Ltd ("BeiGene Australia")	Australia	US\$56,947,230	100%	Medical, pharmaceutical research and development and commercial, Australia
BeiGene (Beijing) Co., Ltd. ("BeiGene Beijing")	PRC*	US\$46,711,000	100%	Medical and pharmaceutical research and development, PRC
BeiGene Biologics Co., Ltd. ("BeiGene Biologics")	PRC*	RMB2,000,000,000	100%	Medical and pharmaceutical research and development and manufacturing, PRC
BeiGene (Canada) ULC	Canada	CAD 100	100%	Medical, pharmaceutical research and development and commercial, Canada
BeiGene ESP, S.L.	Spain	EUR 3,000	100%	Medical, pharmaceutical research and development and commercial, Spain
BeiGene France Sarl	France	EUR 7,500	100%	Medical, pharmaceutical research and development and commercial, France
BeiGene Guangzhou Biologics Manufacturing Co., Ltd. ("BeiGene Guangzhou Factory")	PRC*	RMB1,000,000,000	100%	Medical and pharmaceutical research and development and manufacturing, PRC
BeiGene (Guangzhou) Co., Ltd. ("BeiGene Guangzhou")	PRC*	US\$238,000,000	100%	Medical and pharmaceutical research, PRC
BeiGene Germany GmbH	Germany	EUR 25,000	100%	Medical, pharmaceutical research and development and commercial, Germany
BeiGene (Hong Kong) Co., Limited. ("BeiGene HK")	Hong Kong, China	HK\$1	100%	Investment holding
Beijing Innerway Bio-tech Co., Ltd. ("Innerway")	PRC*	US\$4,000,000	100%	No substantial business, holding property for company operations
BeiGene (Italy) Sarl	Italy	EUR 10,000	100%	Medical, pharmaceutical research and development and commercial, Italy
BeiGene Ireland Limited ("BeiGene Ireland")	Republic of Ireland	-	100%	Medical, pharmaceutical research and development and commercial, Republic of Ireland
BeiGene Korea Y.H.	South Korea	KRW 100,000,000	100%	Medical, pharmaceutical research and development and commercial, South Korea
BeiGene Pharmaceuticals (Guangzhou) Co., Ltd. ("BeiGene Pharmaceutical (Guangzhou)")	PRC*	RMB3,800,000	100%	Medical and pharmaceutical research, PRC

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. ORGANIZATION (Continued)

Name of Company	Place of Incorporation	Particulars of issued/paid-in capital	Percentage of Ownership by the Company	Principal Activities and Place of Operation
BeiGene Pharmaceutical (Shanghai) Co., Ltd. ("BeiGene Pharmaceutical (Shanghai)")	PRC*	US\$1,000,000	100%	Medical and pharmaceutical consulting, marketing and promotional services, PRC
BeiGene (Shanghai) Co., Ltd. ("BeiGene Shanghai")	PRC*	RMB34,344,310	100%	Medical and pharmaceutical research and development, PRC
BeiGene Singapore Pte., Ltd.	Singapore	SGD 1	100%	Medical, pharmaceutical research and development and commercial, Singapore
BeiGene (Suzhou) Co., Ltd. ("BeiGene Suzhou")	PRC*	US\$144,000,000	100%	Medical and pharmaceutical research and manufacturing, PRC
BeiGene Switzerland GmbH ("BeiGene Switzerland")	Switzerland	CHF 20,000	100%	Medical, pharmaceutical research and development and commercial, Switzerland
BeiGene (Taiwan) Limited	Taiwan, China	TWD 500,000	100%	Medical, pharmaceutical research and development and commercial, Taiwan, China
BeiGene UK, Ltd. ("BeiGene UK")	United Kingdom	GBP 120	100%	Research, development, manufacture and distribution or licensing of pharmaceutical, and related products, United Kingdom
BeiGene United Kingdom, Ltd.	United Kingdom	GBP 100	100%	Investment holding
BeiGene USA, Inc. ("BeiGene USA")	U.S.	US\$1	100%	Medical, pharmaceutical research and development and commercial, U.S.
BeiGene International GmbH	Switzerland	CHF 20,000	100%	Medical, pharmaceutical research and development and commercial, Switzerland
BeiGene (Shanghai) Research & Development Co., Ltd.	PRC*	RMB70,000,000	100%	Medical and pharmaceutical research and development, PRC
BeiGene NZ, Limited	New Zealand	-	100%	Medical, pharmaceutical research and development and commercial, New Zealand
BeiGene Pharmaceuticals GmbH	Switzerland	CHF20,000	100%	Medical, pharmaceutical research and development and commercial, Switzerland

* Limited liability company established in PRC

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”). The consolidated financial statements include the financial statements of the Company and its subsidiaries. All significant intercompany transactions and balances between the Company and its wholly-owned subsidiaries are eliminated upon consolidation.

Noncontrolling interests are recognized to reflect the portion of the equity of subsidiaries which are not attributable, directly or indirectly, to the controlling shareholders. Prior to 2020, the Company consolidated its interests in its joint ventures, BeiGene Biologics Co., Ltd. (“BeiGene Biologics”) and MapKure, LLC (“MapKure”), under the voting model and recognized the minority shareholders’ equity interest as a noncontrolling interest in its consolidated financial statements. In June 2020, the Company deconsolidated MapKure and recorded an equity method investment for its remaining ownership interest in the joint venture (see Note 6). In November 2020, the Company acquired the remaining equity interest in BeiGene Biologics. Subsequent to the share purchase, BeiGene Biologics is a wholly owned subsidiary of the Company (see Note 9).

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the period. Areas where management uses subjective judgment include, but are not limited to, estimating the useful lives of long-lived assets, estimating variable consideration in product sales and collaboration revenue arrangements, identifying separate accounting units and the standalone selling price of each performance obligation in the Company’s revenue arrangements, estimating the fair value of net assets acquired in business combinations, assessing the impairment of long-lived assets, valuation and recognition of share-based compensation expenses, realizability of deferred tax assets, estimating uncertain tax positions, valuation of inventory, estimating the allowance for credit losses, determining defined benefit pension plan obligations, measurement of right-of-use assets and lease liabilities and the fair value of financial instruments. Management bases the estimates on historical experience, known trends and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Functional Currency and Foreign Currency Translation

Functional currency

The Company uses the United States dollar (“US\$” or “U.S. dollar”) as its reporting currency. Operations in subsidiaries are recorded in the functional currency of the respective subsidiary. The determination of functional currency is based on the criteria of Accounting Standard Codification (“ASC”) 830, *Foreign Currency Matters*.

Foreign currency translation

For subsidiaries whose functional currencies are not the U.S. dollar, the Company uses the average exchange rate for the year and the exchange rate at the balance sheet date, to translate the operating results and financial position to U.S. dollar, the reporting currency, respectively. Translation differences are recorded in accumulated other comprehensive loss, a component of shareholders’ equity. Transactions denominated in currencies other than the functional currency are translated into the functional currency at the exchange rates prevailing on the transaction dates. Foreign currency denominated financial assets and liabilities are remeasured at the exchange rates prevailing at the balance sheet date. Exchange gains and losses are included in the consolidated statements of comprehensive loss.

Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents

Cash and cash equivalents consist of cash on hand and bank deposits, which are unrestricted as to withdrawal and use. The Company considers all highly liquid investments with an original maturity date of three months or less at the date of purchase to be cash equivalents. Cash equivalents which consist primarily of money market funds are stated at fair value.

Restricted cash

Restricted cash primarily consists of RMB-denominated cash deposits pledged in designated bank accounts as collateral for bank loans and letters of credit. The Company classifies restricted cash as current or non-current based on the term of the restriction.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Accounts Receivable and Allowance for Credit Losses

Trade accounts receivable are recorded at their invoiced amounts, net of trade discounts and allowances as well as an allowance for credit losses. The allowance for credit losses reflects the Company's current estimate of credit losses expected to be incurred over the life of the receivables. The Company considers various factors in establishing, monitoring, and adjusting its allowance for credit losses including the aging of receivables and aging trends, customer creditworthiness and specific exposures related to particular customers. The Company also monitors other risk factors and forward-looking information, such as country specific risks and economic factors that may affect a customer's ability to pay in establishing and adjusting its allowance for credit losses. Accounts receivable are written off after all collection efforts have ceased.

Inventory

Prior to the regulatory approval of product candidates, the Company may incur expenses for the manufacture of drug product to support the commercial launch of those products. Until the date at which regulatory approval has been received or is otherwise considered probable, all such costs are recorded as research and development expenses as incurred.

Inventories are stated at the lower of cost and net realizable value, with cost determined in a manner that approximates the first-in, first-out method. The Company periodically analyzes its inventory levels, and writes down inventory that has become obsolete, inventory that has a cost basis in excess of its estimated realizable value and inventory in excess of expected sales requirements as cost of product sales. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required, which would be recorded in the consolidated statements of operations.

Investments

The Company's investments consist of available-for-sale debt securities, public equity securities with readily determinable fair values, private equity securities without readily determinable fair values, and equity-method investments. The classification of an investment is determined based on the nature of the investment, the Company's ability and intent to hold the investment, and the degree to which the Company may exercise influence over the investee.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Investments (Continued)

- Available-for-sale debt securities are stated at fair value, with the unrealized gains and losses, net of tax, reported in other comprehensive loss. The net carrying value of debt securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is computed using the effective interest method and included in interest income. Interest and dividends are included in interest income. Available-for-sale debt securities with original maturities greater than three months at the date of purchase and less than one year from the date of the balance sheet are classified as short-term. Available-for-sale debt securities with maturities beyond one year may be classified as short-term marketable securities due to their highly liquid nature and because they represent the Company's investments that are available for current operations.
- Public equity securities with readily determinable fair values are recorded at fair value. Subsequent changes in fair value are recorded in other income, net. Derivative financial instruments to purchase public equity securities are recorded at fair value. The estimated fair value of derivative financial instruments is determined based on the Black-Scholes valuation model. Changes in fair value of derivative instruments are recorded in other income, net.
- Private equity securities without readily determinable fair values and where the Company does not have significant influence are measured at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Adjustments to private equity securities are recorded in other income, net.
- Equity investments in common stock or in-substance common stock where the Company has significant influence over the financial and operating policies of the investee are accounted for as equity-method investments. Equity-method investments are initially recorded at cost and subsequently adjusted based on the Company's percentage ownership in the investee's income and expenses, as well as dividends, if any. The Company records its share of the investee's results of operations in other income, net. The Company records impairment losses on our equity method investments if it deems the impairment to be other-than-temporary. The Company deems an impairment to be other-than-temporary based on various factors, including but not limited to, the length of time the fair value is below the carrying value and ability to retain the investment to allow for a recovery in fair value.

Realized gains or losses on sales of investments are determined based on the specific identification method.

The Company regularly evaluates its investments in debt and equity for impairment. The Company recognizes an allowance on available-for-sale debt securities when a portion of the unrealized loss is attributable to a credit loss and a corresponding credit loss in net income. No impairment losses or allowance for credit losses on investments were recorded for any periods presented.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets as follows:

	Useful Lives
Building	20 years
Manufacturing equipment	3 to 10 years
Laboratory Equipment	3 to 5 years
Software, Electronic and Office Equipment	3 to 5 years
Leasehold Improvements	Lesser of useful life or lease term

Leases

Effective January 1, 2019, the Company adopted ASC, Topic 842, *Leases* ("ASC 842") using the effective date method. The Company determines if an arrangement is a lease at inception. The Company has lease agreements with lease and non-lease components, which are accounted for as a single lease component based on the Company's policy election to combine lease and non-lease components for its leases. Leases are classified as operating or finance leases in accordance with the recognition criteria in ASC 842-20-25. The Company's lease portfolio consists entirely of operating leases as of December 31, 2020. The Company's leases do not contain any material residual value guarantees or material restrictive covenants.

At the commencement date of a lease, the Company determines the classification of the lease based on the relevant factors present and records a right-of-use ("ROU") asset and lease liability. ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. ROU assets and lease liabilities are calculated as the present value of the lease payments not yet paid. Variable lease payments not dependent on an index or rate are excluded from the ROU asset and lease liability calculations and are recognized in expense in the period which the obligation for those payments is incurred. As the rate implicit in the Company's leases is not typically readily available, the Company uses an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. This incremental borrowing rate reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. ROU assets include any lease prepayments and are reduced by lease incentives. Operating lease expense for lease payments is recognized on a straight-line basis over the lease term. Lease terms are based on the non-cancelable term of the lease and may contain options to extend the lease when it is reasonably certain that the Company will exercise that option.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Leases (Continued)

Operating leases are included in operating lease right-of-use assets and operating lease liabilities on the consolidated balance sheet. Lease liabilities that become due within one year of the balance sheet date are classified as current liabilities.

Leases with an initial lease term of 12 months or less are not recorded on the consolidated balance sheet. Lease expense for these leases is recognized on a straight-line basis over the lease term.

Land Use Right, Net

All land in the PRC is owned by the PRC government. The PRC government may sell land use rights for a specified period of time. Land use rights represent operating leases in accordance with ASC 842. The purchase price of land use rights represents lease prepayments to the PRC government and is recorded as an operating lease ROU asset on the balance sheet. The ROU asset is amortized over the remaining lease term.

In 2017, the Company acquired a land use right from the local Bureau of Land and Resources in Guangzhou for the purpose of constructing and operating the biologics manufacturing facility in Guangzhou. In 2019, the Company acquired a second Guangzhou land use right from the local Bureau of Land and Resources in Guangzhou. Both Guangzhou land use rights are being amortized over the respective terms of the land use rights, which are each 50 years.

In 2018, the Company acquired a land use right in conjunction with the Innerway asset acquisition (see Note 4). The land use right is being amortized over the term of the land use right, which is 36 years.

In 2020, the Company acquired a land use right from the local Bureau of Land and Resources in Suzhou to expand its research, development and manufacturing facility in Suzhou. The land use right is being amortized over the term of the land use right, which is 30 years.

Business Combinations

The Company accounts for its business combinations using the acquisition method of accounting in accordance with ASC topic 805 ("ASC 805"): *Business Combinations*. The acquisition method of accounting requires all of the following steps: (i) identifying the acquirer, (ii) determining the acquisition date, (iii) recognizing and measuring the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree, and (iv) recognizing and measuring goodwill or a gain from a bargain purchase. The consideration transferred in a business combination is measured as the aggregate of the fair values at the date of exchange of the assets given, liabilities incurred, and equity instruments issued as well as the contingent considerations and all contractual contingencies as of the acquisition date.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Business Combinations *(Continued)*

The costs directly attributable to the acquisition are expensed as incurred. Identifiable assets, liabilities and contingent liabilities acquired or assumed are measured separately at their fair value as of the acquisition date, irrespective of the extent of any noncontrolling interests. The excess of (i) acquisition consideration, fair value of the noncontrolling interests and acquisition date fair value of any previously held equity interest in the acquiree over (ii) the fair value of the identifiable net assets of the acquiree, is recorded as goodwill. If the cost of acquisition is less than the fair value of the net assets of the subsidiary acquired, the difference is recognized directly in the consolidated statements of operations as a gain.

The Company allocates the fair value of purchase consideration to the tangible assets acquired, liabilities assumed and intangible assets acquired based on their estimated fair values. The excess of the fair value of purchase consideration over the fair values of these identifiable assets and liabilities is recorded as goodwill. Such valuations require management to make significant estimates and assumptions, especially with respect to intangible assets. Significant estimates in valuing certain intangible assets may include, but are not limited to, future expected cash flows from acquired assets, timing and probability of success of clinical events and regulatory approvals, and assumptions on useful lives and discount rates. Management's estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Additional information, such as that related to income tax and other contingencies, existing as of the acquisition date but unknown to us may become known during the remainder of the measurement period, not to exceed one year from the acquisition date, which may result in changes to the amounts and allocations recorded.

Acquisitions that do not meet the accounting definition of a business combination are accounted for as asset acquisitions. For transactions determined to be asset acquisitions, the Company allocates the total cost of the acquisition, including transaction costs, to the net assets acquired based on their relative fair values.

Goodwill and Other Intangible Assets

Goodwill is an asset representing the future economic benefits arising from other assets acquired in a business combination that are not individually identified and separately recognized. The Company allocates the cost of an acquired entity to the assets acquired and liabilities assumed based on their estimated fair values at the date of acquisition. The excess of the purchase price for acquisitions over the fair value of the net assets acquired, including other intangible assets, is recorded as goodwill. Goodwill is not amortized, but is tested for impairment at least annually or more frequently if events or changes in circumstances would indicate a potential impairment.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Goodwill and Other Intangible Assets *(Continued)*

The Company has elected to first assess qualitative factors to determine whether it is more likely than not that the fair value of the Company's reporting unit is less than its carrying amount, including goodwill. The qualitative assessment includes the Company's evaluation of relevant events and circumstances affecting the Company's single reporting unit, including macroeconomic, industry, and market conditions, the Company's overall financial performance, and trends in the market price of the Company's ADSs. If qualitative factors indicate that it is more likely than not that the Company's reporting unit's fair value is less than its carrying amount, then the Company will perform the quantitative impairment test by comparing the reporting unit's carrying amount, including goodwill, to its fair value. If the carrying amount of the reporting unit exceeds its fair value, an impairment loss will be recognized in an amount equal to that excess. For the years ended December 31, 2020 and 2019, the Company determined that there were no indicators of impairment of goodwill.

Intangible assets acquired through business combinations are recognized as assets separate from goodwill and are measured at fair value upon acquisition. Intangible assets acquired in transactions that are not business combinations are recorded at the allocated portion of total consideration transferred based on their relative fair value in relation to net assets acquired. Acquired identifiable intangible assets consist of distribution rights for approved cancer therapies licensed from BMS, and are amortized on a straight-line basis over the estimated useful lives of the assets, which is 10 years, and the trading license which represents the Guangzhou drug distribution license acquired in September 2018 (see Note 4). The Company amortized the trading license over the remainder of the initial license term through February 2020.

Intangible assets with finite useful lives are tested for impairment when events or circumstances occur that could indicate that the carrying amount of an asset may not be recoverable. When these events occur, the Company evaluates the recoverability of the intangible assets by comparing the carrying amount of the assets to the future undiscounted cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected undiscounted cash flows is less than the carrying amount of the assets, the Company recognizes an impairment loss based on the excess of the carrying amount of the assets over their fair value. Fair value is generally determined by discounting the cash flows expected to be generated by the assets, when the market prices are not readily available. For the years ended December 31, 2020 and 2019, the Company determined that there were no indicators of impairment of its other intangible assets.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Impairment of Long-Lived Assets

Long-lived assets are reviewed for impairment in accordance with authoritative guidance for impairment or disposal of long-lived assets. Long-lived assets are reviewed for events or changes in circumstances, which indicate that their carrying value may not be recoverable. Long-lived assets are reported at the lower of carrying amount or fair value less cost to sell. For the years ended December 31, 2020 and 2019, there was no impairment of the value of the Company's long-lived assets.

Fair Value Measurements

Fair value of financial instruments

The Company applies ASC topic 820 ("ASC 820"), *Fair Value Measurements and Disclosures*, in measuring fair value. ASC 820 defines fair value, establishes a framework for measuring fair value and requires disclosures to be provided on fair value measurement. ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 – Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 – Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Fair Value Measurements *(Continued)*

Financial instruments measured at fair value on a recurring basis

The following tables set forth assets measured at fair value on a recurring basis as of December 31, 2020 and 2019:

	Quoted Price in Active Market for Identical Assets (Level 1) US\$' 000	Significant Other Observable Inputs (Level 2) US\$' 000	Significant Unobservable Inputs (Level 3) US\$' 000
As of December 31, 2020			
Cash equivalents			
U.S. treasury securities	286,072	–	–
Money market funds	80,838	–	–
Short-term investments (Note 6):			
U.S. treasury securities	3,268,725	–	–
Other non-current assets (Note 6):			
Equity securities with readily determinable fair values	<u>10,810</u>	<u>6,669</u>	<u>–</u>
Total	<u>3,646,445</u>	<u>6,669</u>	<u>–</u>
As of December 31, 2019			
Cash equivalents			
U.S. treasury securities	16,442	–	–
Money market funds	50,461	–	–
Short-term investments (Note 6):			
U.S. treasury securities	<u>364,728</u>	<u>–</u>	<u>–</u>
Total	<u>431,631</u>	<u>–</u>	<u>–</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Fair Value Measurements *(Continued)*

Financial instruments measured at fair value on a recurring basis (Continued)

The Company's cash equivalents are highly liquid investments with original maturities of 3 months or less. Short-term investments represent the Company's investments in available-for-sale debt securities. The Company determines the fair value of cash equivalents and available-for-sale debt securities using a market approach based on quoted prices in active markets.

The Company's equity securities carried at fair value consist of holdings in common stock and warrants to purchase additional shares of common stock of Leap Therapeutics, Inc. ("Leap"), which were acquired in connection with a collaboration and license agreement entered into in January 2020. The common stock investment in Leap, a publicly-traded biotechnology company, is measured and carried at fair value and classified as Level 1. The warrants to purchase additional shares of common stock in Leap are classified as a Level 2 investment and are measured using the Black-Scholes option-pricing valuation model, which utilizes a constant maturity risk-free rate and reflects the term of the warrants, dividend yield and stock price volatility, that is based on the historical volatility of similar companies. Refer to Note 2, *Investments* for details of the determination of the carrying amount of private equity investments without readily determinable fair values and equity method investments.

As of December 31, 2020 and 2019, the fair values of cash and cash equivalents, restricted cash, accounts receivable, accounts payable, and short-term debt approximated their carrying values due to their short-term nature. Long-term bank loans and the Shareholder Loan approximate their fair value due to the fact that the related interest rates approximate the rates currently offered by financial institutions for similar debt instrument of comparable maturities.

Revenue Recognition

Effective January 1, 2018, the Company adopted ASC, Topic 606, *Revenue from Contracts with Customers* ("ASC 606") using the modified retrospective method.

Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Revenue Recognition *(Continued)*

Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Product Revenue

The Company generates product revenues in China through the sale of its internally developed drugs tislelizumab and BRUKINSA[®], and the sale of in-licensed products in China through its agreements with Amgen and BMS. Under the commercial profit share arrangement with Amgen, the Company is the principal for in-licensed product sales to customers in China during the commercialization period and recognizes 100% of net product revenue on these sales. Amounts due to Amgen for its portion of net product sales are recorded as cost of sales. In the United States, the Company generates product revenues from the sale of BRUKINSA[®].

In China, the Company sells its internally developed products to multiple distributors, who in turn sells the product to hospitals or pharmacies within their authorized territories to be sold ultimately to patients. In-licensed products are sold to a first tier distributor who subsequently resells the products to second tier distributors who ultimately sell the products to health care providers and patients. In the United States, the Company distributes BRUKINSA[®] through specialty pharmacies and specialty distributors. The specialty pharmacies and specialty distributors subsequently resell the product to health care providers and patients.

The Company is the principal under the product sales as the Company controls the products with the ability to direct the use of, and obtain substantially all the remaining benefits from the products before they are sold to the customer. For product sales transactions, the Company has a single performance obligation which is to sell the products to its customer. The Company includes variable consideration in the transaction price to the extent it is probable that a significant reversal will not occur and estimates variable consideration from rebates, chargebacks, trade discounts and allowances, sales returns allowances and other incentives using the expected value method. Revenues for product sales are recognized at a point in time when the single performance obligation is satisfied upon delivery to the customer. The Company's payment terms are approximately 45-90 days. Actual amounts of consideration ultimately received may differ from the Company's estimates. The Company will reassess estimates for variable consideration periodically. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Product Revenue *(Continued)*

In China, rebates are offered to distributors. The Company records a provision for rebates at the time of sale based on contracted rates and historical redemption rates. Assumptions used to establish the provision include the level of distributor inventories, sales volumes and contract pricing and estimated acceptance of government pricing or reimbursement amounts (such as provincial acceptance of the National Reimbursement Drug List pricing in the PRC). The Company regularly reviews the information related to these estimates and adjusts the provision accordingly.

In the United States, estimates for variable consideration for which reserves are established at the time of sale include government rebates, chargebacks, trade discounts and allowances, sales returns allowances and other incentives that are offered within contracts between the Company and its US customers, health care providers and other indirect customers. Where appropriate, these estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns.

The Company bases its sales returns allowance on estimated distributor inventories, customer demand as reported by third-party sources, and actual returns history, as well as other factors, as appropriate. For newly launched products where actual returns history is not yet available, the sales returns allowance is initially calculated based on benchmarking data from similar products and industry experience. If the historical or benchmarking data the Company uses to calculate these estimates do not properly reflect future returns, then a change in the allowance would be made in the period in which such a determination is made and revenues in that period could be materially affected. Any changes from the historical trend rates are considered in determining the current sales return allowance. To date, sales returns have not been significant.

Collaboration Revenue

At contract inception, the Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently.

In determining the appropriate amount of revenue to be recognized as it fulfills its obligations under each of its agreements, the Company performs the five-step model under ASC 606 noted above.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Collaboration Revenue (Continued)

The Company's collaborative arrangements may contain more than one unit of account, or performance obligation, including grants of licenses to intellectual property rights, agreement to provide research and development services and other deliverables. The collaborative arrangements do not include a right of return for any deliverable. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. In developing the stand-alone selling price for a performance obligation, the Company considers competitor pricing for a similar or identical product, market awareness of and perception of the product, expected product life and current market trends. In general, the consideration allocated to each performance obligation is recognized when the respective obligation is satisfied either by delivering a good or providing a service, limited to the consideration that is not constrained. Non-refundable payments received before all of the relevant criteria for revenue recognition are satisfied are recorded as advances from customers.

Licenses of Intellectual Property: Upfront non-refundable payments for licensing the Company's intellectual property are evaluated to determine if the license is distinct from the other performance obligations identified in the arrangement. For licenses determined to be distinct, the Company recognizes revenues from non-refundable up-front fees allocated to the license at a point in time, when the license is transferred to the licensee and the licensee is able to use and benefit from the license.

Research and Development Services: The portion of the transaction price allocated to research and development services performance obligations is deferred and recognized as collaboration revenue over time as delivery or performance of such services occurs. R&D reimbursement revenue for revenue attributable to the clinical trials that BMS had opted into is recognized as delivery or performance of such services occurs.

Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestones related to the Company's development-based activities may include initiation of various phases of clinical trials. Due to the uncertainty involved in meeting these development-based targets, they are generally fully constrained at contract inception. The Company will assess whether the variable consideration is fully constrained each reporting period based on the facts and circumstances surrounding the clinical trials. Upon changes to constraint associated with the developmental milestones, variable consideration will be included in the transaction price when a significant reversal of revenue recognized is not expected to occur and allocated to the separate performance obligations. Regulatory milestones are fully constrained until the period in which those regulatory approvals are achieved due to the inherent uncertainty with the approval process. Regulatory milestones are included in the transaction price in the period regulatory approval is obtained.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Collaboration Revenue *(Continued)*

Royalties: For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Research and Development Expenses

Research and development expenses represent costs associated with the collaborative arrangements, which primarily include (i) payroll and related costs (including share-based compensation) associated with research and development personnel, (ii) costs related to clinical trials and preclinical testing of the Company's technologies under development, (iii) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, (iv) expenses for research services provided by universities and contract laboratories, including sponsored research funding, and (v) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Company's research and development services and have no alternative future uses.

Clinical trial costs are a significant component of the Company's research and development expenses. The Company has a history of contracting with third parties that perform various clinical trial activities on behalf of the Company in the ongoing development of the Company's product candidates. Expenses related to clinical trials are accrued based on the Company's estimates of the actual services performed by the third parties for the respective period. If the contracted amounts are modified (for instance, as a result of changes in the clinical trial protocol or scope of work to be performed), the Company will modify the related accruals accordingly on a prospective basis. Revisions in the scope of a contract are charged to expense in the period in which the facts that give rise to the revision become reasonably certain.

The process of estimating the Company's research and development expenses involves reviewing open contracts and purchase orders, communicating with its personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated costs incurred for the services when the Company has not yet been invoiced or otherwise notified of the actual costs. The majority of the Company's service providers invoice it in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. The Company makes estimates of the expenses as of each balance sheet date in its financial statements based on facts and circumstances known to the Company at that time. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting expenses that are too high or too low in any particular period. There were no material adjustments for a change in estimate to research and development expenses in the accompanying consolidated financial statements for the years ended December 31, 2020 and 2019.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Acquired In-Process Research and Development Expense

The Company has acquired rights to develop and commercialize product candidates. Upfront payments that relate to the acquisition of a new drug compound, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the new drug compound did not also include processes or activities that would constitute a “business” as defined under GAAP, the drug has not achieved regulatory approval for marketing and, absent obtaining such approval, has no established alternative future use. Milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized over the estimated remaining useful life of the related product. Royalties owed on sales of the products licensed pursuant to the agreements are expensed in the period the related revenues are recognized.

Government Grants

Government financial incentives that involve no conditions or continuing performance obligations of the Company are recognized as other non-operating income upon receipt. In the event government grants or incentives involve continuing performance obligations, the Company will capitalize the payment as a liability and recognize the same financial statement caption as the performance obligation relates over the performance period.

Comprehensive Loss

Comprehensive loss is defined as the changes in equity of the Company during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. Among other disclosures, ASC 220, *Comprehensive Income*, requires that all items that are required to be recognized under current accounting standards as components of comprehensive loss be reported in a financial statement that is displayed with the same prominence as other financial statements. For each of the periods presented, the Company’s comprehensive loss includes net loss, foreign currency translation adjustments, pension liability adjustments and unrealized holding gains/losses associated with the available-for-sale debt securities, and is presented in the consolidated statements of comprehensive loss.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Share-Based Compensation

Awards granted to employees

The Company applies ASC 718, *Compensation—Stock Compensation* (“ASC 718”), to account for its employee share-based payments. In accordance with ASC 718, the Company determines whether an award should be classified and accounted for as a liability award or equity award. All the Company’s grants of share-based awards to employees were classified as equity awards and are recognized in the financial statements based on their grant date fair values. Specifically, the grant date fair value of share options is calculated using an option pricing model. The fair value of restricted shares and restricted share units are based on the closing market price of our ADSs on the NASDAQ Global Select Market on the date of grant. The Company has elected to recognize compensation expense using the straight-line method for all employee equity awards granted with graded vesting based on service conditions provided that the amount of compensation cost recognized at any date is at least equal to the portion of the grant-date value of the options that are vested at that date. The Company uses the accelerated method for all awards granted with graded vesting based on performance conditions. To the extent the required vesting conditions are not met resulting in the forfeiture of the share-based awards, previously recognized compensation expense relating to those awards are reversed. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in the subsequent period if actual forfeitures differ from initial estimates.

Forfeiture rates are estimated based on historical and future expectations of employee turnover rates and are adjusted to reflect future changes in circumstances and facts, if any. Share-based compensation expense is recorded net of estimated forfeitures such that expense is recorded only for those share-based awards that are expected to vest. To the extent the Company revises these estimates in the future, the share-based payments could be materially impacted in the period of revision, as well as in following periods. The Company, with the assistance of an independent third-party valuation firm, determined the estimated fair value of the stock options granted to employees using the binomial option pricing model.

Awards granted to non-employees

The Company has accounted for equity instruments issued to non-employees in accordance with the provisions of ASC 718 and ASC 505, *Equity*. All transactions in which goods or services are received in exchange for equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The grant date is the measurement date of the fair value of the equity instrument issued. The expense is recognized in the same manner as if the Company had paid cash for the services provided by the non-employees in accordance with ASC 505-50, *Equity-based payments to non-employees*. The Company estimated the fair value of share options granted to non-employees using the same method as employees.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Share-Based Compensation *(Continued)*

Modification of awards

A change in any of the terms or conditions of the awards is accounted for as a modification of the award. Incremental compensation cost is measured as the excess, if any, of the fair value of the modified award over the fair value of the original award immediately before its terms are modified, measured based on the fair value of the awards and other pertinent factors at the modification date. For vested awards, the Company recognizes incremental compensation cost in the period the modification occurs. For unvested awards, the Company recognizes over the remaining requisite service period, the sum of the incremental compensation cost and the remaining unrecognized compensation cost for the original award on the modification date. If the fair value of the modified award is lower than the fair value of the original award immediately before modification, the minimum compensation cost the Company recognizes is the cost of the original award.

Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized.

The Company evaluates its uncertain tax positions using the provisions of ASC 740, *Income Taxes*, which prescribes a recognition threshold that a tax position is required to meet before being recognized in the financial statements. The Company recognizes in the financial statements the benefit of a tax position which is “more likely than not” to be sustained under examination based solely on the technical merits of the position assuming a review by tax authorities having all relevant information. Tax positions that meet the recognition threshold are measured using a cumulative probability approach, at the largest amount of tax benefit that has a greater than fifty percent likelihood of being realized upon settlement. It is the Company’s policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

Loss Per Share

Loss per share is calculated in accordance with ASC 260, *Earnings per Share*. Basic loss per ordinary share is computed by dividing net loss attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period using the two-class method. Under the two-class method, net income is allocated between ordinary shares and participating securities based on dividends declared (or accumulated) and participating rights in undistributed earnings as if all the earnings for the reporting period had been distributed. The Company’s restricted shares are participating securities because they have contractual rights to share in the profits of the Company.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Loss Per Share (Continued)

However, the restricted shares do not have contractual rights and obligations to share in the losses of the Company. For the periods presented herein, the computation of basic loss per share using the two-class method is not applicable as the Company is in a net loss position.

Diluted loss per share is calculated by dividing net loss attributable to ordinary shareholders as adjusted for the effect of dilutive ordinary equivalent shares, if any, by the weighted average number of ordinary and dilutive ordinary equivalent shares outstanding during the period. Ordinary equivalent shares consist of the ordinary shares issuable upon the conversion of the Company's convertible preferred shares using the if-converted method, and ordinary shares issuable upon the conversion of the share options and unvested restricted shares, using the treasury stock method.

Ordinary share equivalents are excluded from the computation of diluted loss per share if their effects would be anti-dilutive. Basic and diluted loss per ordinary share is presented in the Company's consolidated statements of operations.

Segment Information

In accordance with ASC 280, *Segment Reporting*, the Company's chief operating decision maker, the Chief Executive Officer, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Company as a whole and hence, the Company has only one reportable segment: pharmaceutical products.

Concentration of Risks

Concentration of credit risk

Financial instruments that are potentially subject to credit risk consist of cash and cash equivalents and short-term investments. The carrying amounts of cash and cash equivalents and short-term investments represent the maximum amount of loss due to credit risk. As of December 31, 2020 and 2019, US\$1,381,950,000 and US\$618,011,000 were deposited with various major reputable financial institutions located in the PRC and international financial institutions outside of the PRC. The deposits placed with financial institutions are not protected by statutory or commercial insurance. In the event of bankruptcy of one of these financial institutions, the Company may be unable to claim its deposits back in full. Management believes that these financial institutions are of high credit quality and continually monitors the credit worthiness of these financial institutions. As of December 31, 2020 and 2019, the Company had short-term investments amounting to US\$3,268,725,000 and US\$364,728,000, respectively.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Concentration of Risks (Continued)

Concentration of credit risk (Continued)

At December 31, 2020, the Company's short-term investments were comprised of U.S. treasury securities. The Company believes that U.S. treasury securities are of high credit quality and continually monitors the credit worthiness of these institutions.

Customer concentration risk

For the year ended December 31, 2020, sales to the Company's two largest product distributors, China Resources and Sinopharm, represented approximately 38.7% and 25.4% of product revenue, respectively, and collectively, represented approximately 59.6% of total accounts receivable as of December 31, 2020.

For the years ended December 31, 2019, substantially all of the Company's revenue was from BMS and the Company's product distributor, China Resources, in China.

Business, customer, political, social and economic risks

The Company participates in a dynamic biopharmaceutical industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: changes in the overall demand for services and products; competitive pressures due to existing competitors and new entrants; advances and new trends in new drugs and industry standards; changes in clinical research organizations, contract manufacturers and other key vendors; changes in certain strategic relationships or customer relationships; regulatory considerations; intellectual property considerations; and risks associated with the Company's ability to attract and retain employees necessary to support its growth. The Company's operations could be also adversely affected by significant political, economic and social uncertainties in the PRC and in relations between the PRC and United States.

Currency convertibility risk

A significant portion of the Company's expenses, assets and liabilities are denominated in RMB. On January 1, 1994, the PRC government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China (the "PBOC"). However, the unification of the exchange rates does not imply that the RMB may be readily convertible into U.S. dollar or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approvals of foreign currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Concentration of Risks (Continued)

Currency convertibility risk (Continued)

Additionally, the value of the RMB is subject to changes in central government policies and international economic and political developments affecting supply and demand in the PRC foreign exchange trading system market.

Foreign currency exchange rate risk

Since July 21, 2005, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. For RMB against U.S. dollar, there was appreciation of approximately 6.3% and depreciation of approximately 1.3% in the years ended December 31, 2020 and 2019. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

To the extent that the Company needs to convert U.S. dollar into RMB for capital expenditures and working capital and other business purposes, appreciation of RMB against U.S. dollar would have an adverse effect on the RMB amount the Company would receive from the conversion. Conversely, if the Company decides to convert RMB into U.S. dollar for the purpose of making payments for dividends on ordinary shares, strategic acquisitions or investments or other business purposes, appreciation of U.S. dollar against RMB would have a negative effect on the U.S. dollar amount available to the Company. In addition, a significant depreciation of the RMB against the U.S. dollar may significantly reduce the U.S. dollar equivalent of the Company's earnings or losses.

Recent Accounting Pronouncements

New accounting standards which have been adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses*. Subsequently, the FASB issued ASU 2019-05, *Financial Instruments—Credit Losses* (Topic 326): Targeted Transition Relief and ASU 2019-11 Codification Improvements to Topic 326, *Financial Instruments—Credit Losses* (collectively, the "Credit Loss ASUs"). The Credit Loss ASUs change the methodology to be used to measure credit losses for certain financial instruments and financial assets, including trade receivables. The new methodology requires the recognition of an allowance that reflects the current estimate of credit losses expected to be incurred over the life of the financial asset. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The Company adopted the standard on January 1, 2020. Based on the composition of the Company's trade receivables and investment portfolio, the adoption of this standard did not have a material impact on the Company's financial position or results of operations upon adoption. The Company has updated its accounting policy for trade accounts receivable and is providing additional disclosure about its allowance for credit losses, as required by the standard, upon adoption.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES *(Continued)*

Recent Accounting Pronouncements *(Continued)*

New accounting standards which have been adopted (Continued)

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement* (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement. The update eliminates, modifies, and adds certain disclosure requirements for fair value measurements. The added disclosure requirements and the modified disclosure on the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented. All other changes to disclosure requirements in this update should be applied retrospectively to all periods presented upon their effective date. The Company adopted this standard on January 1, 2020. There was no material impact to the Company's financial position or results of operations upon adoption.

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software* (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. This update requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to defer and recognize as an asset. This guidance should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company adopted this standard on January 1, 2020. There was no material impact to the Company's financial position or results of operations upon adoption.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808)*: Clarifying the Interaction between Topic 808 and Topic 606. This update clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer and precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. This guidance should be applied retrospectively to the date of initial application of Topic 606. The Company adopted this standard on January 1, 2020. There was no material impact to the Company's financial position or results of operations upon adoption.

New accounting standards which have not yet been adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes* (Topic 740): Simplifying the Accounting for Income Taxes. This update simplifies the accounting for income taxes as part of the FASB's overall initiative to reduce complexity in accounting standards. The amendments include removal of certain exceptions to the general principles of ASC 740, *Income taxes*, and simplification in several other areas such as accounting for a franchise tax (or similar tax) that is partially based on income. The update is effective in fiscal years beginning after December 15, 2020, and interim periods therein, and early adoption is permitted. Certain amendments in this update should be applied retrospectively or modified retrospectively, all other amendments should be applied prospectively. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS

The Company enters into collaborative arrangements for the research and development, manufacture and/or commercialization of drug products and drug candidates. To date, these collaborative arrangements have included out-licenses of internally developed products and drug candidates to other parties, in-licenses of products and drug candidates from other parties, and profit- and cost-sharing arrangements. These arrangements may include non-refundable upfront payments, contingent obligations for potential development, regulatory and commercial performance milestone payments, cost-sharing and reimbursement arrangements, royalty payments, and profit sharing.

Out-Licensing Arrangements

To date, the Company's collaboration revenue related to its out-licensing collaborative agreements has consisted of upfront license fees, research and development reimbursement revenue, and research and development services revenue from its collaboration agreement with BMS for tislelizumab.

The following table summarizes total collaboration revenue recognized for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020	2019
Revenue from Collaborators	US\$'000	US\$'000
Reimbursement of research and development costs	–	27,634
Research and development service revenue	–	27,982
Other	–	150,000
Total	–	205,616

Celgene Corporation, a Bristol Myers Squibb company ("BMS")

On July 5, 2017, the Company entered into a license agreement with Celgene Corporation, now a BMS company, pursuant to which the Company granted to the BMS parties an exclusive right to develop and commercialize the Company's investigational PD-1 inhibitor, tislelizumab, in all fields of treatment, other than hematology, in the United States, Europe, Japan and the rest of world other than Asia (the "PD-1 License Agreement"). In connection with the closing of the transactions on August 31, 2017, the Company and BMS amended and restated the PD-1 License Agreement (the "A&R PD-1 License Agreement") to, among other things, clarify the parties' responsibilities relating to the conducting and funding of certain global registration clinical trials and clarify the scope of the regulatory materials transferred by BeiGene to BMS. The Company entered into a mutual agreement with BMS to terminate the A&R PD-1 License Agreement effective June 14, 2019 in advance of the acquisition of Celgene by BMS.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

Out-Licensing Arrangements *(Continued)*

Celgene Corporation, a Bristol Myers Squibb company ("BMS") (Continued)

Under the terms of the A&R PD-1 License Agreement, BMS paid the Company US\$263,000,000 in upfront non-refundable fees, of which US\$92,050,000 was paid in the third quarter of 2017 and the remaining US\$170,950,000 was paid in December 2017. The Company allocated US\$13,000,000 of upfront fees to the fair value of assets related to the Company's acquisition of Celgene Shanghai, a wholly-owned subsidiary of Celgene Holdings East Corporation established under the laws of China, which was completed contemporaneously with the A&R PD-1 License Agreement. The Company was also eligible to receive product development and commercial milestone payments based on the successful achievement of development and regulatory and commercialization goals, respectively, and potential royalty payments.

In addition to the exclusive right to develop and commercialize tislelizumab, the terms of the A&R PD-1 License Agreement provided BMS with the right to collaborate with the Company on the development of tislelizumab for specified indications, including required participation on a joint development committee and a joint steering committee as well as a joint commercialization committee upon achievement of commercialization. BMS reimbursed the Company for certain research and development costs at a cost plus agreed upon markup for the development of tislelizumab related to the clinical trials that BMS opted into, as outlined in the development plan.

Under ASC 606, the Company identified the following deliverables of the collaboration agreement as distinct performance obligations: (a) the license provided to BMS for the exclusive right to develop and commercialize tislelizumab, in all fields of treatment, other than hematology, in the United States, Europe, Japan and the rest of world other than Asia ("the license"); and (b) the research and development services provided to BMS to develop tislelizumab within specified indications ("R&D services"). For each deliverable, the Company determined the stand-alone selling price and allocated the non-constrained consideration of US\$250,000,000 to the units of accounting using the relative selling price method. The consideration allocated to the license was recognized upon transfer of the license to BMS at contract inception and the consideration allocated to the R&D services was deferred and recognized over the term of the respective clinical studies for the specified indications. The payments associated with the defined developmental, regulatory, and commercialization goals were considered variable consideration and were fully constrained at contract inception through the date of termination.

In connection with the termination in June 2019, the Company regained full global rights to tislelizumab and received a US\$150,000,000 payment from BMS. The payment was recognized as other collaboration revenue upon termination as the Company had no further performance obligations under the collaboration. Upon termination, the Company also recognized the remainder of the deferred revenue balance related to the upfront consideration allocated to research and development services at the time of the original collaboration. The Company's license from BMS to distribute the approved cancer therapies ABRAXANE®, REVLIMID®, and VIDAZA® in China was not affected by the termination of the tislelizumab collaboration.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

Out-Licensing Arrangements *(Continued)*

Celgene Corporation, a Bristol Myers Squibb company (“BMS”) (Continued)

For the year ended December 31, 2019, the Company recognized collaboration revenue of US\$205,616,000 related to the BMS collaboration, which consisted of US\$27,634,000 of research and development reimbursement revenue for the trials that BMS had opted into through the termination of the collaboration agreement; US\$27,982,000 of research and development services revenue, which reflects the recognition of the remaining upfront consideration that was allocated to research and development services at the time of the collaboration and was recognized over the term of the respective clinical studies for the specified indications; and US\$150,000,000 of other collaboration revenue related to the payment received from BMS in connection with the termination of the collaboration agreement.

In-Licensing Arrangements – Commercial

Amgen

On October 31, 2019, the Company entered into a global strategic oncology collaboration with Amgen (the “Amgen Collaboration Agreement”) for the commercialization and development in China, excluding Hong Kong, Taiwan and Macao, of Amgen’s XGEVA[®], KYPROLIS[®], and BLINCYTO[®], and the joint global development of a portfolio of oncology assets in Amgen’s pipeline, with BeiGene responsible for development and commercialization in China. On January 2, 2020, following approval by the Company’s shareholders and satisfaction of other closing conditions, the agreement became effective.

Under the agreement, the Company is responsible for the commercialization of XGEVA[®], KYPROLIS[®] and BLINCYTO[®] in China for five or seven years. Amgen is responsible for manufacturing of the products globally and will supply the products to the Company at an agreed upon price. The Company and Amgen will share equally in the China commercial profits and losses during the commercialization period. Following the commercialization period, the Company has the right to retain one product and is entitled to receive royalties on sales in China for an additional five years on the products not retained. XGEVA[®] was approved in China in 2019 for patients with giant cell tumor of the bone and a supplemental new drug application has been filed for prevention of skeletal-related events in cancer patients with bone metastases. In July 2020, the Company began commercializing XGEVA[®] in China. In December 2020, BLINCYTO[®] was approved in China for injection for the treatment of adult patients with R/R B-cell precursor ALL. Additionally, a new drug application has been filed in China for KYPROLIS[®] as a treatment for patients with multiple myeloma.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

In-Licensing Arrangements – Commercial *(Continued)*

Amgen (Continued)

Amgen and the Company are also jointly developing a portfolio of Amgen oncology pipeline assets under the collaboration. The Company is responsible for conducting clinical development activities in China and co-funding global development costs by contributing cash and development services up to a total cap of US\$1,250,000,000. Amgen is responsible for all development, regulatory and commercial activities outside of China. For each pipeline asset that is approved in China, the Company will receive commercial rights for seven years from approval. The Company has the right to retain approximately one out of every three approved pipeline assets, other than sotorasib (AMG 510), Amgen's investigational KRAS G12C inhibitor, for commercialization in China. The Company and Amgen will share equally in the China commercial profits and losses during the commercialization period. The Company is entitled to receive royalties from sales in China for pipeline assets returned to Amgen for five years after the seven-year commercialization period. The Company is also entitled to receive royalties from global sales of each product outside of China (with the exception of sotorasib).

The Amgen Collaboration Agreement is within the scope of ASC 808, as both parties are active participants and are exposed to the risks and rewards dependent on the commercial success of the activities performed under the agreement. The Company is the principal for product sales to customers in China during the commercialization period and will recognize 100% of net product revenue on these sales. Amounts due to Amgen for its portion of net product sales will be recorded as cost of sales. Cost reimbursements due to or from Amgen under the profit share will be recognized as incurred and recorded to cost of sales; selling, general and administrative expense; or research and development expense, based on the underlying nature of the related activity subject to reimbursement. Costs incurred for the Company's portion of the global co-development funding are recorded to research and development expense as incurred.

In connection with the Amgen Collaboration Agreement, a Share Purchase Agreement ("SPA") was entered into by the parties on October 31, 2019. On January 2, 2020, the closing date of the transaction, Amgen purchased 15,895,001 of the Company's ADSs for US\$174.85 per ADS, representing a 20.5% ownership stake in the Company. Per the SPA, the cash proceeds shall be used as necessary to fund the Company's development obligations under the Amgen Collaboration Agreement. Pursuant to the SPA, Amgen also received the right to designate one member of the Company's board of directors, and Mr. Anthony C. Hooper joined the Company's board of directors as the Amgen designee in January 2020.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

In-Licensing Arrangements – Commercial *(Continued)*

Amgen (Continued)

In determining the fair value of the common stock at closing, the Company considered the closing price of the common stock on the closing date of the transaction and included a lack of marketability discount because the shares are subject to certain restrictions. The fair value of the shares on the closing date was determined to be US\$132.74 per ADS, or US\$2,109,902,000 in the aggregate. The Company determined that the premium paid by Amgen on the share purchase represents a cost share liability due to the Company's co-development obligations. The fair value of the cost share liability on the closing date was determined to be US\$601,857,000 based on the Company's discounted estimated future cash flows related to the pipeline assets. The estimation of future cash flows involved management assumptions of revenue growth rates and probability of technical and regulatory success of the pipeline assets. The total cash proceeds of US\$2,779,241,000 were allocated based on the relative fair value method, with US\$2,162,407,000 recorded to equity and US\$616,834,000 recorded as a research and development cost share liability. The cost share liability is being amortized proportionately as the Company contributes cash and development services to its total co-development funding cap.

Amounts recorded related to the cash proceeds received from the Amgen collaboration for the year ended December 31, 2020 were as follows:

	Year Ended December 31, 2020 US\$'000
Fair value of equity issued to Amgen	2,162,407
Fair value of research and development cost share liability	<u>616,834</u>
Total cash proceeds	<u><u>2,779,241</u></u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

In-Licensing Arrangements – Commercial *(Continued)*

Amgen (Continued)

Amounts recorded related to the Company's portion of the co-development funding on the pipeline assets for the year ended December 31, 2020 were as follows:

	Year Ended December 31, 2020 US\$' 000
Research and development expense	117,005
Amortization of research and development cost share liability	<u>113,986</u>
Total amount due to Amgen for BeiGene's portion of the development funding	<u>230,991</u>
Total amount of development funding paid or payable in cash	224,396
Total amount of development funding paid with development services	6,595
	As of December 31, 2020 US\$' 000
Remaining portion of development funding cap	1,019,009

As of December 31, 2020, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of December 31, 2020 US\$' 000
Research and development cost share liability, current portion	127,808
Research and development cost share liability, non-current portion	<u>375,040</u>
Total research and development cost share liability	<u>502,848</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

In-Licensing Arrangements – Commercial *(Continued)*

Amgen (Continued)

The total reimbursement due under the commercial profit-sharing agreement for in-line product sales is classified in the income statement for the year ended December 31, 2020 as follows:

	Year Ended December 31, 2020 US\$' 000
Cost of sales – product	(1,210)
Selling, general and administrative	(9,750)
Research and development	<u>(660)</u>
Total	<u><u>(11,620)</u></u>

For the year ended December 31, 2020, the total amount of drug purchases from Amgen was US\$38,392,000.

Amgen is a substantial shareholder holding approximately 20.5% of the issued share capital of the Company and, therefore, a connected person of the Company under Chapter 14A of the HK Listing Rules and a related party of the Company. As a result, the transactions contemplated under the Amgen Collaboration Agreement constitute continuing connected transactions of the Company under Chapter 14A of the HK Listing Rules.

Celgene Logistics Sàrl, a BMS company

On July 5, 2017, BeiGene and Celgene Logistics Sàrl, now a BMS company, entered into a license and supply agreement pursuant to which BeiGene was granted the right to exclusively distribute and promote BMS's approved cancer therapies, ABRAXANE®, REVLIMID®, and VIDAZA® in China, excluding Hong Kong, Macau and Taiwan (the "China License Agreement"). The China License Agreement became effective on August 31, 2017, contemporaneously with the closing of the acquisition of Celgene Shanghai and the A&R PD-1 License Agreement. The Company began distributing these in-licensed products in China in September 2017. The Company subsequently assigned the agreement to its wholly-owned subsidiary, BeiGene Switzerland.

In-Licensing Arrangements – Development

The Company has in-licensed the rights to develop, manufacture and, if approved, commercialize multiple development stage drug candidates globally or in specific territories. These arrangements typically include non-refundable upfront payments, contingent obligations for potential development, regulatory and commercial performance milestone payments, cost-sharing arrangements, royalty payments, and profit sharing.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

In-Licensing Arrangements – Commercial (Continued)

Our significant license agreements are described below:

EUSA Pharma

In January 2020, the Company entered into an exclusive development and commercialization agreement with EUSA Pharma (“EUSA”) for the orphan biologic products SYLVANT® (siltuximab) and QARZIBA® (dinutuximab beta) in China. Under the terms of the agreement, EUSA granted the Company exclusive rights to SYLVANT® in greater China and to QARZIBA® in mainland China. Under the agreement, the Company will fund and undertake all clinical development and regulatory submissions in the territories, and will commercialize both products once approved. EUSA received a US\$40,000,000 upfront payment and will be eligible to receive payments upon the achievement of regulatory and commercial milestones up to a total of US\$160,000,000. EUSA will also be eligible to receive tiered royalties on future product sales. The upfront payment was expensed to research and development expense during the year ended December 31, 2020 in accordance with the Company’s acquired in-process research and development expense policy.

Assembly Biosciences, Inc.

In July 2020, the Company entered into a collaboration agreement with Assembly Biosciences, Inc. (“Assembly”) for Assembly’s portfolio of three clinical-stage core inhibitor candidates for the treatment of patients with chronic hepatitis B virus (“HBV”) infection in China. Under the terms of the agreement, Assembly granted BeiGene exclusive rights to develop and commercialize ABI-H0731, ABI-H2158 and ABI-H3733 in China, including Hong Kong, Macau, and Taiwan. BeiGene is responsible for development, regulatory submissions, and commercialization in China. Assembly retains full worldwide rights outside of the partnered territory for its HBV portfolio. Assembly received an upfront payment of US\$40,000,000 and is eligible to receive payments upon achievement of development, regulatory and commercial milestones up to a total of US\$503,750,000. Assembly is also eligible to receive tiered royalties on net sales. The upfront payment was expensed to research and development expense during the year ended December 31, 2020 in accordance with the Company’s acquired in-process research and development expense policy.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

In-Licensing Arrangements – Commercial *(Continued)*

Bio-Thera Solutions, Ltd.

In August 2020, the Company entered into a license, distribution and supply agreement with Bio-Thera Solutions, Ltd. (“Bio-Thera”) for Bio-Thera’s BAT1706, an investigational biosimilar to Avastin® (bevacizumab) in China. The agreement became effective on September 10, 2020 upon approval of Bio-Thera’s shareholders, and was subsequently assigned by the Company to its affiliate BeiGene (Guangzhou) Co., Ltd. (“BeiGene Guangzhou”) on September 18, 2020, as permitted by the agreement. Under the terms of the agreement, Bio-Thera agreed to grant BeiGene the right to develop, manufacture, and commercialize BAT1706 in China, including Hong Kong, Macau, and Taiwan. Bio-Thera will retain rights outside of the partnered territory. Bio-Thera received an upfront payment of US\$20,000,000 in October 2020 and is eligible to receive payments upon the achievement of regulatory and commercial milestones up to a total of US\$145,000,000. Bio-Thera will also be eligible to receive tiered double digit royalties on future net product sales. The upfront payment was expensed to research and development expense during the year ended December 31, 2020 in accordance with the Company’s acquired in-process research and development expense policy.

Seagen, Inc.

In November 2019, the Company entered into a license agreement with Seagen, Inc. (formerly known as “Seattle Genetics, Inc.”) for an advanced pre-clinical product candidate for treating cancer. The agent utilizes a proprietary Seagen antibody-based technology. Under the terms of the agreement, Seagen retained rights to the product candidate in the Americas (United States, Canada and Latin American countries), Europe and Japan. The Company was granted exclusive rights to develop and commercialize the product candidate in Asia (except Japan) and the rest of the world. Seagen will lead global development and BeiGene will fund and operationalize the portion of global clinical trials attributable to its territories. BeiGene will also be responsible for all clinical development and regulatory submissions specific to its territories. Seagen received an upfront payment of US\$20,000,000 and is eligible to receive progress-dependent milestones and tiered royalties on any product sales. Seagen is a related party due to a common shareholder, and that shareholder has different representatives serving on each companies’ respective board of directors. The upfront payment was expensed to research and development expense during the year ended December 31, 2019 in accordance with the Company’s acquired in-process research and development expense policy.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

In-Licensing Arrangements – Commercial (Continued)

BioAtla, Inc.

In April 2019, the Company entered into a global co-development and collaboration agreement with BioAtla, Inc. (“BioAtla”) for the development, manufacturing and commercialization of BioAtla’s investigational CAB-CTLA-4 antibody (BA3071), whereby BioAtla had agreed to co-develop the CAB-CTLA-4 antibody to defined early clinical objectives and the Company had agreed to then lead the parties’ joint efforts to develop the product candidate and be responsible for global regulatory filings and commercialization. Subject to the terms of the agreement, the Company held a co-exclusive license with BioAtla to develop and manufacture the product candidate globally and an exclusive license to commercialize the product candidate globally. The Company had agreed to be responsible for all costs of development, manufacturing and commercialization in Asia (excluding Japan), Australia and New Zealand (the “Company Territory”), and the parties had agreed to share development and manufacturing costs and commercial profits and losses upon specified terms in the rest of the world. The Company paid BioAtla an upfront payment of US\$20,000,000 and BioAtla was eligible to receive a milestone payment upon reaching the defined early clinical objectives. BioAtla was also eligible to receive additional payments in subsequent development and regulatory milestones globally and commercial milestones in the Company Territory, together with tiered royalties on sales in the Company Territory. The upfront payment was expensed to research and development expense during the year ended December 31, 2019 in accordance with the Company’s acquired in-process research and development expense policy.

In October 2020, the Company and BioAtla amended the global co-development and collaboration agreement. Under the amended terms of the agreement, BeiGene holds an exclusive global license to BA3071 and is solely responsible for its global clinical development and commercialization and has the right to receive all profits on any future sales, net of royalty payments to BioAtla. In addition to the upfront payment BioAtla received upon execution of the original agreement, BioAtla is eligible to receive development and regulatory milestone payments together with increased tiered royalties on worldwide sales.

Zymeworks, Inc.

In November 2018, the Company and Zymeworks entered into collaboration and license agreements whereby the Company acquired licenses to develop and commercialize Zymeworks’ clinical-stage bispecific antibody candidate ZW25 and its preclinical-stage bispecific antibody drug conjugate (“ADC”) ZW49 in Asia (excluding Japan), Australia, and New Zealand. In addition, Zymeworks granted BeiGene a license to Zymeworks’ proprietary Azymetric and EFECT platforms to develop and commercialize globally up to three other bispecific antibodies using the platforms.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

3. COLLABORATIVE AND LICENSING ARRANGEMENTS *(Continued)*

In-Licensing Arrangements – Commercial *(Continued)*

Zymeworks, Inc. (Continued)

Under the collaboration agreements, BeiGene will be responsible for all clinical development and regulatory submissions in the licensed territories. BeiGene and Zymeworks have also agreed to collaborate on global development of ZW25 and ZW49 in HER2-expressing solid tumors, including gastric and breast cancer, with BeiGene enrolling patients and contributing clinical trial data from the licensed territories. Zymeworks retains full rights to both ZW25 and ZW49 outside of the specified countries and will continue to lead global development of these drug candidates.

Under the terms of the license and collaboration agreements for ZW49 and ZW25, Zymeworks received total upfront payments of US\$40,000,000 and is eligible to receive additional payments upon the achievement of development and commercial milestones for both product candidates. In addition, Zymeworks will be eligible to receive tiered royalties on future sales of ZW25 and ZW49 in the licensed territory.

Under the terms of the research and license agreement for the Azymetric and EFECT platforms, Zymeworks received an upfront payment of US\$20,000,000 and is eligible to receive additional payments upon the achievement of development and commercial milestones for up to three bispecific product candidates developed under the agreement. In addition, Zymeworks will be eligible to receive tiered royalties on future global sales of bispecific products developed by BeiGene under the agreement.

The upfront payments were expensed to research and development expense during the year ended December 31, 2018 in accordance with the Company's acquired in-process research and development expense policy. The Company recognized US\$15,000,000 of Zymeworks development milestone payments within research and development expense during the years ended December 31, 2020.

Other

In addition to the collaborations discussed above, the Company has entered into additional collaborative arrangements during the years ending December 31, 2020 and 2019. The Company may be required to pay additional amounts upon the achievement of various development and commercial milestones under these agreements. The Company may also incur significant research and development costs if the related product candidate were to advance to late-stage clinical trials. In addition, if any products related to these collaborations are approved for sale, the Company may be required to pay significant milestones upon approval and milestones and/or royalties on future sales. The payment of these amounts, however, is contingent upon the occurrence of various future events, which have a high degree of uncertainty of occurrence.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

4. ASSET ACQUISITIONS

BeiGene Pharmaceuticals (Guangzhou) Co., Ltd.

In September 2018, BeiGene Guangzhou acquired 100% of the equity interests of Baiji Shenzhou (Guangzhou) Pharmaceuticals Co., Ltd. (formerly known as Huajian Pharmaceuticals Co., Ltd.), which subsequently changed its name to BeiGene Pharmaceuticals (Guangzhou) Co., Ltd., a pharmaceutical distribution company, for total cash consideration of US\$612,000, including transaction costs of US\$59,000. The acquisition was concentrated in a single identifiable asset, a drug distribution license, and thus the Company has concluded that the transaction is an asset acquisition as it does not meet the accounting definition of a business combination. The total cost was allocated to the drug distribution license and corresponding deferred tax liability, resulting in a US\$816,000 intangible asset for the license and a deferred tax liability of US\$204,000.

Beijing Innerway Bio-tech Co., Ltd.

In October 2018, BeiGene HK completed the acquisition of 100% of the equity interests of Beijing Innerway Bio-tech Co., Ltd. ("Innerway"), the owner of the Company's research, development and office facility in Changping, Beijing, China, for total cash consideration of US\$38,654,000. The acquisition was concentrated in a single identifiable asset or group of assets, the building and associated land use right, and thus the Company has concluded that the transaction is an asset acquisition as it does not meet the accounting definition of a business combination. The total cost of the transaction of US\$38,865,000, which includes transaction costs of US\$211,000, was allocated based on the relative fair values of the net assets acquired, as follows:

	Amount US\$' 000
Land use right	33,783
Building	15,874
Deferred tax liability	(11,221)
Other	429
	<hr/>
Total cost	38,865

5. RESTRICTED CASH

The Company's restricted cash balance of US\$8,055,000 and US\$2,764,000 as of December 31, 2020 and 2019, respectively, primarily consist of RMB-denominated cash deposits held in designated bank accounts for collateral for letters of credit. The Company classifies restricted cash as current or non-current based on term of restriction.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

6. INVESTMENTS

Short-Term Investments

Short-term investments as of December 31, 2020 consisted of the following available-for-sale debt securities:

	Amortized Cost US\$' 000	Gross Unrealized Gains US\$' 000	Gross Unrealized Losses US\$' 000	Fair Value (Net Carrying Amount) US\$' 000
U.S. treasury securities	3,267,875	850	-	3,268,725
Total	3,267,875	850	-	3,268,725

Short-term investments as of December 31, 2019 consisted of the following available-for-sale debt securities:

	Amortized Cost US\$' 000	Gross Unrealized Gains US\$' 000	Gross Unrealized Losses US\$' 000	Fair Value (Net Carrying Amount) US\$' 000
U.S. treasury securities	363,440	1,288	-	364,728
Total	363,440	1,288	-	364,728

The Company does not consider the investments in U.S. treasury securities to be other-than-temporarily impaired at December 31, 2020. As of December 31, 2020, the Company's available-for-sale debt securities consisted entirely of short-term U.S. treasury securities, which were determined to have zero risk of expected credit loss. Accordingly, no allowance for credit loss was recorded as of December 31, 2020.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

6. INVESTMENTS *(Continued)*

Equity Securities with Readily Determinable Fair Values

Leap

In January 2020, the Company purchased US\$5,000,000 of Series B mandatorily convertible, non-voting preferred stock of Leap in connection with a strategic collaboration and license agreement the Company entered into with Leap. The Series B shares were subsequently converted into shares of Leap common stock and warrants to purchase additional shares of common stock upon approval of Leap's shareholders in March 2020. As of December 31, 2020, the Company's ownership interest in the outstanding common stock of Leap was 8.1% based on information from Leap. Inclusive of the shares of common stock issuable upon the exercise of the currently exercisable warrants, the Company's interest is approximately 14.9% based on information from Leap. The Company measures the investment in the common stock and warrants at fair value, with changes in fair value recorded to other income, net. The fair value of the common stock and warrants was US\$10,810,000 and US\$6,669,000, respectively, as of December 31, 2020. During the year ended December 31, 2020, the Company recorded an unrealized gain of US\$12,479,000 in the consolidated statement of operations.

Private Equity Securities without Readily Determinable Fair Values

The Company invests in equity securities of certain companies whose securities are not publicly traded and fair value is not readily determinable and where the Company has concluded it does not have significant influence based on its ownership percentage and other factors. These investments are recorded at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. The Company held investments of US\$9,705,000 and nil in equity securities without readily determinable fair values as of December 31, 2020 and December 31, 2019, respectively. There were no adjustments to the carrying values of these securities for the year ended December 31, 2020.

Equity-Method Investments

MapKure

In June 2019, the Company announced the formation of MapKure, an entity jointly owned by the Company and SpringWorks Therapeutics, Inc. ("SpringWorks"). The Company out-licensed to MapKure the Company's product candidate BGB-3245, an investigational oral, selective small molecule inhibitor of monomer and dimer forms of activating B-RAF mutations including V600 BRAF mutations, non-V600 B-RAF mutations, and RAF fusions. The Company received 10,000,000 Series A preferred units of MapKure, or a 71.4% ownership interest in exchange for its contribution of the intellectual property. SpringWorks purchased 3,500,000 Series A preferred units, or a 25% ownership interest, and other investors purchased 250,000 Series A preferred units or 1.8% ownership each. Following the initial closing, the Company consolidated its interests in MapKure under the voting model due to its controlling financial interest.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

6. INVESTMENTS *(Continued)*

Equity-Method Investments *(Continued)*

MapKure (Continued)

In June 2020, MapKure held a second closing under the existing terms of the SPA in which it issued additional Series A preferred units to SpringWorks and the other investors that purchased units in the first closing (the “Second Closing”), and the Company’s ownership interest decreased to 55.6%. As the requisite Series A voting requirements in MapKure’s governing documents require 70% combined voting power for certain actions, the Company determined that it lost its controlling financial interest after the Second Closing. Therefore, the Company deconsolidated MapKure and recognized a gain of US\$11,307,000 for the excess of the fair value of its 55.6% ownership interest in MapKure and carrying amount of the prior noncontrolling interest over the carrying amount of MapKure’s net assets within other income during the year ended December 31, 2020.

Upon deconsolidation, the Company recorded an equity investment of US\$10,000,000, which represents the estimated fair value of its 55.6% ownership interest in MapKure. Effective June 8, 2020, the Company is accounting for the investment as an equity-method investment and records its portion of MapKure’s earnings or losses within other income, net. The Company recognized losses of US\$491,000 for its portion of MapKure’s net loss for the year ended December 31, 2020. As of December 31, 2020, the carrying amount of the Company’s investment in MapKure was US\$9,509,000.

Guangzhou GET Phase I Biomedical Industry Investment Fund Partnership (Limited Partnership)

In July 2020, BeiGene (Guangzhou) invested US\$11,782,000 (RMB80,000,000) in an existing investment fund, Guangzhou GET Phase I Biomedical Industry Investment Fund Partnership (Limited Partnership) (“GET Bio-fund”). The stated purpose of GET Bio-fund is to promote and upgrade the local industrial transformation in Guangzhou and it is committed to invest at least 60% of the total fund in the biotechnology, medical device, and medical information industries.

GET Bio-fund has four limited partners and one general partner, Guangzhou GET Biomedical Industry Investment Fund Management Co., Ltd. (“GET Bio-fund Management”). GET Bio-fund has an agreed duration for seven years, with the first five years as the investment period and the following two years as the projected payback period. The agreed upon duration may be extended for two additional years with the approval of all of the partners. BeiGene Guangzhou, as a limited partner, holds an ownership interest in the fund of 26.3%. The investment committee for the fund has seven members and requires resolutions to be approved by at least five of the seven members. BeiGene Guangzhou holds one position on the investment committee and GET Bio-fund Management holds three positions. The Company determined that it has the ability to exercise significant influence over the fund due to the Company’s ownership interest and involvement on the investment committee, and the investment represents an equity method investment. The Company recognized losses of US\$68,000 for its portion of the fund’s net loss for the year ended December 31, 2020. As of December 31, 2020, the carrying amount of the Company’s investment in the fund was US\$12,189,000.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

6. INVESTMENTS *(Continued)*

Other Equity-Method Investment

In addition to the equity-method investments mentioned above, the Company made an additional equity-method investment during the year ended December 31, 2020 that it does not consider to be individually significant to its financial statements. The Company recognized the equity-method investment at cost and subsequently adjusted the basis based on the Company's share of the results of operations. The Company records its share of the investee's results of operations within other income, net.

7. ACCOUNTS RECEIVABLES

	As of December 31,	
	2020	2019
	US\$' 000	US\$' 000
Accounts receivable	60,515	70,878
Impairment	<u>(112)</u>	<u>–</u>
Total	<u>60,403</u>	<u>70,878</u>

The Group's trading terms with its customers are mainly on credit and the credit periods generally range from 45 to 90 days. The Group seeks to maintain strict control over its outstanding receivables and overdue balances are regularly reviewed. The Group does not hold any collateral or other credit enhancements over its accounts receivable balances. Accounts receivables are non-interest-bearing.

An aging analysis of the accounts receivables, based on the invoice date, is as follows:

	As of December 31,	
	2020	2019
	US\$' 000	US\$' 000
Within 3 months	60,403	58,752
3 months to 6 months	<u>–</u>	<u>12,126</u>
Total	<u>60,403</u>	<u>70,878</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

7. ACCOUNTS RECEIVABLES *(Continued)*

The roll-forward of the allowance for credit losses related to trade accounts receivable for the year ended December 31, 2020 consists of the following activity:

	Allowance for Credit Losses US\$' 000
Balance as of December 31, 2019	–
Current period provision for expected credit losses	109
Amounts written-off, net of recoveries of amounts previously reserved	–
Exchange rate changes	3
	3
Balance as of December 31, 2020	112

8. INVENTORIES

The Company's inventory balance consisted of the following:

	As of December 31,	
	2020	2019
	US\$' 000	US\$' 000
Raw materials	19,330	–
Work in process	1,378	–
Finished goods	68,585	28,553
	68,585	28,553
Total inventories	89,293	28,553

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

9. MANUFACTURING FACILITY IN GUANGZHOU, CHINA

Manufacturing legal entity structure

BeiGene Shanghai, originally established as a wholly-owned subsidiary of BeiGene HK, and currently a wholly-owned subsidiary of BeiGene Biologics, as described below, provides clinical development services for BeiGene affiliates and is the clinical trial authorization (“CTA”) holder and marketing authorization application (“MAA”) holder for tislelizumab in China.

In March 2017, BeiGene HK, a wholly owned subsidiary of the Company, and Guangzhou GET Technology Development Co., Ltd. (now Guangzhou High-tech Zone Technology Holding Group Co., Ltd.) (“GET”), entered into a definitive agreement to establish a commercial scale biologics manufacturing facility in Guangzhou, Guangdong Province, PRC. BeiGene HK and GET entered into an Equity Joint Venture Contract (the “JV Agreement”).

Under the terms of the JV Agreement, BeiGene HK made an initial cash capital contribution of RMB200,000,000 and a subsequent contribution of one or more biologics assets in exchange for a 95% equity interest in BeiGene Biologics. GET made a cash capital contribution of RMB100,000,000 to BeiGene Biologics, representing a 5% equity interest in BeiGene Biologics. In addition, on March 7, 2017, BeiGene Biologics entered into a contract with GET, under which GET agreed to provide a RMB900,000,000 loan (the “Shareholder Loan”) to BeiGene Biologics (see Note 16). In September 2019, BeiGene Biologics completed the first phase of construction of a biologics manufacturing facility in Guangzhou, through a wholly owned subsidiary, the BeiGene Guangzhou Biologics Manufacturing Co., Ltd. (“BeiGene Guangzhou Factory”), to manufacture biologics for the Company and its subsidiaries.

BeiGene HK and BeiGene Biologics subsequently entered into an Equity Transfer Agreement to transfer 100% of the equity interest of BeiGene Shanghai to BeiGene Biologics, as required by the JV agreement, such that the CTA holder and MAA holder for tislelizumab in China was controlled by BeiGene Biologics. Upon the transfer of equity in BeiGene Shanghai, BeiGene HK’s equity interest in BeiGene Shanghai became 95%.

In September 2020, BeiGene HK entered into a share purchase agreement (“JV Share Purchase Agreement”) with GET to acquire GET’s 5% equity interest in BeiGene Biologics for a total purchase price of US\$28,723,000 (RMB195,262,000). The transaction was finalized in November 2020 upon completion of the business registration filing. The share purchase was recorded as an equity transaction. The carrying amount of the noncontrolling interest balance of US\$9,116,000 was adjusted to nil to reflect the increase in BeiGene HK’s ownership interest to 100%, and the difference in the fair value of the consideration paid and the carrying amount of the noncontrolling interest of US\$19,599,000 was recorded to additional paid in capital. In connection with the JV Share Purchase Agreement, BeiGene Biologics repaid the outstanding principal of the Shareholder Loan of US\$132,061,000 (RMB900,000,000) and accrued interest of US\$36,558,000 (RMB249,140,000) (see Note 16).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

9. MANUFACTURING FACILITY IN GUANGZHOU, CHINA *(Continued)*

Manufacturing legal entity structure *(Continued)*

In connection with the JV share purchase, the Company entered into a loan agreement with China Minsheng Bank for a total loan facility of up to US\$200,000,000 (“Senior Loan”), of which US\$120,000,000 was used to fund the JV share repurchase and repayment of the shareholder loan and US\$80,000,000 could be used for general working capital purposes. The Company may extend the original maturity date for up to two additional twelve month periods. In October 2020, the Company drew down US\$80,000,000 of the working capital facility and US\$118,320,000 of the acquisition facility to be used for the JV share repurchase. In addition, the Company entered into a loan agreement with Zhuhai Hillhouse Zhaohui Equity Investment Partnership (“Zhuhai Hillhouse”) for a total loan facility of US\$73,640,000 (RMB500,000,000) (“Related Party Loan”), of which US\$14,728,000 (RMB100,000,000) could be used for general corporate purposes and US\$58,912,000 (RMB400,000,000) can only be applied towards the repayment of the Senior Loan facility, including principal, interest and fees. The Company has drawn down US\$14,728,000 (RMB100,000,000) of the Related Party Loan as of December 31, 2020. See Note 16 for further discussion of the loans.

Commercial distribution legal entity structure

BeiGene (Guangzhou) Co., Ltd. (“BGC”), a wholly-owned subsidiary of BeiGene HK, was organized in July 2017. In September 2018, BGC acquired 100% of the equity interests of Baiji Shenzhou (Guangzhou) Pharmaceuticals Co., Ltd. (formerly known as Huajian Pharmaceuticals Co., Ltd.), which subsequently changed its name to BeiGene Pharmaceuticals (Guangzhou) Co., Ltd. (“BPG”). BPG owns drug distribution licenses necessary to distribute pharmaceutical products in China. The Company acquired these drug distribution licenses through the acquisition of BPG, as it is difficult to obtain a newly issued domestic drug distribution license in China. The transaction was accounted for as an asset acquisition (see Note 4).

Commercial supply agreement and facility expansion

In January 2018, the Company entered into a commercial supply agreement with Boehringer Ingelheim Biopharmaceuticals (China) Ltd. (“Boehringer Ingelheim”) for tislelizumab, which is being manufactured at Boehringer Ingelheim’s facility in Shanghai, China as part of a Marketing Authorization Holder (“MAH”) trial project pioneered by the Company and Boehringer Ingelheim. Under the terms of the commercial supply agreement, Boehringer Ingelheim has agreed to manufacture tislelizumab in China under an exclusive multi-year arrangement, with contract extension possible. In addition, the Company obtained certain preferred rights for future capacity expansion by Boehringer Ingelheim in China.

In October 2018, the Company entered into a binding letter of intent (“LOI”) with Boehringer Ingelheim to increase the amount of tislelizumab supplied under the agreement through the expansion of Boehringer Ingelheim’s facility to add a second bioreactor production line. Under the terms of the binding LOI, the Company provided initial funding for the facility expansion and made an additional payment for contingency costs in 2020. These payments will be credited against future purchases of tislelizumab over the term of the supply agreement.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

9. MANUFACTURING FACILITY IN GUANGZHOU, CHINA *(Continued)*

Commercial supply agreement and facility expansion *(Continued)*

The payment was recorded as a noncurrent asset since it is considered a long-term prepayment for future product costs that will provide future benefit to the Company through credits on purchases of tislelizumab from Boehringer Ingelheim over the term of the supply agreement.

10. LEASES

The Company has operating leases for office and manufacturing facilities in the United States, Switzerland, and China. The leases have remaining lease terms of up to five years, some of which include options to extend the leases that have not been included in the calculation of the Company's lease liabilities and ROU assets. The Company has land use rights, which represent land acquired for the biologics manufacturing facility in Guangzhou, and the land acquired for the Company's research, development and office facility in Changping, Beijing. A second Guangzhou land use right was acquired in May 2019 for potential expansion of the Company's research and development activities. The Company acquired a land use right in Suzhou in April 2020 to expand its research, development and manufacturing facility. The land use rights represent lease prepayments and are expensed over the remaining term of the rights, which is 50 years for the initial Guangzhou land use right, 50 years for the second Guangzhou land use right, 36 years for the Changping land use right, and 30 years for the Suzhou land use right. The Company also has certain leases with terms of 12 months or less for certain equipment, office and lab space, which are not recorded on the balance sheet.

The components of lease expense were as follows:

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
Operating lease cost	18,271	13,980
Variable lease cost	2,465	1,784
Short-term lease cost	1,018	1,001
	<u>21,754</u>	<u>16,765</u>
Total lease cost	<u>21,754</u>	<u>16,765</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

10. LEASES *(Continued)*

Supplemental balance sheet information related to leases was as follows:

	As of December 31,	
	2020	2019
	US\$'000	US\$'000
Operating lease right-of-use assets	41,850	35,555
Land use rights, net	<u>48,731</u>	<u>46,965</u>
 Total operating lease right-of-use assets	 <u><u>90,581</u></u>	 <u><u>82,520</u></u>
 Current portion of operating lease liabilities	 13,895	 10,814
Operating lease liabilities, non-current portion	<u>29,417</u>	<u>25,833</u>
 Total lease liabilities	 <u><u>43,312</u></u>	 <u><u>36,647</u></u>

Maturities of operating lease liabilities are as follows:

	US\$'000
Year ending December 31, 2021	16,108
Year ending December 31, 2022	13,626
Year ending December 31, 2023	9,894
Year ending December 31, 2024	7,234
Year ending December 31, 2025	668
Thereafter	<u>255</u>
 Total lease payments	 47,785
Less imputed interest	<u>(4,473)</u>
 Present value of lease liabilities	 <u><u>43,312</u></u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

10. LEASES (Continued)

Other supplemental information related to leases is summarized below:

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
Operating cash flows used in operating leases	17,571	12,405
ROU assets obtained in exchange for new operating lease liabilities	17,634	20,108
	As of December 31,	
	2020	2019
Weighted-average remaining lease term (years)	3	3
Weighted-average discount rate	6.26%	7.07%

11. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are recorded at cost less accumulated depreciation and consisted of the following:

	As of December 31,	
	2020	2019
	US\$' 000	US\$' 000
Laboratory equipment	78,640	47,154
Leasehold improvements	37,643	24,008
Building	111,527	109,514
Manufacturing equipment	96,669	62,775
Software, electronics and office equipment	20,782	14,705
	<hr/>	<hr/>
Property and equipment, at cost	345,261	258,156
Less: Accumulated depreciation	(73,354)	(36,709)
Construction in progress	85,779	20,955
	<hr/>	<hr/>
Property, plant and equipment, net	<u>357,686</u>	<u>242,402</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

11. PROPERTY, PLANT AND EQUIPMENT *(Continued)*

Construction in progress (“CIP”) as of December 31, 2020 and 2019 primarily related to the buildout of additional capacity at the Guangzhou manufacturing facility. CIP by fixed asset class are summarized as follows:

	As of December 31,	
	2020	2019
	US\$' 000	US\$' 000
Building	48,824	6,014
Manufacturing equipment	29,858	8,046
Laboratory equipment	4,507	4,496
Other	<u>2,590</u>	<u>2,399</u>
 Total	 <u>85,779</u>	 <u>20,955</u>

Depreciation expense for the years ended December 31, 2020 and 2019 were US\$30,943,000 and US\$17,291,000, respectively.

12. INTANGIBLE ASSETS

Intangible assets as of December 31, 2020 and December 31, 2019 are summarized as follows:

	As of December 31, 2020			As of December 31, 2019		
	Gross carrying amount US\$' 000	Accumulated amortization US\$' 000	Intangible assets, net US\$' 000	Gross carrying amount US\$' 000	Accumulated amortization US\$' 000	Intangible assets, net US\$' 000
Finite-lived intangible assets:						
Product distribution rights	7,500	(2,500)	5,000	7,500	(1,750)	5,750
Trading license	<u>816</u>	<u>(816)</u>	<u>—</u>	<u>816</u>	<u>(720)</u>	<u>96</u>
 Total finite-lived intangible assets	 <u>8,316</u>	 <u>(3,316)</u>	 <u>5,000</u>	 <u>8,316</u>	 <u>(2,470)</u>	 <u>5,846</u>

Product distribution rights consist of distribution rights for the approved cancer therapies licensed from BMS acquired as part of the BMS collaboration. The Company is amortizing the product distribution rights over a period of 10 years from the date of acquisition. The trading license represents the Guangzhou drug distribution license acquired in September 2018. The Company amortized the drug distribution trading license over the remainder of the initial license term through February 2020. The trading license has been renewed through February 2024.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

12. INTANGIBLE ASSETS *(Continued)*

Amortization expense of intangible assets for the years ended December 31, 2020 and 2019 was US\$846,000 and US\$1,326,000, respectively. As of December 31, 2020, expected amortization expense for the unamortized finite-lived intangible assets is approximately US\$750,000 in 2021, US\$750,000 in 2022, US\$750,000 in 2023, US\$750,000 in 2024, US\$750,000 in 2025, and US\$1,250,000 in 2026 and thereafter.

13. INCOME TAXES

The components of income (loss) before income taxes are as follows:

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
PRC	(369,066)	(231,997)
U.S.	33,608	24,478
Other	<u>(1,282,736)</u>	<u>(736,067)</u>
Total	<u><u>(1,618,194)</u></u>	<u><u>(943,586)</u></u>

The current and deferred components of the income tax expense (benefit) from continuing operations are as follows:

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
Current Tax Expense (Benefit):		
PRC	16,121	16,368
U.S.	(5,678)	65
Other	<u>68</u>	<u>12</u>
Total	<u>10,511</u>	<u>16,445</u>
Deferred Tax Expense (Benefit):		
PRC	(1,152)	(4,738)
U.S.	(27,030)	(4,715)
Other	<u>-</u>	<u>-</u>
Total	<u>(28,182)</u>	<u>(9,453)</u>
Income Tax (Benefit) Expense	<u><u>(17,671)</u></u>	<u><u>6,992</u></u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

13. INCOME TAXES *(Continued)*

The reconciliation of the statutory tax rate to our effective income tax rate is as follow:

	Year Ended December 31,	
	2020 US\$' 000	2019 US\$' 000
Loss before tax	(1,618,194)	(943,586)
China statutory tax rate	25%	25%
Expected taxation at China statutory tax rate	(404,549)	(235,897)
Foreign and preferential tax rate differential	218,473	191,820
Non-deductible expenses	8,436	(273)
Stock compensation expenses	(22,032)	(5,698)
Effect of tax rate change	(3,827)	(63,395)
Change in valuation allowance	209,085	146,118
Research tax credits and incentives	(23,257)	(25,683)
	<u>(17,671)</u>	<u>6,992</u>
Taxation for the year	<u>(17,671)</u>	<u>6,992</u>
Effective tax rate	<u>1.1%</u>	<u>(0.7)%</u>

Significant components of deferred tax assets (liabilities) are as follows:

	Year Ended December 31,	
	2020 US\$' 000	2019 US\$' 000
Deferred Tax Assets:		
Accruals and reserves	33,512	27,304
Net operating losses carryforward	358,425	155,499
Stock-based compensation	13,981	12,651
Research tax credits	58,835	33,979
Depreciable and amortizable assets	724,779	575,128
Lease liability obligation	9,066	7,864
	<u>1,198,598</u>	<u>812,425</u>
Gross deferred tax assets	<u>1,198,598</u>	<u>812,425</u>
Less valuation allowance	(1,134,585)	(777,583)
	<u>64,013</u>	<u>34,842</u>
Total deferred tax assets	<u>64,013</u>	<u>34,842</u>
Deferred tax liabilities:		
Right of use lease asset	(8,843)	(7,480)
	<u>(8,843)</u>	<u>(7,480)</u>
Total deferred tax liabilities	<u>(8,843)</u>	<u>(7,480)</u>
Net deferred tax asset	<u>55,170</u>	<u>27,362</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

13. INCOME TAXES *(Continued)*

Valuation allowances have been provided on deferred tax assets where, based on all available evidence, it was considered more likely than not that some portion or all of the recorded deferred tax assets will not be realized in future periods. After consideration of all positive and negative evidence, the Company believes that as of December 31, 2020 it is more likely than not that certain deferred tax assets will not be realized for our subsidiaries in Australia, Switzerland, the United States, and for certain subsidiaries in China. For the years ended December 31, 2020 and 2019, there were increases in the valuation allowance of US\$209,085,000 and US\$146,118,000, respectively. Adjustments could be required in the future if the Company estimates that the amount of deferred tax assets to be realized is more or less than the net amount recorded.

As of December 31, 2020 and 2019, the Company had net operating losses of approximately US\$2,230,857,000 and US\$810,505,000, respectively, of which net operating losses as of December 31, 2020 included US\$20,773,000 from the Company's Australian subsidiary, BeiGene AUS Pty Ltd., that has indefinite carryforward, US\$419,080,000 derived from certain of the Company's subsidiaries in the PRC which expire in years 2023 through 2030, US\$1,628,753,000 derived from BeiGene Switzerland GmbH that expires in years 2025 through 2027, and US\$162,251,000 derived from BeiGene USA, Inc. that has indefinite carryforward. The Company has approximately US\$63,597,000 of U.S. research tax credits which will expire between 2035 and 2040 if not utilized.

The gross unrecognized tax benefits for the years ended December 31, 2020 and 2019 were as follows:

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
Beginning balance, as of January 1	4,633	2,295
Additions based on tax positions related to prior tax years	–	46
Reductions based on tax positions related to prior tax years	–	(17)
Additions based on tax positions related to the current tax year	2,497	2,435
Reductions based on lapse of statute of limitations	(7)	(126)
	<u>7,123</u>	<u>4,633</u>
Ending balance, as of December 31	<u>7,123</u>	<u>4,633</u>

Current and prior year additions include assessment of U.S. federal and state tax credits and incentives. None of the unrecognized tax benefits as of December 31, 2020 would impact the consolidated income tax rate if ultimately recognized due to valuation allowances. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly change within the next 12 months.

The Company has elected to record interest and penalties related to income taxes as a component of income tax expense. For the years ended December 31, 2020 and 2019, the Company's accrued interest and penalties, where applicable, related to uncertain tax positions were not material.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

13. INCOME TAXES *(Continued)*

The Company conducts business in a number of tax jurisdictions and, as such, is required to file income tax returns in multiple jurisdictions globally. As of December 31, 2020, Australia tax matters are open to examination for the years 2013 through 2020, China tax matters are open to examination for the years 2014 through 2020, and U.S. federal tax matters are open to examination for years 2015 through 2020. Various U.S. states and other non-US tax jurisdictions in which the Company files tax returns remain open to examination for 2010 through 2020.

The Company qualifies for the Technology Advanced Service Enterprises (“TASE”) and High and New Technology Enterprise (“HNTE”) status for certain subsidiaries in China, which expire at the end of 2021. The income tax benefits attributable to this status for the year ended December 31, 2020 was approximately US\$1,614,000, or less than US\$0.01 per share outstanding.

During the years ended December 31, 2020 and 2019, the Company completed intra-group transfers of certain intangible assets in anticipation of potential commercialization, which resulted in the establishment of deferred tax assets that were fully offset by valuation allowances.

As of December 31, 2020, the Company continues to assert indefinite reinvestment on the excess of the financial reporting bases over tax bases in the Company’s investments in foreign subsidiaries. A deferred tax liability has not been established for the approximately US\$7,980,000 of cumulative undistributed foreign earnings. Determination of the unrecognized deferred tax liability is not practicable due to uncertainty regarding the remittance structure and overall complexity of the hypothetical calculation.

14. SUPPLEMENTAL BALANCE SHEET INFORMATION

Prepaid expenses and other current assets consist of the following:

	As of December 31,	
	2020	2019
	US\$' 000	US\$' 000
Prepaid research and development costs	71,341	65,886
Prepaid taxes	30,392	9,498
Payroll tax receivable	3,580	5,365
Non-trade receivable	4,464	–
Interest receivable	6,619	1,932
Prepaid insurance	1,347	711
Prepaid manufacturing cost	25,996	3,829
Income tax receivable	4,607	–
Other	11,666	3,017
Total	<u>160,012</u>	<u>90,238</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

14. SUPPLEMENTAL BALANCE SHEET INFORMATION *(Continued)*

Other non-current assets consist of the following:

	As of December 31,	
	2020	2019
	US\$' 000	US\$' 000
Goodwill	109	109
Prepayment of property and equipment	16,984	10,289
Payment of facility capacity expansion activities (1)	29,778	24,881
Prepaid VAT	10,913	29,967
Rental deposits and other	5,962	3,209
Long-term investments	49,344	—
	<u>113,090</u>	<u>68,455</u>
Total	<u>113,090</u>	<u>68,455</u>

- (1) Represents payments for a facility expansion under a commercial supply agreement. The payment will provide future benefit to the Company through credits on future supply purchases as further described in Note 9.

Accrued expenses and other payables consisted of the following:

	As of December 31,	
	2020	2019
	US\$' 000	US\$' 000
Compensation related	106,765	54,156
External research and development activities related	143,302	62,794
Commercial activities	66,131	25,645
Individual income tax and other taxes	14,373	9,648
Sales rebates and returns related	11,874	3,198
Other	3,699	8,115
	<u>346,144</u>	<u>163,556</u>
Total accrued expenses and other payables	<u>346,144</u>	<u>163,556</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

14. SUPPLEMENTAL BALANCE SHEET INFORMATION *(Continued)*

Other long-term liabilities consist of the following:

	As of December 31,	
	2020	2019
	US\$'000	US\$'000
Deferred government grant income	49,139	46,391
Pension liability	8,113	–
Other	177	171
	<u>57,429</u>	<u>46,562</u>
Total other long-term liabilities	<u>57,429</u>	<u>46,562</u>

15. ACCOUNTS PAYABLES

An aging analysis of the accounts payables as of December 31, 2020 and December 31, 2019, based on the invoice date, is as follows:

	As of December 31,	
	2020	2019
	US\$'000	US\$'000
Within 3 months	230,638	118,787
3 to 6 months	312	1,889
6 months to 1 year	147	1,272
Over 1 year	860	540
	<u>231,957</u>	<u>122,488</u>
Total	<u>231,957</u>	<u>122,488</u>

The accounts payable are non-interest-bearing and repayable within the normal operating cycle or on demand.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

16. DEBT

The following table summarizes the Company's short-term and long-term debt obligations as of December 31, 2020 and 2019:

Lender	Agreement Date	Line of Credit US\$' 000/RMB' 000	Term	Maturity Date	Interest Rate	As of		As of	
						December 31, 2020 US\$' 000	RMB' 000	December 31, 2019 US\$' 000	RMB' 000
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	307	2,000	-	-
China Minsheng Bank (the "Senior Loan")	September 24, 2020	US\$200,000		(2)	5.8%	198,320	1,294,010	-	-
Zhuhai Hillhouse (the "Related Party Loan")	September 24, 2020	RMB500,000		(3)	5.8%	15,326	100,000	-	-
Other short-term debt (4)						<u>121,062</u>	<u>789,918</u>	<u>-</u>	<u>-</u>
Total short-term debt						<u>335,015</u>	<u>2,185,928</u>	<u>-</u>	<u>-</u>
China Construction Bank	April 4, 2018	RMB580,000	9-year	April 4, 2027	(1)	88,584	578,000	83,311	580,000
Industrial Bank Co. Ltd.	September 3, 2019	RMB348,000	3-year	(5)	4.9%	-	-	-	-
China Merchants Bank	January 22, 2020	(6)	9-year	January 20, 2029	(6)	53,641	350,000	-	-
China Merchants Bank	November 9, 2020	RMB378,000	9-year	November 8, 2029	(7)	<u>41,412</u>	<u>270,206</u>	<u>-</u>	<u>-</u>
Total long-term bank loans						<u>183,637</u>	<u>1,198,206</u>	<u>83,311</u>	<u>580,000</u>
GET (the "Shareholder Loan")	March 7, 2017	RMB900,000	(8)	September 28, 2020	8.0%	<u>-</u>	<u>-</u>	<u>157,384</u>	<u>900,000</u>
Shareholder loan						<u>-</u>	<u>-</u>	<u>157,384</u>	<u>900,000</u>

- The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.9% as of December 31, 2020. The loan is secured by BeiGene Guangzhou Factory's land use right and certain BeiGene Guangzhou Factory fixed assets in the first phase of the Guangzhou manufacturing facility's build out.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

16. DEBT (Continued)

2. US\$120,000,000 of the Senior Loan was designated to fund the JV share purchase and repayment of the shareholder loan and US\$80,000,000 was designated for general working capital purposes. The Senior Loan has an original maturity date of October 8, 2021, which is the first anniversary of the first date of utilization of the loan. The Company may extend the original maturity date for up to two additional twelve month periods. On October 9, 2020, the Company drew down US\$80,000,000 of the working capital facility and US\$118,320,000 of the acquisition facility to fund the JV share repurchase.
3. RMB100,000,000 of the Related Party Loan was designated for general corporate purposes and RMB400,000,000 was designated for repayment of the Senior Loan, including principal, interest and fees. The loan matures at the earlier of: (i) November 9, 2021, which is one month after the Senior Loan maturity date, if not extended, or (ii) 10 business days after the Senior Loan is fully repaid. On September 30, 2020, the Company drew down the first tranche of US\$14,728,000 (RMB100,000,000). Zhuhai Hillhouse is a related party of the Company, as it is an affiliate of Hillhouse Capital. Hillhouse Capital is a shareholder of the Company, and a Hillhouse Capital employee is a member of the Company's board of directors.
4. During the year ended December 31, 2020, the Company entered into additional short-term working capital loans with China Industrial Bank and China Merchants Bank to borrow up to RMB1,480,000,000 in aggregate, with maturity dates ranging from April 19, 2021 to December 16, 2021. The Company drew down US\$129,937,000 (RMB869,918,000) during the year ended December 31, 2020. The weighted average interest rate for the short-term working capital loans was approximately 4.4% as of December 31, 2020. One of the short-term working capital loans in the amount of US\$26,510,000 (RMB180,000,000) is secured by the Company's research and development facility in Beijing and the associated land use right owned by its subsidiary, Innerway.
5. The loan facility was secured with RMB deposited at Industrial Bank. In December 2019, the Company repaid the outstanding principal of US\$24,419,000 (RMB170,000,000).
6. On January 22, 2020, BeiGene Guangzhou Factory entered into a nine-year bank loan with China Merchants Bank to borrow up to RMB1,100,000,000 at a floating interest rate benchmarked against prevailing interest rates of certain PRC financial institutions. The loan is secured by BeiGene Guangzhou Factory's second land use right and fixed assets that will be placed into service upon completion of the second phase of the Guangzhou manufacturing facility's build out. In connection with the Company's short-term loan agreements with China Merchants Bank entered into during the year ended December 31, 2020, the borrowing capacity was reduced from RMB1,100,000,000 to RMB350,000,000. The loan interest rate was 4.4% as of December 31, 2020.
7. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.3% as of December 31, 2020. The loan is secured by fixed assets that will be placed into service upon completion of the third phase of the Guangzhou manufacturing facility's build out.
8. The Shareholder Loan had a conversion feature, settled in a variable number of shares of common stock upon conversion (the "debt-to-equity conversion"). On April 14, 2017, BeiGene Biologics drew down the entire Shareholder Loan of RMB900,000,000 from GET. On September 28, 2020, BeiGene HK entered into the JV Share Purchase Agreement with GET to acquire GET's 5% equity interest in BeiGene Biologics (see Note 9). In connection with the JV Share Purchase Agreement, BeiGene Biologics repaid the outstanding principal amount of the Shareholder Loan of US\$132,061,000 (RMB900,000,000) and accrued interest of US\$36,558,000 (RMB249,140,000) on September 28, 2020.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

16. DEBT (Continued)

Contractual Maturities of Debt Obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2020 are as follows:

Maturity dates	Amounts US\$' 000
Year ending December 31, 2021	335,015
Year ending December 31, 2022	2,759
Year ending December 31, 2023	12,260
Year ending December 31, 2024	28,025
Year ending December 31, 2025	35,081
Thereafter	<u>105,512</u>
Total	<u><u>518,652</u></u>

Interest Expense

Interest on bank loans and the Related Party Loan is paid quarterly until the respective loans are fully settled. Interest expense recognized for the years ended December 31, 2020 and 2019 amounted to US\$18,309,000 and US\$15,155,000, respectively, among which, US\$338,000 and US\$4,857,000 was capitalized, respectively.

17. PRODUCT REVENUE

The Company's product revenue is derived from the sale of its internally developed products BRUKINSA® in the United States and China and tislelizumab in China, as well as the sale of REVLIMID®, VIDAZA® and ABRAXANE® in China under a license from BMS and XGEVA® in China under a license from Amgen. On March 25, 2020, the Company announced that the NMPA suspended the importation, sales and use of ABRAXANE® in China supplied to BeiGene by Celgene, a BMS company, and the drug was subsequently recalled by BMS and is not currently available for sale in China.

The table below presents the Company's net product sales for the years ended December 31, 2020 and 2019.

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
Product revenue – gross	324,672	228,760
Less: Rebates and sales returns	<u>(15,798)</u>	<u>(6,164)</u>
Product revenue – net	<u><u>308,874</u></u>	<u><u>222,596</u></u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

17. PRODUCT REVENUE *(Continued)*

The following table disaggregates net product revenue by product for the years ended December 31, 2020 and 2019.

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
Tislelizumab	163,358	–
BRUKINSA®	41,702	1,039
REVLIMID®	47,372	78,044
VIDAZA®	29,975	32,234
ABRAXANE®	17,770	111,279
XGEVA®	8,496	–
Other	201	–
	<u>308,874</u>	<u>222,596</u>
Total product revenue – net	<u>308,874</u>	<u>222,596</u>

The following table presents the roll-forward of accrued sales rebates and returns for the years ended December 31, 2020 and December 31, 2019.

	Sales Rebates and Returns US\$' 000
Balance as of December 31, 2018	4,749
Accrual	6,164
Payment	<u>(7,715)</u>
Balance as of December 31, 2019	3,198
Accrual	15,798
Payment	<u>(7,122)</u>
Balance as of December 31, 2020	<u>11,874</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

18. LOSS BEFORE INCOME TAX EXPENSE

The Group's loss before income tax expense is arrived at after charging/(crediting):

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
Cost of inventories sold	70,657	71,190
Depreciation and amortization expense	30,943	17,291
Research and development costs (note)	1,294,877	927,338
Amortization of operating lease right-of-use assets	18,271	13,980
Amortization of license rights	846	1,326
Auditor's remuneration	2,642	2,241
Employee benefit expense (including directors' and chief executive's remuneration):		
Wages, salaries and other benefits	466,962	286,716
Share-based compensation expenses	183,481	134,154
Pension scheme contributions (defined contribution scheme)	13,372	13,753
	<u>663,815</u>	<u>434,623</u>
Gain on sale of available-for-sale securities	(1,492)	(6,044)
Foreign exchange differences, net	(4,813)	5,448
Bank interest income	(20,352)	(19,497)
Loss on disposal of property and equipment	9	2

Note:

During the year ended December 31, 2020 and 2019, research and development costs of approximately US\$346,203,000 and US\$257,497,000 were also included in employee benefit expense.

19. LOSS PER SHARE

Loss per share was calculated as follows:

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
Numerator:		
Net loss attributable to BeiGene, Ltd.	(1,596,906)	(948,628)
Denominator:		
Weighted average shares outstanding for computing basic and diluted loss per share	<u>1,085,131,783</u>	<u>780,701,283</u>
Net loss per share attributable to BeiGene, Ltd., basic and diluted (in US\$)	<u>(1.47)</u>	<u>(1.22)</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

19. LOSS PER SHARE *(Continued)*

For the years ended December 31, 2020 and 2019, the computation of basic loss per share using the two-class method was not applicable, as the Company was in a net loss position.

The effects of all share options and restricted share units were excluded from the calculation of diluted loss per share as their effect would have been anti-dilutive during the years ended December 31, 2020 and 2019.

20. SHARE-BASED COMPENSATION EXPENSE

2016 Share Option and Incentive Plan

In January 2016, in connection with its U.S. IPO, the board of directors and shareholders of the Company approved the 2016 Share Option and Incentive Plan (the “2016 Plan”), which became effective in February 2016. The Company initially reserved 65,029,595 ordinary shares for the issuance of awards under the 2016 Plan, plus any shares available under the 2011 Option Plan (the “2011 Plan”), and not subject to any outstanding options as of the effective date of the 2016 Plan, along with underlying share awards under the 2011 Plan that are cancelled or forfeited without issuance of ordinary shares. As of December 31, 2020, ordinary shares cancelled or forfeited under the 2011 Plan that were carried over to the 2016 Plan totaled 1,832,415. The 2016 Plan provided for an annual increase in the shares available for issuance, to be added on the first day of each fiscal year, beginning on January 1, 2017, equal to the lesser of (i) five percent (5)% of the outstanding shares of the Company’s ordinary shares on the last day of the immediately preceding fiscal year or (ii) such number of shares determined by the Company’s board of directors or the compensation committee. On January 1, 2018, 29,603,616 ordinary shares were added to the 2016 Plan under this provision. However, in August 2018, in connection with the Hong Kong IPO, the board of directors of the Company approved an amended and restated 2016 Plan to remove this “evergreen” provision and implement other changes required by HK Listing Rules. In December 2018, the board of directors approved a second amended and restated 2016 Plan to increase the number of shares authorized for issuance by 38,553,159 ordinary shares, as well as amend the cap on annual compensation to independent directors and make other changes. In June 2020, the shareholders approved an Amendment No. 1 to the 2016 Plan to increase the number of shares authorized for issuance by 57,200,000 ordinary shares and to extend the term of the plan through April 13, 2030. The number of shares available for issuance under the 2016 Plan is subject to adjustment in the event of a share split, share dividend or other change in the Company’s capitalization.

As of December 31, 2020, share-based awards to acquire 67,484,221 ordinary shares were available for future grant under the 2016 Plan.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

20. SHARE-BASED COMPENSATION EXPENSE *(Continued)*

2018 Inducement Equity Plan

In June 2018, the board of directors of the Company approved the 2018 Inducement Equity Plan (the “2018 Plan”) and reserved 12,000,000 ordinary shares to be used exclusively for grants of awards to individuals who were not previously employees of the Company or its subsidiaries, as a material inducement to the individual’s entry into employment with the Company or its subsidiaries, within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. The 2018 Plan was approved by the board of directors upon recommendation of the compensation committee, without shareholder approval pursuant to Rule 5635(c)(4) of the NASDAQ Listing Rules. The terms and conditions of the 2018 Plan, and the forms of award agreements to be used thereunder, are substantially similar to the 2016 Plan and the forms of award agreements thereunder. In August 2018, in connection with the listing of the Company’s ordinary shares on The Stock Exchange of Hong Kong Limited (“HKEx”), the board of directors of the Company approved an amended and restated 2018 Plan to implement changes required by the HK Listing Rules.

As of December 31, 2020, share-based awards to acquire 9,103,756 ordinary shares were available for future grant under the 2018 Plan.

2018 Employee Share Purchase Plan

In June 2018, the shareholders of the Company approved the 2018 Employee Share Purchase Plan (the “ESPP”). Initially, 3,500,000 ordinary shares of the Company were reserved for issuance under the ESPP. In August 2018, in connection with the Hong Kong IPO, the board of directors of the Company approved an amended and restated ESPP to remove an “evergreen” share replenishment provision originally included in the plan and implement other changes required by the HK Listing Rules. In December 2018, the board of directors approved a second amended and restated ESPP to increase the number of shares authorized for issuance by 3,855,315 ordinary shares to 7,355,315 ordinary shares. The ESPP allows eligible employees to purchase the Company’s ordinary shares (including in the form of ADSs) at the end of each offering period, which will generally be six months, at a 15% discount to the market price of the Company’s ADSs at the beginning or the end of each offering period, whichever is lower, using funds deducted from their payroll during the offering period. Eligible employees are able to authorize payroll deductions of up to 10% of their eligible earnings, subject to applicable limitations.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

20. SHARE-BASED COMPENSATION EXPENSE *(Continued)*

2018 Employee Share Purchase Plan *(Continued)*

The following tables summarizes the shares issued under the ESPP:

Issuance Date	Number of Ordinary Shares Issued	Market Price ¹		Purchase Price ²		Proceeds US\$'000
		ADS US\$	Ordinary US\$	ADS US\$	Ordinary US\$	
August 31, 2020	485,069	164.06	12.62	139.45	10.73	5,203
February 28, 2020	425,425	145.54	11.20	123.71	9.52	4,048
August 30, 2019	233,194	143.75	11.06	122.19	9.40	2,192
February 28, 2019	154,505	137.05	10.54	116.49	8.96	1,385

¹ The market price is the lower of the closing price on the NASDAQ Stock Market on the issuance date or the offering date, in accordance with the terms of the ESPP.

² The purchase price is the price which was discounted from the applicable market price, in accordance with the terms of the ESPP.

As of December 31, 2020, 6,056,056 ordinary shares were available for future issuance under the ESPP.

Share options

Generally, share options have a contractual term of 10 years and vest over a three- to five-year period, with the first tranche vesting one calendar year after the grant date or the service relationship start date and the remainder of the awards vesting on a monthly basis thereafter. Restricted shares and restricted share units generally vest over a four-year period, with the first tranche vesting one calendar year after the grant date or the service relationship start date and the remainder of the awards vesting on a yearly basis thereafter, or sometimes vest upon the achievement of pre-specified performance conditions.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

20. SHARE-BASED COMPENSATION EXPENSE *(Continued)*

Share options *(Continued)*

The following table summarizes the Company's share option activities under the 2011, 2016 and 2018 Plans:

	Number of Options	Weighted Average Exercise Price US\$	Weighted Average Grant Date Fair Value US\$	Weighted Average Remaining Contractual Term Years	Aggregate Intrinsic Value US\$'000
Outstanding at December 31, 2018	116,082,647	3.21			
Granted	12,641,590	9.38	5.06		
Exercised	(16,730,441)	2.60			171,429
Forfeited	<u>(3,576,542)</u>	5.09			
Outstanding at December 31, 2019	108,417,254	3.96			
Granted	8,999,536	13.54	7.15		
Exercised	(29,707,587)	2.82			416,509
Forfeited	<u>(2,717,488)</u>	7.22			
Outstanding at December 31, 2020	<u>84,991,715</u>	5.27		6.45	1,242,276
Exercisable as of December 31, 2020	<u>58,701,454</u>	3.37		5.72	968,680
Vested and expected to vest at December 31, 2020	<u>82,099,824</u>	5.12		6.39	1,212,180

As of December 31, 2020, the unrecognized compensation cost related to 23,398,370 unvested share options expected to vest was US\$117,154,000. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.0 years.

The total fair value of employee share option awards vested during the years ended December 31, 2020 and 2019 was US\$55,127,000 and US\$58,670,000, respectively.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

20. SHARE-BASED COMPENSATION EXPENSE *(Continued)*

Fair value of options

The Company uses the binomial option-pricing model in determining the estimated fair value of the options granted. The model requires the input of highly subjective assumptions including the estimated expected stock price volatility and, the exercise multiple for which employees are likely to exercise share options. For expected volatilities, the trading history and observation period of the Company's own share price movement has not been long enough to match the life of the share option. Therefore, the Company has made reference to the historical price volatilities of ordinary shares of several comparable companies in the same industry as the Company. For the exercise multiple, the Company was not able to develop an exercise pattern as reference, thus the exercise multiple is based on management's estimation, which the Company believes is representative of the future exercise pattern of the options. The risk-free rate for periods within the contractual life of the option is based on the U.S. Treasury Bills yield curve in effect at the time of grant.

The following table presents the range of fair values and the assumptions used to estimate those fair values of the share options granted in the years presented:

	Year Ended December 31,	
	2020	2019
Fair value of ordinary share	US\$4.95 ~ US\$11.89	US\$4.64 ~ US\$8.28
Risk-free interest rate	0.6% ~ 1.1%	1.5% ~ 2.8%
Expected exercise multiple	2.8	2.2 ~ 2.8
Expected volatility	58% ~ 59%	58% ~ 60%
Expected dividend yield	0%	0%
Contractual life	10 years	10 years

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

20. SHARE-BASED COMPENSATION EXPENSE *(Continued)*

Restricted shares

The following table summarizes the Company's restricted share activities under the 2016 Plan:

	Numbers of Shares	Weighted- Average Grant Date Fair Value US\$
Outstanding at December 31, 2018	300,000	2.25
Granted	–	–
Vested	(75,000)	2.27
Forfeited	<u>(150,000)</u>	2.24
Outstanding at December 31, 2019	75,000	2.27
Granted	–	–
Vested	(75,000)	2.27
Forfeited	<u>–</u>	–
Outstanding at December 31, 2020	<u>–</u>	–
Expected to vest at December 31, 2020	<u>–</u>	–

The Company had no non-employee restricted share activities during the year ended December 31, 2020.

As of December 31, 2020, all compensation cost related to restricted shares was fully recognized.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

20. SHARE-BASED COMPENSATION EXPENSE *(Continued)*

Restricted share units

The following table summarizes the Company's restricted share unit activities under the 2016 and 2018 Plans:

	Numbers of Shares	Weighted- Average Grant Date Fair Value US\$
Outstanding at December 31, 2018	14,102,452	11.85
Granted	18,637,333	10.10
Vested	(3,474,068)	11.75
Forfeited	<u>(2,413,450)</u>	11.07
Outstanding at December 31, 2019	26,852,267	10.72
Granted	18,820,581	14.20
Vested	(7,302,828)	10.88
Forfeited	<u>(3,493,048)</u>	11.36
Outstanding at December 31, 2020	<u>34,876,972</u>	12.50
Expected to vest at December 31, 2020	<u>31,040,505</u>	12.50

As of December 31, 2020, the unrecognized compensation cost related to unvested restricted share units expected to vest was US\$334,716,000. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 3.2 years.

The following table summarizes total share-based compensation cost recognized for the years ended December 31, 2020 and 2019:

	Year Ended December 31,	
	2020 US\$'000	2019 US\$'000
Research and development	92,999	76,293
Selling, general and administrative	<u>90,482</u>	<u>57,861</u>
Total	<u>183,481</u>	<u>134,154</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

21. ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

The movement of accumulated other comprehensive income (loss) was as follows:

	Foreign Currency Translation Adjustments US\$' 000	Unrealized Gains/Losses on Available- for-Sale Securities US\$' 000	Pension Liability Adjustments US\$' 000	Total US\$' 000
December 31, 2018	(212)	1,738	–	1,526
Other comprehensive income (loss) before reclassifications	(9,079)	5,596	–	(3,483)
Amounts reclassified from accumulated other comprehensive income (loss) ⁽¹⁾	–	(6,044)	–	(6,044)
Net-current period other comprehensive loss	<u>(9,079)</u>	<u>(448)</u>	<u>–</u>	<u>(9,527)</u>
December 31, 2019	<u>(9,291)</u>	<u>1,290</u>	<u>–</u>	<u>(8,001)</u>
Other comprehensive income (loss) before reclassifications	23,475	1,073	(8,113)	16,435
Amounts reclassified from accumulated other comprehensive income (loss) ⁽¹⁾	–	(1,492)	–	(1,492)
Net-current period other comprehensive (loss) income	<u>23,475</u>	<u>(419)</u>	<u>(8,113)</u>	<u>14,943</u>
December 31, 2020	<u>14,184</u>	<u>871</u>	<u>(8,113)</u>	<u>6,942</u>

(1) The amounts reclassified from accumulated other comprehensive (loss) income were included in other income, net in the consolidated statements of operations.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

22. SHAREHOLDERS' EQUITY

During the years ended December 31, 2020 and 2019, the Company completed the following equity offerings:

In January 2020, the Company sold 15,895,001 ADSs, representing a 20.5% ownership stake in the Company, to Amgen for aggregate cash proceeds of US\$2,779,241,000, or US\$174.85 per ADS, pursuant to the SPA executed in connection with the Amgen Collaboration Agreement. On March 17, 2020, BeiGene, Ltd. and Amgen entered into an Amendment No. 2 (the "Second Amendment") to the Share Purchase Agreement in order to account for periodic dilution from the issuance of shares by the Company, which was restated in its entirety on September 24, 2020 (the "Restated Second Amendment"). Pursuant to the Restated Second Amendment, Amgen will have an option (the "Direct Purchase Option") to subscribe for additional ordinary shares of the Company in the form of ADSs (the "Additional Shares") in an amount necessary to enable it to increase (and subsequently maintain) its ownership at approximately 20.6% of the Company's outstanding shares. The Direct Purchase Option is exercisable on a monthly basis, but only if Amgen's interest in the outstanding shares of the Company at the monthly reference date is less than 20.4%. The Direct Purchase Option (i) will be exercisable by Amgen solely as a result of dilution arising from issuance of new shares under the Company's equity incentive plans from time to time, and (ii) is subject to annual approval by the Company's independent shareholders each year during the term of the Restated Second Amendment. The exercise period of the Direct Purchase Option commenced on December 1, 2020 and will terminate on the earliest of: (a) the date on which Amgen and its affiliates collectively own less than 20% of the outstanding share capital of the Company as a result of Amgen's sale of shares; (b) at least 60-day advance written notice from either Amgen or the Company that such party wishes to terminate the Direct Purchase Option; or (c) December 1, 2023. The Direct Purchase Option has no vesting period.

In July 2020, the Company issued 145,838,979 ordinary shares, par value US\$0.0001, to eight existing investors, including entities associated with Hillhouse Capital and Baker Bros. Advisors LP, as well as Amgen, in a registered direct offering under the Company's effective Registration Statement on Form S-3 (File No. 333-238181). Each ordinary share was sold for a purchase price of US\$14.2308 per share (US\$185.00 per ADS), resulting in net proceeds, after offering expenses, of US\$2,069,610,000. Amgen purchased 29,614,832 ordinary shares for US\$421,443,000 as part of this offering. The offering was made without an underwriter or a placement agent, and as a result the Company did not pay any underwriting discounts or commissions in connection with the offering.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

23. RESTRICTED NET ASSETS

The Company's ability to pay dividends may depend on the Company receiving distributions of funds from its PRC subsidiaries. Relevant PRC laws and regulations permit payments of dividends by the Company's PRC subsidiaries only out of its retained earnings, if any, as determined in accordance with PRC accounting standards and regulations. The results of operations reflected in the consolidated financial statements prepared in accordance with GAAP differ from those reflected in the statutory financial statements of the Company's PRC subsidiaries.

In accordance with the company law of the PRC, a domestic enterprise is required to provide statutory reserves of at least 10% of its annual after-tax profit until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts. A domestic enterprise is also required to provide discretionary surplus reserve, at the discretion of the Board of Directors, from the profits determined in accordance with the enterprise's PRC statutory accounts. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. The Company's PRC subsidiaries were established as domestic invested enterprises and therefore were subject to the above-mentioned restrictions on distributable profits.

During the years ended December 31, 2020 and 2019, no appropriation to statutory reserves was made, because the PRC subsidiaries had substantial losses during such periods.

As a result of these PRC laws and regulations, including the requirement to make annual appropriations of at least 10% of after-tax income and set aside as general reserve fund prior to payment of dividends, the Company's PRC subsidiaries are restricted in their ability to transfer a portion of their net assets to the Company.

Foreign exchange and other regulations in the PRC may further restrict the Company's PRC subsidiaries from transferring funds to the Company in the form of dividends, loans, and advances. As of December 31, 2020 and 2019, amounts restricted were the net assets of the Company's PRC subsidiaries, which amounted to US\$119,776,000 and US\$109,633,000, respectively.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

24. EMPLOYEE BENEFIT PLANS

Defined Contribution Plans

Full-time employees of the Company in the PRC participate in a government mandated defined contribution plan, pursuant to which certain pension benefits, medical care, employee housing fund and other welfare benefits are provided to employees. Chinese labor regulations require that the Company's PRC subsidiaries make contributions to the government for these benefits based on certain percentages of the employees' salaries. The Company has no legal obligation for the benefits beyond the contributions made. The total amounts for such employee benefits, which were expensed as incurred, were US\$23,717,000 and US\$23,282,000 for the years ended December 31, 2020 and 2019, respectively.

The Company maintains a defined contribution 401(k) savings plan (the "401(k) Plan") for U.S. employees. The 401(k) Plan covers all U.S. employees, and allows participants to defer a portion of their annual compensation on a pretax basis. In addition, the Company has a matching contribution to the 401(k) Plan, which, in the 2020 plan year, matched dollar for dollar of eligible contributions up to 4%. Company contributions to the 401(k) plan totaled US\$4,840,000 and US\$2,389,000 in the years ended December 31, 2020 and 2019, respectively.

The Company maintains a government mandated program to cover its employees in Switzerland for pension, death, or disability. The program is considered a defined contribution plan. Employer and employee contributions are made based on various percentages of salaries and wages that vary based on employee age and other factors. Company contributions into the program amounted to US\$2,960,000 and US\$528,000 in the years ended December 31, 2020 and 2019, respectively.

Employee benefit expenses for the remaining subsidiaries were immaterial.

Defined Benefit Plan

The Company also maintains a defined benefit pension plan covering its employees in Switzerland (the "Swiss Plan"). This plan is a government mandated fund that provides benefits to employees upon retirement, death, or disability. Contributions are made based on various percentages of participants' salaries and wages determined based on participants' age and other factors. As of December 31, 2020, the projected benefit obligation and plan assets under the Swiss Plan were approximately US\$23,566,000 and US\$15,453,000, respectively. The funded status of the Swiss Plan is included in other long-term liabilities in the accompanying consolidated balance sheets. The initial determination of the pension liability was recorded as other comprehensive loss during the year ended December 31, 2020 (see Note 21).

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

24. EMPLOYEE BENEFIT PLANS *(Continued)*

Defined Benefit Plan *(Continued)*

The Company's annual contribution to the Swiss Plan is estimated to be approximately US\$1,357,000 in 2021 and is expected to evolve thereafter proportionally with changes in staffing and compensation levels, actuarial assumptions and actual investment returns on plan assets.

The following table reflects the total expected benefit payments to Swiss Plan participants and have been estimated based on the same assumptions used to measure the Company's benefit obligations as of December 31, 2020:

	Amounts US\$' 000
2021	139
2022	171
2023	203
2024	382
2025	238
2026 – 2030	<u>1,919</u>
Total	<u><u>3,052</u></u>

25. COMMITMENTS AND CONTINGENCIES

Purchase Commitments

As of December 31, 2020, the Company had purchase commitments amounting to US\$123,383,000, of which US\$101,236,000 related to minimum purchase requirements for supply purchased from contract manufacturing organizations and US\$22,147,000 related to binding purchase order obligations of inventory from BMS and Amgen. The Company does not have any minimum purchase requirements for inventory from BMS or Amgen.

Capital commitments

The Company had capital commitments amounting to US\$44,972,000 for the acquisition of property, plant and equipment as of December 31, 2020, which were mainly for BeiGene Guangzhou Factory's manufacturing facility, expansion of BGC's research and development activities in Guangzhou, China, and research and development operations at the Changping facility in Beijing, China.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

25. COMMITMENTS AND CONTINGENCIES *(Continued)*

Co-development funding commitment

Under the Amgen Collaboration Agreement, the Company is responsible for co-funding global development costs for the Amgen oncology pipeline assets up to a total cap of US\$1,250,000,000. The Company is funding its portion of the co-development costs by contributing cash and/or development services. As of December 31, 2020, the Company's remaining co-development funding commitment was US\$1,019,009,000.

Other Business Agreements

The Company enters into agreements in the ordinary course of business with CROs to provide research and development services. These contracts are generally cancelable at any time by the Company with prior written notice.

The Company also enters into collaboration agreements with institutions and companies to license intellectual property. The Company may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with its collaboration agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. These commitments are not recorded on the consolidated balance sheet because the achievement and timing of these milestones are not fixed and determinable. When the achievement of these milestones or sales have occurred, the corresponding amounts are recognized in the consolidated financial statements.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

26. DIRECTORS' AND CHIEF EXECUTIVE'S REMUNERATION

Directors' and chief executive's remuneration for the years ended December 31, 2020 and 2019, were disclosed pursuant to the HK Listing Rules, section 383(1)(a), (b), (c) and (f) of the Hong Kong Companies Ordinance and Part 2 of the Companies (Disclosure of Information about Benefits of Directors) Regulation, is as follows:

	Year ended December 31,	
	2020	2019
	US\$'000	US\$'000
Fees	560	445
Other emoluments:		
Salaries, allowances and benefits in kind	786	1,013
Performance related bonuses	637	544
Share-based compensation expenses*	16,890	14,439
Pension scheme contributions	10	13
	<u>18,323</u>	<u>16,009</u>
	<u>18,883</u>	<u>16,454</u>

* Share-based compensation amount disclosed in Note 26 (including above table) and Note 27 represented the amount determined under U.S. GAAP and recognized in the relevant accounting periods mentioned above.

For the years ended December 31, 2020 and 2019, certain directors were granted share options or restricted share units, in respect of their services to the Group, under the share option plans of the Company, further details of which are set out in Note 20. The fair value of such options or restricted share units, which has been recognized in the consolidated statement of operations over the vesting period, was determined as at the date of grant and the accounting amount recognized in the respective accounting periods is included in the above directors' and chief executive's remuneration disclosures.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

26. DIRECTORS' AND CHIEF EXECUTIVE'S REMUNERATION (Continued)

(a) Independent non-executive directors

The remuneration paid to independent non-executive directors for the years ended December 31, 2020 and 2019 were as follows:

Year ended December 31, 2020

	Fees US\$' 000	Salaries, allowances and benefits in kind US\$' 000	Performance related bonuses US\$' 000	Share-based compensation expense US\$' 000	Pension scheme contributions US\$' 000	Total remuneration US\$' 000
Timothy Chen	70	-	-	290	-	360
Donald W. Glazer	63	-	-	290	-	353
Michael Goller	61	-	-	290	-	351
Ranjeev Krishana	63	-	-	290	-	353
Thomas Malley	78	-	-	290	-	368
Qingqing Yi	73	-	-	290	-	363
Jing-Shyh (Sam) Su	59	-	-	445	-	504
Corsee Sanders	24	-	-	118	-	142
	<u>491</u>	<u>-</u>	<u>-</u>	<u>2,303</u>	<u>-</u>	<u>2,794</u>

Year ended December 31, 2019

	Fees US\$' 000	Salaries, allowances and benefits in kind US\$' 000	Performance related bonuses US\$' 000	Share-based compensation expense US\$' 000	Pension scheme contributions US\$' 000	Total remuneration US\$' 000
Timothy Chen	68	-	-	300	-	368
Donald W. Glazer	63	-	-	300	-	363
Michael Goller	55	-	-	300	-	355
Ranjeev Krishana	58	-	-	300	-	358
Thomas Malley	73	-	-	300	-	373
Qingqing Yi	71	-	-	300	-	371
Jing-Shyh (Sam) Su	57	-	-	310	-	367
	<u>445</u>	<u>-</u>	<u>-</u>	<u>2,110</u>	<u>-</u>	<u>2,555</u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

26. DIRECTORS' AND CHIEF EXECUTIVE'S REMUNERATION (Continued)

(b) Executive director, a non-executive director and chief executive

For the years ended December 31, 2020 and 2019, the Board of Directors comprised one executive director, John V. Oyler, who is also the chief executive of the Company. The remuneration paid to John V. Oyler for the years ended December 31, 2020 and 2019 were as follows:

	Year ended December 31,	
	2020 US\$' 000	2019 US\$' 000
Fees	-	-
Other emoluments:		
Salaries, allowances and benefits in kind	786	1,013
Performance related bonuses	637	544
Share-based compensation expenses	14,376	12,329
Pension scheme contributions	10	13
	<u>15,809</u>	<u>13,899</u>
	<u>15,809</u>	<u>13,899</u>

For the year ended December 31, 2020, the Board of Directors comprised two non-executive director, Xiaodong Wang and Anthony C. Hooper. For the year ended December 31, 2019, the Board of Directors comprised one non-executive director, Xiaodong Wang. Xiaodong Wang did not receive any compensation as a director. The compensation received by Xiaodong Wang as a consultant during the years ended December 31, 2020 and 2019 were detailed below and also included in Note 28.

Year ended December 31, 2020

	Fees US\$' 000	Salaries, allowances and benefits in kind US\$' 000	Performance related bonuses US\$' 000	Share-based compensation expense US\$' 000	Pension scheme contributions US\$' 000	Total remuneration US\$' 000
Xiaodong Wang	100	-	150	6,157	-	6,407
Anthony C. Hooper	69	-	-	211	-	280
	<u>169</u>	<u>-</u>	<u>150</u>	<u>6,368</u>	<u>-</u>	<u>6,687</u>

Year ended December 31, 2019

	Fees US\$' 000	Salaries, allowances and benefits in kind US\$' 000	Performance related bonuses US\$' 000	Share-based compensation expense US\$' 000	Pension scheme contributions US\$' 000	Total remuneration US\$' 000
Xiaodong Wang	100	-	150	6,377	-	6,627

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

27. FIVE HIGHEST PAID EMPLOYEES

The five highest paid employees for the years ended December 31, 2020 and 2019 included the following number of directors and chief executive, details of whose remuneration are set out in Note 26 above.

	Headcounts	
	2020	2019
Directors and chief executive	2	2
Neither directors nor chief executive	<u>3</u>	<u>3</u>
	<u><u>5</u></u>	<u><u>5</u></u>

Details of the remuneration for the year of the remaining highest paid employees who are neither a director nor chief executive of the Company are as follows:

	Year ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
Salaries, allowances and benefits in kind	1,732	1,654
Performance related bonuses	1,037	893
Share-based compensation expenses	13,268	10,849
Pension scheme contributions	<u>33</u>	<u>21</u>
	<u><u>16,070</u></u>	<u><u>13,417</u></u>

The number of non-director and non-chief executive highest paid employees whose remuneration fell within the following bands is as follows:

	Number of employees	
	2020	2019
HK\$25,000,001 to HK\$30,000,000	1	2
HK\$30,000,001 to HK\$35,000,000	1	–
HK\$40,000,001 to HK\$46,000,000	–	1
HK\$60,000,001 to HK\$65,000,000	<u>1</u>	<u>–</u>
	<u><u>3</u></u>	<u><u>3</u></u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

27. FIVE HIGHEST PAID EMPLOYEES *(Continued)*

For the years ended December 31, 2020 and 2019, share options, or restricted share units were granted to a non-director and non-chief executive highest paid employee in respect of his services to the Group, further details of such equity award plans are included in the disclosures in Note 20. The fair value of such options, which have been recognized in the statement of operations over the vesting period, was determined as at the date of grant and the accounting amount recognized in the respective accounting periods is included in the above non-director and non-chief executive highest paid employees' remuneration disclosures.

28. RELATED PARTY TRANSACTIONS

In addition to the transactions detailed elsewhere in this financial information, the Company had the following related party transactions for the years ended December 31, 2020 and 2019:

Xiaodong Wang, Chairman of Scientific Advisory Board, director and shareholder, provided consulting service to the Group, and the compensation received by Dr. Wang for such service during the year ended December 31, 2020 consisted of (i) US\$100,000 (2019: US\$100,000) in consulting fees, (ii) US\$150,000 (2019: US\$150,000) as a performance-based cash bonus, (iii) an option to purchase 560,599 ordinary shares (2019: 747,708 ordinary shares) with a grant date fair value of US\$4,000,000 (2019: US\$3,750,000).

The cash component of the above related party transaction also constitutes a fully-exempt continuing connected transaction under Chapter 14A of the HK Listing Rules.

Seagen, Inc.

On November 5, 2019, the Company entered into a license agreement with Seagen, Inc. for an advanced pre-clinical product candidate for treating cancer. The agent utilizes a proprietary Seagen antibody-based technology. Under the terms of the agreement, Seagen retained rights to the product candidate in the Americas (United States, Canada and Latin American countries), Europe and Japan. The Company was granted exclusive rights to develop and commercialize the product candidate in Asia (except Japan) and the rest of the world. Seagen will lead global development and BeiGene will fund and operationalize the portion of global clinical trials attributable to its territories. BeiGene will also be responsible for all clinical development and regulatory submissions specific to its territories. Seagen received an upfront payment of US\$20,000,000 and is eligible to receive progress dependent milestones and tiered royalties on any product sales. Seagen is a related party due to a common shareholder, and that shareholder has different representatives serving on each companies' respective board of directors. The upfront payment was expensed to research and development expense during the year ended December 31, 2019 in accordance with the Company's acquired in-process research and development expense policy.

The above related party transaction does not constitute a connected transaction under Chapter 14A of the HK Listing Rules.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

29. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

The following table summarizes the unaudited statements of operations for each quarter of 2020 and 2019 (in thousands, except share and per share amounts). The unaudited quarterly information has been prepared on a basis consistent with the audited financial statements and includes all adjustments that the Company considers necessary for a fair presentation of the information shown. The operating results for any fiscal quarter are not necessarily indicative of the operating results for a full fiscal year or for any future period and there can be no assurances that any trend reflected in such results will continue in the future.

	Quarter Ended			
	March 31, US\$' 000	June 30, US\$' 000	September 30, US\$' 000	December 31, US\$' 000
2020				
Revenue	52,059	65,635	91,080	100,100
Loss from operations	(373,756)	(358,877)	(440,137)	(484,912)
Net loss	(364,939)	(336,318)	(426,617)	(472,649)
Net loss attributable to ordinary shareholders	(363,735)	(335,202)	(425,224)	(472,745)
Basic and diluted net loss per share (in US\$) ⁽¹⁾	(0.36)	(0.33)	(0.37)	(0.40)
	Quarter Ended			
	March 31, US\$' 000	June 30, US\$' 000	September 30, US\$' 000	December 31, US\$' 000
2019				
Revenue	77,833	243,346	50,141	56,892
Loss from operations	(173,755)	(85,833)	(312,266)	(388,037)
Net loss	(168,069)	(85,954)	(308,660)	(387,895)
Net loss attributable to ordinary shareholders	(167,640)	(85,570)	(307,357)	(388,061)
Basic and diluted net loss per share (in US\$) ⁽¹⁾	(0.22)	(0.11)	(0.39)	(0.49)

(1) Per ordinary share amounts for the quarters and full years have been calculated separately. Accordingly, the sum of quarterly amounts may not equal the annual amount because of differences in the weighted average ordinary shares outstanding during each period, principally due to the effect of share issuances by the Company during the year.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

30. SEGMENT AND GEOGRAPHIC INFORMATION

The Company operates in one segment: pharmaceutical products. Its chief operating decision maker is the Chief Executive Officer, who makes operating decisions, assesses performance, and allocates resources on a consolidated basis.

The Company's long-lived assets are substantially located in the PRC.

Net product revenues by geographic area are based upon the location of the customer, and net collaboration revenue is recorded in the jurisdiction in which the related income is expected to be sourced from. Total net revenues by geographic area are presented as follows:

	Year Ended December 31,	
	2020	2019
	US\$' 000	US\$' 000
PRC	290,646	221,557
U.S.	18,228	134,689
Other	—	71,966
	<hr/>	<hr/>
Total	<u>308,874</u>	<u>428,212</u>

31. SUBSEQUENT EVENTS

On January 11, 2021, the Company entered into a collaboration and license agreement with Novartis to develop, manufacture and commercialize tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan. The Company has agreed to jointly develop tislelizumab with Novartis in these licensed countries, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals. In addition, both companies may conduct clinical trials globally to explore combinations of tislelizumab with other cancer treatments, and the Company has an option to co-detail the product in North America, funded in part by Novartis. Under the agreement the Company will receive an upfront cash payment of US\$650,000,000 from Novartis and is eligible to receive up to US\$1,300,000,000 upon the achievement of regulatory milestones, US\$250,000,000 upon the achievement of sales milestones, and royalties on future sales of tislelizumab in the licensed territory. On February 26, 2021, the Company announced the closing of the collaboration and license agreement with Novartis. On March 11, 2021, the Company subsequently received the upfront cash payment of US\$650,000,000.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

31. SUBSEQUENT EVENTS *(Continued)*

On January 29, 2021, the Shanghai Stock Exchange (the “SSE”) accepted a listing application submitted by the Company for a proposed public offering of the Company’s ordinary shares and listing of such shares on the Science and Technology Innovation Board (the “STAR Market”) of the SSE (the “STAR Offering”). The STAR Offering will be conducted within the PRC, and such shares will be issued to and subscribed for by investors in Renminbi (“RMB”) in the PRC and listed and traded on the STAR Market in RMB (the “RMB Shares”). The RMB Shares will not be fungible with the Company’s ordinary shares listed on the HKEx or with the Company’s ADSs listed on the NASDAQ Global Select Market. The number of RMB Shares (including the over-allotment option) to be issued will not exceed 132,313,549 ordinary shares, representing no more than 10% of the sum of the total number of issued ordinary shares of the Company as of January 7, 2021 and the total number of RMB Shares to be issued in the STAR Offering. The consummation of the STAR Offering is subject to, among other things, market conditions, the approval of the shareholders of the Company, and applicable regulatory approvals.

32. RECONCILIATION BETWEEN U.S. GAAP AND INTERNATIONAL FINANCIAL REPORTING STANDARDS

The consolidated financial statements are prepared in accordance with U.S. GAAP, which differ in certain respects from International Financial Reporting Standards (“IFRSs”). The effects of material differences between the financial information of the Group prepared under U.S. GAAP and IFRSs are as follows:

Consolidated statement of operations data	Year ended December 31, 2020			
	Amounts as reported under	IFRSs adjustments		Amounts under IFRSs
	U.S. GAAP	US\$' 000	US\$' 000	US\$' 000
	US\$' 000	US\$' 000	US\$' 000	US\$' 000
			Tax benefit/ deficiency on	
		Share-based compensation	share-based compensation	
		(note (i))	(note (iii))	
Research and development	(1,294,877)	(5,338)	-	(1,300,215)
Selling, general and administrative	(600,176)	(12,280)	-	(612,456)
Loss before income tax expense	(1,618,194)	(17,618)	-	(1,635,812)
Income tax (expense) benefit	17,671	1,143	(41,404)	(22,590)
Net loss	(1,600,523)	(16,475)	(41,404)	(1,658,402)
Net loss attributable to BeiGene, Ltd.	(1,596,906)	(16,475)	(41,404)	(1,654,785)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

32. RECONCILIATION BETWEEN U.S. GAAP AND INTERNATIONAL FINANCIAL REPORTING STANDARDS *(Continued)*

Consolidated statement of operations data	Year ended December 31, 2019			
	Amounts as reported under U.S. GAAP US\$' 000	IFRSs adjustments		Amounts under IFRSs US\$' 000
		US\$' 000	US\$' 000	
		Share-based compensation (note (i))	Tax benefit/ deficiency on share-based compensation (note (iii))	
Research and development	(927,338)	(23,380)	–	(950,718)
Selling, general and administrative	(388,249)	(8,820)	–	(397,069)
Loss before income tax expense	(943,586)	(32,200)	–	(975,786)
Income tax expense	(6,992)	2,048	(19,977)	(24,921)
Net loss	(950,578)	(30,152)	(19,977)	(1,000,707)
Net loss attributable to BeiGene, Ltd.	(948,628)	(30,152)	(19,977)	(998,757)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

32. RECONCILIATION BETWEEN U.S. GAAP AND INTERNATIONAL FINANCIAL REPORTING STANDARDS (Continued)

Consolidated balance sheet data	As at December 31, 2020				
	Amounts as reported under US GAAP US\$' 000	US\$' 000	IFRSs adjustments US\$' 000		Amounts under IFRSs US\$' 000
			Share based compensation (note (i))	Preferred Shares (note (ii))	Tax benefit/ deficiency on share based compensation (note (iii))
Deferred tax assets	65,962	1,143	-	-	76,029
		<u>8,924*</u>	<u>-</u>	<u>-</u>	
Total assets	5,600,757	<u>10,067</u>	<u>-</u>	<u>-</u>	5,610,824
Additional paid-in capital	7,414,932	17,618	307,894*	41,404	7,927,963
		107,701*	-	38,414*	
Accumulated deficit	(3,552,749)	(17,618)	(307,894)*	(41,404)	(4,055,713)
		1,143	-	-	
		<u>(98,777)*</u>	<u>-</u>	<u>(38,414)*</u>	
Total equity	3,869,243	<u>10,067</u>	<u>-</u>	<u>-</u>	3,879,310

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

32. RECONCILIATION BETWEEN U.S. GAAP AND INTERNATIONAL FINANCIAL REPORTING STANDARDS *(Continued)*

Consolidated balance sheet data	As at December 31, 2019				Amounts under IFRSs US\$' 000
	Amounts as reported under US GAAP US\$' 000	IFRSs adjustments			
		US\$' 000	US\$' 000	US\$' 000	
			Share based compensation (note (i))	Preferred Shares (note (ii))	Tax benefit/ deficiency on share based compensation (note (iii))
Deferred tax assets	37,894	2,048	–	(8,617)	46,818
		<u>6,876*</u>	<u>–</u>	<u>8,617*</u>	
Total assets	1,612,289	<u>8,924</u>	<u>–</u>	<u>–</u>	1,621,213
Additional paid-in capital	2,925,970	32,200	307,894*	11,360	3,379,979
		75,501*	–	27,054*	
Accumulated deficit	(1,955,843)	(32,200)	(307,894)*	(19,977)	(2,400,928)
		2,048			
		<u>(68,625)*</u>	<u>–</u>	<u>(18,437)*</u>	
Total equity	978,355	<u>8,924</u>	<u>–</u>	<u>–</u>	987,279

* IFRSs adjustments brought forward from prior years.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

32. RECONCILIATION BETWEEN U.S. GAAP AND INTERNATIONAL FINANCIAL REPORTING STANDARDS *(Continued)*

Notes:

(i) Share based compensation

Under U.S. GAAP, the Group has elected to recognize compensation expense using the straight-line method for all employee equity awards granted with graded vesting based on service conditions provided that the amount of compensation cost recognized at any date is at least equal to the portion of the grant date value of the options that are vested at that date.

Under IFRSs, the accelerated method is required to recognize compensation expense for all employee equity awards granted with graded vesting.

A difference of US\$17,618,000 arose between the amount of share-based compensation (included in research and development expenses, and selling, general and administrative expenses) recognized under U.S. GAAP and IFRSs for the year ended December 31, 2020 (2019: US\$32,200,000). The related income tax impact of this item was US\$1,143,000 for the year ended December 31, 2020 (2019: US\$2,048,000).

The accumulated difference on share-based compensation recognized in expenses and additional paid in capital under U.S. GAAP and IFRSs was US\$107,701,000, the related income tax impact on above differences was US\$8,924,000, and net impact on the accumulated deficit was US\$98,777,000 as of December 31, 2019. The differences as of December 31, 2019 were all carried forward as opening IFRSs adjustments to the balance sheet as of January 1, 2020.

(ii) Preferred Shares

Prior to the Company's US IPO, the Company had Preferred Shares, which were converted into ordinary shares at the time of the US IPO. Under U.S. GAAP, the Preferred Shares issued by the Company are classified as mezzanine equity as these convertible preferred shares are redeemable upon the occurrence of a conditional event (i.e., Liquidation Transaction). The holders of the Preferred Shares have a liquidation preference upon the occurrence of the conditional event. The conversion options and contingent redemption options of the convertible preferred shares do not qualify for bifurcation accounting because the conversion options are clearly and closely related to the host instrument and the underlying ordinary shares of the conversion options and redemption options are not publicly traded nor readily convertible into cash. No beneficial conversion features are recognized for the convertible preferred shares as the fair values per ordinary share at the respective commitment dates were less than the most favorable conversion prices. The Company concluded that the Preferred Shares are not redeemable currently and is not probable that the Preferred Shares will become redeemable because the likelihood of the Liquidation Transaction is remote. Therefore, no adjustment will be made to the initial carrying amount of the Preferred Shares until it is probable that they will become redeemable.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

32. RECONCILIATION BETWEEN U.S. GAAP AND INTERNATIONAL FINANCIAL REPORTING STANDARDS *(Continued)*

Notes: *(Continued)*

(ii) Preferred Shares *(Continued)*

Under IFRSs, the Preferred Shares were regarded as a hybrid instrument consisting of a host debt instrument and a conversion option as a derivative. This was the result of certain redemption triggering events of the Preferred Shares being outside the control of the ordinary shareholders of the Company. In addition, the holders of the Preferred Shares were entitled to convert the Preferred Shares into a variable number of the Company's ordinary shares upon occurrence of certain anti-dilution events. Under IFRSs, the Company initially recorded all of the Preferred Shares as financial liabilities at fair value, with subsequent changes in the amount of the fair value of the Preferred Shares recognized in the statement of operations in the year in which they arose. Hence, all the fair value changes in the Preferred Shares of US\$307,894,000 prior to the conversion into the Company's ordinary shares in February 2016 was recognized in the statement of operations under IFRSs, and the cumulative effect of such fair value changes was recognized in the additional paid in capital account upon the conversion of the Preferred Shares into the ordinary shares. The effect of such IFRSs adjustments on accumulated deficit and additional paid-in capital was US\$307,894,000 which was all carried forward to opening balance sheets of subsequent financial years/periods.

(iii) Tax benefit/deficiency on share-based compensation

Under U.S. GAAP, deferred taxes are calculated based on the cumulative share-based compensation expense recognized in the financial statements, and ASC 2016-09 required all excess tax benefits and tax deficiencies to be recorded as income tax expense or benefit in the statement of operations, rather than in shareholders' equity.

Under IFRSs, deferred taxes are calculated based on the estimated tax deduction determined at each reporting date. If the tax deduction exceeds cumulative compensation cost for an individual award, deferred tax based on the excess is credited to shareholders' equity. If the tax deduction is less than or equal to cumulative compensation cost for an individual award, deferred taxes are recorded in statement of operations.

As the deferred tax assets impact was determined to the extent of future available taxable profit against which the estimated additional tax deduction can be utilized, there is no difference on deferred tax assets for tax benefit on share-based compensation expenses recognized under U.S. GAAP and IFRSs as of December 31, 2020 and 2019. The cumulative income tax benefit on excess tax deductions of US\$41,404,000 for the year ended December 31, 2020 (2019: US\$19,977,000) was recognized in equity under IFRSs, rather than in the statement of operations under U.S. GAAP.

The accumulated difference of excess tax deduction of US\$38,414,000 recognized in equity amounted to US\$38,414,000 as of December 31, 2019 and are carried forward as opening adjustments to the balance sheet as of January 1, 2020 under IFRSs.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

32. RECONCILIATION BETWEEN U.S. GAAP AND INTERNATIONAL FINANCIAL REPORTING STANDARDS *(Continued)*

Notes: *(Continued)*

(iv) Lease

The Group adopted the new lease standard effective January 1, 2019 using the modified retrospective method and did not restate historical comparative periods under U.S. GAAP. As a lessee, the Group recognized a lease liability based on the present value of the total remaining lease payments, and a corresponding right of use asset under U.S. GAAP. The Group subsequently recognize an operating lease expense on straight line basis over the lease term.

IFRS 16, Lease requires entities to present interest expense on the lease liability and depreciation on the right of use assets separately in the statement of operations. This will change the allocation of expenses and the total amount of expenses recognized for each period of the lease term. The combination of a straight-line depreciation of the right-of-use asset and the effective interest rate method applied to the lease liability will result in a higher total charge to profit or loss in the initial years of the lease terms, and a decreasing expense during the latter years of the lease terms.

Based on the Group's assessment, the differences on lease recognized under U.S. GAAP and IFRSs did not have material impact on audited financial statements as of December 31, 2020 and for the year ended December 31, 2020.

(v) Investment

Under U.S. GAAP, the Group elected to measure an equity security without a readily determinable fair value that does not qualify for the practical expedient to estimate fair value at its cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

Under IFRSs, the group measured the investments in equity instruments at fair value through profit or loss (FVTPL).

Based on the Group's assessment, the differences on investment recognized under U.S. GAAP and IFRSs did not have material impact on audited financial statement as of December 31, 2020 and for the year ended December 31, 2020.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

33. STATEMENT OF FINANCIAL POSITION OF THE COMPANY

	As of December 31,	
	2020	2019
	US\$' 000	US\$' 000
Assets		
Current assets:		
Cash and cash equivalents	332,372	64,462
Short-term investments	2,885,650	232,204
Accounts receivable	419,936	206,055
Prepaid expenses and other current assets	92,171	74,624
Total current assets	<u>3,730,129</u>	<u>577,345</u>
Non-current assets:		
Long-term equity investments	138,305	175,385
Property and equipment, net	6,087	4,874
Other non-current assets	931,899	418,511
Total non-current assets	<u>1,076,291</u>	<u>598,770</u>
Total assets	<u><u>4,806,420</u></u>	<u><u>1,176,115</u></u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	127,478	169,557
Accrued expenses and other payables	61,974	42,559
Research and development cost share liability, current portion	127,808	–
Short-term debt	244,298	–
Total current liabilities	<u>561,558</u>	<u>212,116</u>
Non-current liabilities:		
Research and development cost share liability, non-current portion	375,040	–
Other long-term liabilities	579	1,794
Total non-current liabilities	<u>375,619</u>	<u>1,794</u>
Total liabilities	<u><u>937,177</u></u>	<u><u>213,910</u></u>
Commitments and contingencies		
Shareholders' equity (deficit):		
Ordinary shares, US\$0.0001 par value per share; 9,500,000,000 shares authorized; 1,190,821,941 and 801,340,698 shares issued and outstanding as of December 31, 2020 and 2019, respectively	118	79
Additional paid-in capital	7,414,932	2,925,970
Accumulated other comprehensive income/(loss)	6,942	(8,001)
Accumulated deficit	(3,552,749)	(1,955,843)
Total equity	<u>3,869,243</u>	<u>962,205</u>
Total liabilities and equity	<u><u>4,806,420</u></u>	<u><u>1,176,115</u></u>

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

33. STATEMENT OF FINANCIAL POSITION OF THE COMPANY *(Continued)*

A summary of the Company's reserves is as follows:

	Ordinary Shares		Additional	Accumulated	Accumulated	Total US\$' 000
	Shares	Amount	Paid-In	OCI	Deficit	
		US\$' 000	Capital	US\$' 000	US\$' 000	
Balance at December 31, 2018	776,263,184	77	2,744,814	1,526	(1,007,215)	1,739,202
Issuance of shares reserved for share						
option exercises	4,505,839	-	-	-	-	-
Share-based compensation	-	-	134,154	-	-	134,154
Exercise of options, ESPP and release of RSUs	20,571,675	2	47,002	-	-	47,004
Other comprehensive loss	-	-	-	(9,527)	-	(9,527)
Net loss	-	-	-	-	(948,628)	(948,628)
Balance at December 31, 2019	801,340,698	79	2,925,970	(8,001)	(1,955,843)	962,205
Proceeds from issuance of ordinary shares,						
net of cost	145,838,979	14	2,069,596	-	-	2,069,610
Issuance of ordinary shares in connection						
with collaboration	206,635,013	21	2,162,386	-	-	2,162,407
Exercise of options, ESPP and release of RSUs	38,020,892	3	93,098	-	-	93,101
Use of shares reserved for share option						
exercises and RSU releases	(1,013,641)	1	-	-	-	1
Share-based compensation	-	-	183,481	-	-	183,481
Acquisition of joint venture ("JV") minority						
interest	-	-	(19,599)	-	-	(19,599)
Other comprehensive income	-	-	-	14,943	-	14,943
Net loss	-	-	-	-	(1,596,906)	(1,596,906)
Balance at December 31, 2020	1,190,821,941	118	7,414,932	6,942	(3,552,749)	3,869,243

The above statement of financial position of the Company have been prepared in accordance with U.S. GAAP, and in conformity with the disclosure requirements of the HK Listing Rules and the Hong Kong Companies Ordinance.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

34. DIVIDENDS

The board of directors of the Company did not recommend the distribution of any annual dividend for the year ended December 31, 2020 (year ended December 31, 2019: nil).

35. APPROVAL OF THE FINANCIAL STATEMENTS

The financial statements were approved and authorized for issue by the Company on March 30, 2021.

DEFINITIONS

“2011 Plan”	the 2011 Option Plan adopted by the Company on April 15, 2011 and most recently amended on April 17, 2015
“2016 Plan”	the Second Amended and Restated 2016 Share Option and Incentive Plan adopted by the Company on January 14, 2016, as amended from time to time, the principal terms of which were set out in the Company’s Proxy Statement/ Circular dated April 28, 2020
“2018 ESPP”	the Second Amended and Restated 2018 Employee Share Purchase Plan approved by our Board on November 7, 2018, and by our Shareholders on December 7, 2018, to replace the Amended and Restated 2018 Employee Share Purchase Plan originally adopted by the Company on June 6, 2018
“2018 Inducement Plan” or “2018 Plan”	the Amended and Restated 2018 Inducement Equity Plan adopted by the Company on June 6, 2018 and most recently amended on August 7, 2018
“ADS(s)”	American Depositary Shares (each representing 13 ordinary shares of the Company)
“affiliate(s)”	with respect to any specified person, any other person, directly or indirectly, controlling or controlled by or under direct or indirect common control with such specified person
“Amgen”	Amgen Inc., a company incorporated under the laws of Delaware, US, on April 7, 1987
“Amgen Collaboration Agreement”	a Collaboration Agreement dated October 31, 2019, by and between BeiGene Switzerland and Amgen, which became effective on January 2, 2020
“Articles”	the fifth amended and restated memorandum and articles of association adopted by special resolution of the Shareholders passed on December 7, 2018, as amended from time to time
“associate(s)”	has the meaning ascribed to it under the HK Listing Rules
“BeiGene”, “Company”, “our Company” or “the Company”	BeiGene, Ltd., an exempted company with limited liability incorporated under the laws of the Cayman Islands on October 28, 2010
“BeiGene Biologics”	BeiGene Biologics Co., Ltd.* (百濟神州生物藥業有限公司), a company incorporated under the laws of the PRC on January 25, 2017 and an indirectly wholly owned subsidiary of the Company

DEFINITIONS

“BeiGene Guangzhou Factory”	BeiGene Guangzhou Biologics Manufacturing Co., Ltd. (廣州百濟神州生物製藥有限公司), a company incorporated under the laws of the PRC on March 3, 2017 and a wholly owned subsidiary of BeiGene Biologics
“BeiGene (Suzhou)”	BeiGene (Suzhou) Co., Ltd. (百濟神州(蘇州)生物科技股份有限公司), a company incorporated under the laws of the PRC on April 9, 2015 and an indirectly wholly owned subsidiary of the Company
“BLA”	biologics license application
“Board”	the Board of Directors of the Company
“CDE”	Center for Drug Evaluation at the NMPA
“China” or “PRC”	the People’s Republic of China and, except where the context requires and only for the purpose of this report, excluding Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan. “Chinese” shall be construed accordingly
“CMOs”	contract manufacturing organizations
“Companies Ordinance”	the Companies Ordinance (Chapter 622 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“connected person(s)”	has the meaning ascribed to it under the HK Listing Rules
“Corporate Governance Code”	the Corporate Governance Code and Corporate Governance Report set out in Appendix 14 of the HK Listing Rules
“CROs”	contract research organizations
“Director(s)”	the director(s) of our Company
“EMA”	European Medicines Agency
“EU”	the European Union
“EUSA”	EUSA Pharma

DEFINITIONS

“FDA”	U.S. Food and Drug Administration
“GDPR”	General Data Protection Regulation (EU) 2016/679
“GET”	Guangzhou GET Technology Development Co., Ltd. (now Guangzhou High-tech Zone Technology Holding Group Co., Ltd.), a limited liability company established under the laws of the PRC on November 27, 1998 and an Independent Third Party
“Group”, “our Group”, “the Group”, “we”, “us”, or “our”	the Company and its subsidiaries from time to time
“HK Listing Rules”	the Rules governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“HKEx”	The Stock Exchange of Hong Kong Limited
“Hong Kong” or “HK”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong dollars” or “HK dollar” or “HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“IFRS”	International Financial Reporting Standards, as issued from time to time by the International Accounting Standards Board
“Independent Third Party(ies)”	any entity or person who is not a connected person of the Company within the meaning ascribed thereto under the HK Listing Rules
“IPO”	initial public offering
“Listing”	the listing of our Shares on the Main Board
“Main Board”	the stock exchange (excluding the option market) operated by the HKEx which is independent from and operates in parallel with the Growth Enterprise Market of the Stock Exchange
“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix 10 of the HK Listing Rules
“NASDAQ”	Nasdaq Stock Market
“NASDAQ Listing Rules”	the listing rules of the Nasdaq Stock Market

DEFINITIONS

“NDA”	new drug application
“NHTSA”	the National Healthcare Security Administration
“NMPA”	National Medical Products Administration, successor to the China Food and Drug Administration
“Novartis”	Novartis Pharma AG
“NRDL”	the National Reimbursement Drug List
“Prospectus”	the prospectus of the Company dated July 30, 2018
“Reporting Period”	the year ended December 31, 2020
“RMB” or “Renminbi”	Renminbi, the lawful currency of PRC
“SAFE”	State Administration of Foreign Exchange
“sBLA”	supplemental biologics license application
“SEC”	Securities and Exchange Commission of the United States
“SFO”	the Securities and Futures Ordinance (Chapter 571 of the Laws of Hong Kong), as amended, supplemented or otherwise modified from time to time
“Share(s)”	ordinary share(s) in the share capital of the Company
“Share Purchase Agreement”	a share purchase agreement dated October 31, 2019, as amended, by and between BeiGene, Ltd. and Amgen
“Shareholder(s)”	holder(s) of the Share(s)
“sNDA”	supplementary new drug applications
“subsidiary(ies)”	has the meaning ascribed to it thereto in section 15 of the Companies Ordinance
“substantial shareholder”	has the meaning ascribed to it in the HK Listing Rules
“United States”, “U.S.” or “US”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US dollars”, “U.S. dollars” or “US\$”	United States dollars, the lawful currency of the United States
“U.S. GAAP”	United States generally accepted accounting principles

GLOSSARY OF TECHNICAL TERMS

“BRAF”	means	a human gene that makes the B-raf protein involved in sending internal cell signals that direct cell growth
“BTK”	means	Bruton’s tyrosine kinase. BTK is a key component of the BCR signaling pathway and is an important regulator of cell proliferation and cell survival in various lymphomas
“cHL”	means	classical Hodgkin’s Lymphoma
“CLL”	means	chronic lymphocytic leukemia
“complete response”	means	the disappearance of all signs of cancer in response to treatment
“FcγR”	means	Fc-gamma receptor
“HCC”	means	hepatocellular carcinoma
“immunoglobulin”	means	glycoprotein molecules produced by plasma cells (white blood cells), which are also known as antibodies. They act as a critical part of the immune response by specifically recognizing and binding to particular antigens, such as bacteria or viruses, and aiding in their destruction
“Kinase”	means	a type of enzyme that catalyzes the transfer of phosphate groups from high-energy, phosphate-donating molecules to specific substrates. The protein kinases make up the majority of all kinases. Protein kinases act on proteins, phosphorylating them on their serine, threonine, tyrosine, or histidine residues. These kinases play a major role in protein and enzyme regulation as well as signaling in the cell
“MCL”	means	mantle cell lymphoma
“NSCLC”	means	non-small cell lung cancer
“PARP”	means	poly ADP ribose polymerase, a family of proteins involved in numerous cellular processes, mostly involving DNA replication and transcriptional regulation, which plays an essential role in cell survival in response to DNA damage
“PD-1”	means	programmed cell death protein 1, an immune checkpoint receptor expressed on T-cells and pro-B-cells that binds two ligands, PD-L1 and PD-L2. PD-1 is a cell surface receptor that plays an important role in down-regulating the immune system by preventing the activation of T-cells

GLOSSARY OF TECHNICAL TERMS

“pivotal trials”	means	a potentially registration-enabling trial or program that is intended to provide clinical data to support a regulatory approval for marketing the drug candidate
“RAF dimer”	means	a protein complex formed by two copies of RAF proteins. This could be a BRAF-BRAF complex, a BRAF-CRAF complex, or a CRAF-CRAF complex
“R/R”	means	relapsed or refractory
“SLL”	means	small lymphocytic lymphoma
“T-Cell”	means	a type of white blood cell that play a large role in immune response and that differs from other white blood cells like B-cells by the presence of the T-cell receptor on the T-cell’s outer surface, which is responsible for recognizing antigens bound to major histocompatibility complex molecules
“TIM-3”	means	T-cell immunoglobulin and mucin-domain containing-3, a Th1-specific cell surface protein that functions as an immune checkpoint, regulating macrophage activation and enhancing the severity of experimental autoimmune encephalomyelitis in mice
“UC”	means	urothelial carcinoma
“VGPR”	means	very good partial response
“WM”	means	Waldenstrom macroglobulinemia