2024 Annual Report

BeiGene

Cancer has no borders. Neither do we.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-37686

BeiGene

BEIGENE, LTD.
(Exact Name of Registrant as Specified in its Charter)

Cayman Islands	**98-1209416**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

c/o Mourant Governance Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman
Cayman Islands KY1-1108
(Address of principal executive offices, including zip code)

+1 (345) 949 4123
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**ONC**	**The Nasdaq Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited**

*Included in connection with the registration of the American Depositary Shares ("ADSs") with the U.S. Securities and Exchange Commission. The ordinary shares are not listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited ("HKEx").

Securities registered pursuant to Section 12(g) of the Act: The RMB shares are ordinary shares of the registrant issued to permitted investors in the People's Republic of China and listed and traded on the STAR Market in Renminbi. The RMB shares are not listed for trading in the United States or on the HKEx and are not fungible with the ordinary shares listed on the HKEx or the ADSs representing the ordinary shares listed on Nasdaq, and in no event will any RMB shares be able to be converted into the ordinary shares listed on the HKEx or the ADSs listed on Nasdaq, or vice versa.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. :

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the ordinary shares, including in the form of ADSs, each representing 13 ordinary shares, held by non-affiliates of the registrant was approximately $8.7 billion, based upon the closing price of the registrant's ADSs on the Nasdaq Global Select Market on June 28, 2024.

As of February 14, 2025, 1,387,367,704 ordinary shares, par value $0.0001 per share, were outstanding, of which 870,983,672 ordinary shares were held in the form of 66,998,744 ADSs, and 115,055,260 were RMB shares.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2024. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

BeiGene, Ltd.
Annual Report on Form 10-K
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Forward-Looking Statements and Market Data

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements that involve substantial risks and uncertainties. These forward-looking statements are based on management's current expectations and projections about future events and trends that may affect the business, financial condition, and operating results. 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. Forward-looking statements often include 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. 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;
- the implementation of our business model, strategic plans for our business, medicines, drug candidates and technology;
- 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;
- the regulatory environment and regulatory developments in the United States, China, the United Kingdom, Switzerland, the European Union and other jurisdictions in which we operate;
- the accuracy of our estimates regarding expenses, revenues, including collaboration revenue, capital requirements and our need for additional financing;
- the potential benefits of strategic collaboration and licensing agreements and our ability to enter into and maintain strategic arrangements;
- our construction and operation of independent production facilities for small molecule medicines and large molecule biologics, as well as clinical R&D facilities, to support the global demand for both commercial and clinical supply;
- 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 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, key milestones, expenses, capital expenditures, capital requirements and share performance;
- the future trading price of our American Depositary Shares ("ADSs") listed on Nasdaq, our ordinary shares listed on HKEx, and our ordinary shares issued to permitted investors in China and listed and traded on the STAR in Renminbi ("RMB Shares"), as well as the impact of securities analysts' reports on these prices;
- anticipated timing and effects of the redomiciliation to Switzerland, including its tax treatment;
- our expectations for our qualifying capital contribution reserves upon redomiciling to Switzerland; and
- our anticipated name change, including the potential benefits and risks.

These statements involve risks and uncertainties, including those that are described in "Item 1A. Risk Factors" of this Annual Report, that may cause actual future events or results to differ materially from those expected. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

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.

PART I

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

Item 1. Business

Overview

We are a leading global oncology company discovering and developing innovative treatments that are more accessible and affordable to cancer patients worldwide. In 2024, we generated total global revenue of approximately $3.8 billion, increasing revenue by approximately $1.4 billion from the prior year, while reducing our operating loss from the prior year by approximately $0.6 billion.

We are serial innovators in hematology and have built a differentiated, wholly-owned, franchise. This includes a proven best-in-class Bruton's Tyrosine Kinase inhibitor ("BTKi"), BRUKINSA®, and two late-stage assets, sonrotoclax ("BCL2i") and our first-in-class BTK-CDAC, both of which have the potential to be best-in-class medicines.

BRUKINSA was designed for complete sustainable inhibition of BTK with the belief that this would improve patient outcomes. This hypothesis was supported in the ALPINE trial, where BRUKINSA demonstrated sustained superior efficacy and lower cardiac toxicity in an all-comers relapsed/refractory ("R/R") chronic lymphocytic leukemia ("CLL") population against ibrutinib. BRUKINSA is the only BTKi to prove superior efficacy to ibrutinib. BRUKINSA has the broadest label in the class, with U.S. approvals in CLL, mantle cell lymphoma ("MCL"), Waldenström's macroglobulinemia ("WM"), marginal zone lymphoma ("MZL") and follicular lymphoma ("FL"). In less than two years from its first approval in CLL, and despite being the third entrant to the market, BRUKINSA has become the leader in new patients starts in the U.S., in both frontline and R/R CLL, as well as all other approved indications. BRUKINSA generated $2.6 billion in sales in 2024, is approved in over 70 markets and remains in the early stage of its launch in many key markets, including Europe, Japan, Korea and Brazil.

Sonrotoclax, our BCL2 inhibitor, is a selective BCL2i designed to have greater potency and selectivity, and potential for better tolerability than venetoclax. Our clinical program for sonrotoclax has enrolled over 1,800 patients to date. It is being tested in late-stage clinical trials with BRUKINSA, including as a fixed duration therapy in the Phase 3 CELESTIAL trial of BRUKINSA + sonrotoclax in 1L CLL, which is fully enrolled.

Our BTK-CDAC, which is designed to promote the degradation, of both wildtype and mutant forms of BTK, including those that commonly result in resistance to BTK inhibitors in patients who experience progressive disease, has enrolled over 500 patients and is the most advanced BTK degrader in the clinic. Data presented at the American Society of Hematology ("ASH") meeting in 2024 showed significant early efficacy signals and safety data in a heavily pretreated population. We plan to initiate a Phase 3 head-to-head trial in 2025 against pirtobrutinib, consistent with our strategy to develop medicines that have potential to meaningfully improve upon the current practice of care. With these three differentiated and synergistic assets, we believe we are uniquely positioned to provide the best solution for all CLL patients along their treatment journey and build a sustainable franchise in the $12 billion global CLL market.

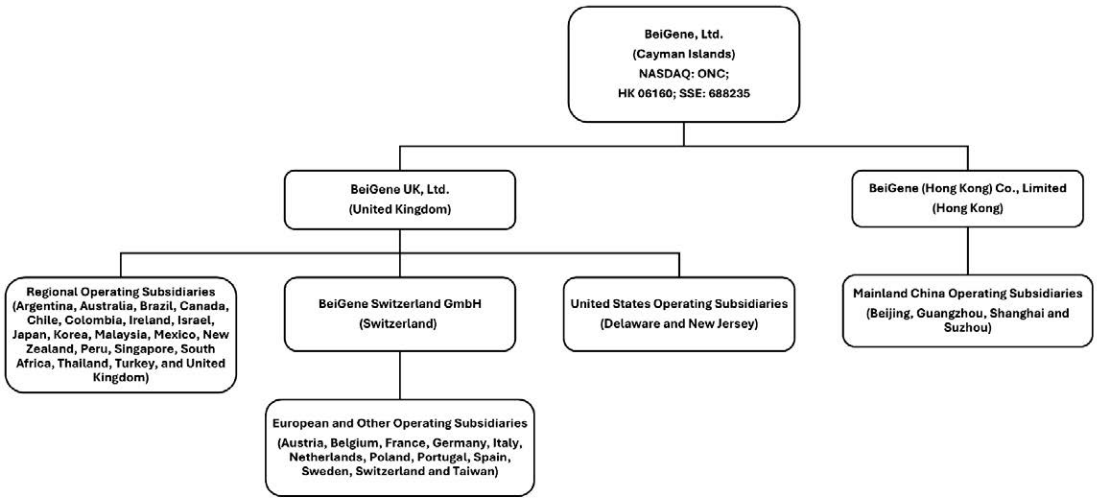
We are a company built to address the long-lived challenges to return on investment in the pharmaceutical industry. Clinical trials represent more than 75% of the total cost of bringing an oncology medicine to patients, yet the industry continues to outsource this function to contract research organizations ("CROs") at an ever-increasing cost per patient. Regulatory policies such as Project Optimus, while well intended, lead to meaningful program delays and increasing Phase 1 trial costs due to increased patient requirements and time. Increased competition exists for nearly every validated target, and pricing reform, such as the Inflation Reduction Act ("IRA") in the U.S., is placing direct and indirect pressure on innovators. Since inception, we have focused on building unique and hard to replicate competitive advantages that address these industry-wide challenges. Most importantly, our internal clinical team of approximately 3,700 colleagues across the globe allows us to break from the traditional CRO model and develop medicines with greater speed and at a lower cost than many of our industry peers while maintaining quality. This capability paired with our internal research and manufacturing capabilities enables a "fast to proof-of-concept" ("PoC") approach that can reduce time in early-stage development. We are innovating with intentionality and building best in class combinations to win in the increasingly competitive commercial landscape.

We have a deep and innovative solid tumor pipeline. In 2024 alone, we advanced 13 differentiated new molecular entities ("NMEs") into the clinic, each of which have the potential to be first-in-class or best-in-class. Our intention is to build depth in the most prevalent cancers, including breast/gynecologic, lung and gastrointestinal. We have main PoC catalysts in the next six to eighteen months for key programs, including, our next-generation CDK4 inhibitor and potentially first-in-class B7H4 antibody-drug conjugate ("ADC") in breast/gynecologic cancers, potential best-in-class pan-KRAS inhibitor in gastrointestinal ("GI") cancer, differentiated mechanism of action ("MoA") and first-in-class EGFR-CDAC in lung cancer, as well as our synergistic and potentially best-in-class PRMT5 and MAT2A inhibitors combination in lung cancer. We also have several exciting early stage assets, including CDK2i, B7H3 ADC, CEA-ADC, FGFR2b ADC, EGFRxMET TsAb, and IRAK4 CDAC.

Since our inception in 2010, we have become a fully integrated global organization with more than 11,000 employees worldwide.

Our Holding Company Structure

We are a holding company currently incorporated in the Cayman Islands with operations primarily conducted through our subsidiaries in the U.S., China, the UK, Switzerland, and Australia. The following diagram depicts a summary of our corporate structure. Our corporate structure contains no variable interest entities. In 2024, we announced plans to redomicile our holding company to Switzerland in 2025.



Our Strategy

We were founded with the vision to create an integrated biopharmaceutical company to address challenges in the pharmaceutical industry, creating impactful medicines that will be affordable and accessible to far more patients around the world. We are uniquely built to address an increasingly challenged industry and improve R&D returns.

We have built a substantial global clinical team of approximately 3,700 people on six continents, allowing us to run clinical trials predominantly without reliance on CROs. We believe independence from traditional CRO models allows us to execute more cost-efficient development and achieve faster time to clinical proof-of-concept. It also allows us to expand the reach of our clinical sites, which supports diverse participation and the collection of robust data across all patient demographics. Our demonstrated ability to complete large-scale, multi-regional clinical trials is an important strategic competitive advantage and addresses an immense challenge in the pharmaceutical industry.

We have built a highly productive and cost-effective oncology research teams with 1,100+ scientists, allowing us to drive serial innovation to enable sustained market leadership. Our efforts have been validated by commercial approvals, clinical data, and collaborations that have secured $1.5 billion in collaboration payments to our company. We design each research program with a differentiated biological hypothesis MoA, which has resulted in multiple commercially approved medicines and a pipeline of wholly-owned assets with potential for combinations and depth in key tumor types. We have invested in diverse technology platforms to pursue innovation, including CDAC protein degraders, bispecific antibodies, tri-specific antibodies, and ADCs allowing us access to diverse modalities and to advance science with urgency and agility. Our CDAC platform, in particular, offers a differentiated approach from small molecules with its catalytic activity, higher barrier to resistance, and scaffold function disruption, and we believe it has the potential to emerge as a best-in-class approach. Our research and innovation capabilities are primed for discovering high-quality and impactful medicines for patients in a highly productive and cost-effective way.

We have built a strong commercial portfolio, with BRUKINSA and TEVIMBRA® driving global revenue.

Solidifying our Sustainable Hematology Franchise

Our hematology franchise is led by BRUKINSA, which is supported by a broad clinical program with over 7,100 patients enrolled in more than 30 countries and regions across more than 35 trials. We continue to solidify our leadership in hematology, utilizing BRUKINSA as our cornerstone asset. We are focused on lifecycle management to build a sustainable hematology franchise maximizing value for our company, shareholders and patients globally. BRUKINSA has allowed us to build a strong franchise in hematology-oncology and we plan to solidify our leadership in CLL with our wholly-owned, emerging best-in-class hematology pipeline consisting of sonrotoclax and our BTK-CDAC, while amplifying our impact in other B-cell malignancies. We believe our BTK-CDAC combinations with BRUKINSA and sonrotoclax show promise to meaningfully outperform fixed duration regimens in CLL, and our three differentiated molecules offer potential best-in-disease combinations to cover the entire CLL patient spectrum and insulate BeiGene from end-of-lifecycle pricing pressure.

Expanding Access to Our PD-1 Inhibitor for Patients Worldwide and Building Global Commercial Capabilities to Support Prolific Pipeline

Our solid tumor franchise is led by our anti-PD-1 monoclonal antibody, TEVIMBRA®, which is currently approved in the U.S., EU, China and other countries. We intend to expand TEVIMBRA's global footprint through ongoing submissions and approvals. We are also developing a high-concentration subcutaneous formulation of TEVIMBRA which we believe will be competitive in global markets. With TEVIMBRA and the potentially best-in-class solid tumor pipeline assets, we are well-positioned to build our solid tumor business and deliver innovative therapies and combinations to patients.

We have a global commercial organization to deliver medicines to patients around the globe. We have established commercial capabilities in key large commercial markets of the U.S., E.U and China, and continue our rapid expansion of capabilities into Asia Pacific, Latin America, and Middle East regions, driving the delivery of highly effective and differentiated medicines to patients around the globe. This has enabled a geographically diversified revenue mix and a truly global business.

Our business model is sustainable and results in strong global financial profile. We believe we are financially well-positioned with cash and cash equivalents of $2.6 billion as of December 31, 2024. Our product revenue has grown 73% since 2023 from our current portfolio and cornerstone assets, which we expect to grow significantly in 2025 and beyond. We significantly reduced our GAAP operating losses and achieved non-GAAP operating income for the first time for fiscal year 2024. We generated positive cash flows from operations for the first time in both the third and fourth quarters of 2024 after years of using cash in our operations. We will continue to be thoughtful and strategic in how we deploy our capital, and consistent with previous collaborations, we will actively explore partnerships that strengthen our business. We are committed to generating long-term value for our shareholders.

Our Commercial and Registration Stage Products

The following table summarizes the status of our commercial products as of February 27, 2025:

PRODUCT	MECHANISM OF ACTION	REGULATORY STATUS	BEIGENE COMMERCIAL RIGHTS	PARTNER
BRUKINSA	BTK inhibitor	Approved in 73 markets, incl. U.S., China, EU, Japan, and other markets	Global	N/A
TEVIMBRA	Anti-PD-1 antibody	Approved in 45 markets, incl. U.S., EU, China, and other markets	Global	N/A
PARTRUVIX	PARP inhibitor	Approved in China	Global	N/A
XGEVA	Anti-RANK ligand antibody	Approved in China	Mainland China	Amgen
BLINCYTO	Anti-CD19 x anti-CD3 bispecific T-cell engager (BiTE)	Approved in China	Mainland China	Amgen
KYPROLIS	Proteasome inhibitor	Approved in China	Mainland China	Amgen
SYLVANT	IL-6 antagonist	Approved in China	Greater China	EUSA Pharma
QARZIBA	Anti-GD2 antibody	Approved in China	Mainland China	EUSA Pharma
POBEVCY® (Avastin biosimilar)	Anti-VEGF antibody	Approved in China	Greater China	Bio-Thera
BAITUOWEI® (goserelin microspheres for injection)	Gonadotropin-releasing hormone (GnRH) agonist	Approved in China	Mainland China	Luye Pharma
TAFINLAR® (dabrafenib)	BRAF inhibitor	Approved in China	China Broad Markets[1]	Novartis
MEKINIST® (trametinib)	MEK inhibitor	Approved in China	China Broad Markets[1]	Novartis
VOTRIENT® (pazopanib)	VEGFR inhibitor	Approved in China	China Broad Markets[1]	Novartis
AFINITOR® (everolimus)	mTOR inhibitor	Approved in China	China Broad Markets[1]	Novartis
ZYKADIA® (ceritinib)	ALK inhibitor	Approved in China	China Broad Markets[1]	Novartis

1. Rights to promote and market in China's broad markets pursuant to a Market Development Agreement with an affiliate of Novartis Pharma AG.

Abbreviations: ALK = anaplastic lymphoma kinase; BRAF = B-rapidly accelerated fibrosarcoma; MEK = mitogen-activated protein kinase (MAPK) / Extracellular-signal regulated kinase (ERK); mTOR = Mammalian target of rapamycin; VEGFR = vascular endothelial growth factor receptor

Please see the section of this Annual Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" for revenue by product.

We commercialize the following internally developed cancer medicines:

BRUKINSA

Market Opportunity

Lymphomas are blood-borne cancers involving lymphatic cells of the immune system. They can be broadly categorized into non-Hodgkin's lymphoma and Hodgkin's lymphoma. In 2024, global revenues for BTK inhibitors were over $10 billion according to company reported financials. Global revenues are projected to be more than $15 billion in 2028, according to published reports. Please see the section of this Annual Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" for BRUKINSA net revenue generated in 2023 and 2024.

BRUKINSA

BRUKINSA is a next-generation, oral, small molecule inhibitor of BTK designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared with other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease-relevant tissues. BRUKINSA has the broadest label globally of any BTK inhibitor and is the only BTK inhibitor to provide the flexibility of once or twice daily dosing.

We are marketing BRUKINSA in the U.S., Europe, China, the UK, Canada, Australia, Japan, Brazil, and other markets.

BRUKINSA has approvals in five indications, including CLL/SLL, WM, R/R MCL, R/R MZL, R/R FL and is approved in more than 70 countries.

In the U.S., BRUKINSA received accelerated approval from the U.S. Food and Drug Administration ("FDA") for MCL in adult patients who have received at least one prior therapy in November 2019. It was then approved for patients with WM based on a head-to-head study vs ibrutinib, followed by an accelerated approval in R/R MZL patients who have received at least one anti-CD20-based regimen. In January 2023, BRUKINSA was approved for the treatment of adult patients with CLL or SLL in both the treatment naive and relapsed setting based on two Phase 3 studies. BRUKINSA is the only BTKi to demonstrate progression-free survival ("PFS") superiority to ibrutinib in R/R CLL/SLL in all patient segments, including high-risk (17p/TP53). In March 2024, BRUKINSA received accelerated approval from the FDA for R/R FL in combination with obinutuzumab.

In Europe, BRUKINSA received approval from the European Commission ("EC") for the treatment of adult patients with WM who have received at least one prior therapy or for the first-line treatment of patients unsuitable for chemo-immunotherapy, as well as for the treatment of patients with R/R MZL and for the treatment of patients with CLL. In November 2023, the EC approved BRUKINSA in combination with obinutuzumab for the treatment of adult patients with R/R FL who have received at least two prior lines of systemic therapy. BRUKINSA is now approved to treat more patient populations in Europe than any other BTK inhibitor.

In China, BRUKINSA has received approval from the China National Medical Products Administration ("NMPA") for treatment-naïve adults with CLL or SLL, treatment-naïve adults with WM, R/R CLL/SLL, TN & R/R WM, and conditional approval for adult patients with MCL who have received at least one prior therapy. Currently, all approved indications for BRUKINSA are included in the updated National Reimbursement Drug List ("NRDL") by the China National Healthcare Security Administration ("NHSA").

BRUKINSA received approval in Japan for WM and CLL/SLL in December 2024.

TEVIMBRA (tislelizumab)

Market Opportunity

Globally, the top four PD-1/PD-L1 antibody medicines had revenues of approximately $45 billion in 2024 based on public reports. The 2024 China PD-1/L1 market (net revenue) was approximately $3.4 billion.

Global revenues are projected to be approximately $50 billion in 2025 and will increase through 2028, according to published reports, driven by multiple factors including indication expansion, approvals and adoptions in earlier lines of therapies, further market penetration, and extension of duration of therapy.

TEVIMBRA

TEVIMBRA 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.

Tislelizumab is approved in China in fourteen indications:

- for neoadjuvant treatment in combination with platinum-based chemotherapy and for adjuvant treatment as monotherapy after surgery in patients with resectable stage II or III non-small cell lung cancer ("NSCLC")' for first-line treatment for patients with extensive-stage small cell lung cancer in combination with etoposide and platinum chemotherapy;
- for the first-line treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma with high PD-L1 expression in combination with fluoropyrimidine and platinum chemotherapy;
- for first-line treatment of patients with unresectable, locally advanced or metastatic squamous NSCLC in combination with chemotherapy;
- for first-line treatment of patients with unresectable, locally advanced or metastatic non-squamous NSCLC, with epidermal growth factor receptor ("EGFR") genomic tumor aberrations negative and anaplastic lymphoma kinase ("ALK") genomic tumor negative in combination with pemetrexed and platinum chemotherapy;

- for second- or third-line treatment of patients with locally advanced or metastatic NSCLC who progressed on prior platinum-based chemotherapy;
- for the treatment of patients with locally advanced or metastatic esophageal squamous cell carcinoma ("ESCC") who have disease progression following or are intolerant to first-line standard chemotherapy;
- for first-line treatment of patients with locally advanced or metastatic ESCC in combination with chemotherapy;
- for first-line treatment of patients with recurrent or metastatic nasopharyngeal cancer ("NPC");
- for first-line treatment of patients with unresectable or metastatic hepatocellular carcinoma ("HCC");
- for the treatment of patients with advanced hepatocellular carcinoma who have received Sorafenib, Lenvatinib or systemic chemotherapy containing Oxaliplatin;
- conditional approval for the treatment of patients with classical Hodgkin's lymphoma ("cHL") who received at least two prior lines of systemic chemotherapy regimens;
- conditional approval for 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; and
- conditional approval for patients with previously treated, locally advanced unresectable or metastatic microsatellite instability-high ("MSI-H") or mismatch repair-deficient ("dMMR") solid tumors.

Full approval for those indications listed as having conditional approval is contingent upon results from ongoing confirmatory clinical trials.

Tislelizumab was included in the NRDL in 2020 for cHL and UC, in 2021 for non-squamous NSCLC, squamous NSCLC and HCC, in 2022 for locally advanced or metastatic NSCLC, MSI-H solid tumors, locally advanced or metastatic ESCC following progression or intolerance to prior first-line chemotherapy, and first-line recurrent or metastatic NPC, and in 2023 for first-line locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma with high PD-L1 expression and first-line unresectable locally advanced, recurrent or metastatic ESCC.

In Europe, the EC has approved TEVIMBRA in six indications:

- for first-line treatment of adult patients with unresectable, locally advanced or metastatic ESCC whose tumors express PD-L1 with a tumor area positivity ("TAP") score $\geq$ 5%, in combination with platinum-based chemotherapy;
- as monotherapy is indicated for the treatment of adult patients with unresectable, recurrent, locally advanced or metastatic ESCC after prior chemotherapy;
- for the first-line treatment of adult patients with non-squamous NSCLC, whose tumors have PDL1 expression on $\geq$ 50% of tumor cells with no EGFR or ALK positive mutations and who have locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic NSCLC, in combination with pemetrexed and platinum-containing chemotherapy;
- for the first-line treatment of adult patients with squamous non-small cell lung cancer who have: locally advanced NSCLC and are not candidates for surgical resection or platinum-based chemoradiation, or metastatic NSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel;
- as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer after prior platinum-based therapy; and
- for the first-line treatment of adult patients with HER-2-negative locally advanced unresectable or metastatic gastric or gastroesophageal junction ("G/GEJ") adenocarcinoma whose tumors express PD L1 with a TAP score $\geq$ 5%, in combination with platinum and fluoropyrimidine-based chemotherapy.

In the U.S., the FDA has approved TEVIMBRA as a treatment for adult patients with unresectable or metastatic ESCC after prior systemic therapy that did not include a PD-(L)1 inhibitor and as the first-line treatment of unresectable or metastatic HER2-negative G/GEJ in adults whose tumors express PD-L1 ($\geq$1) in combination with platinum and fluoropyrimidine-based chemotherapy. Additionally, one Biologics License Application ("BLAs") for TEVIMBRA is under review for first-line treatment of patients with unresectable, locally advanced, or metastatic ESCC.

In Japan, one Japanese New Drug Application ("J-NDA") is under review by the Pharmaceuticals and Medical Devices Agency ("PMDA") for first- and second-line treatment of ESCC.

We have received regulatory approvals for TEVIMBRA marketing applications in multiple geographies, including the EU (comprising 27 countries plus Iceland and Norway) and 16 countries across North America, Europe, APAC, and other markets.

In-Licensed Products from Amgen

We are currently commercializing the following cancer medicines in China under an exclusive license from Amgen:

XGEVA®

XGEVA (denosumab) is an antibody-based RANK ligand ("RANKL") 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 (converted to regular approval) 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, which was successfully renewed for inclusion in 2023. Beginning in January 2024, the SRE indication was also included in the NRDL.

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 (converted to regular approval) and was conditionally approved in April 2022 for pediatric patients with R/R B-cell precursor ALL. We began commercializing BLINCYTO in August 2021.

KYPROLIS®

KYPROLIS (carfilzomib), a proteasome inhibitor, has been approved in over 60 countries for use in patients with R/R MM. It was approved in China as a treatment for patients with R/R MM in July 2021 and we began commercializing KYPROLIS in January 2022. KYPROLIS was included on the NRDL beginning in March 2023 for its approved indication in China.

In-Licensed Products from BMS

As part of our settlement agreement with BMS, our commercialization of the following cancer medicines licensed from BMS terminates as of February 2025:

- REVLIMID® (lenalidomide), an oral immunomodulatory medicine
- VIDAZA® (azacitidine for injection), a pyrimidine nucleoside analog that has been shown to reverse the effects of DNA hypermethylation and promote subsequent gene re-expression.

Other In-Licensed Products

We commercialize the following 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. SYLVANT was approved in China in December 2021 for the treatment of adult patients with multicentric Castleman disease ("MCD") who are HIV negative and HHV-8 negative, also known as iMCD. Beginning in January 2024, Sylvant was included in the NRDL.

QARZIBA®▼

QARZIBA (dinutuximab beta), a mouse-human chimeric monoclonal GD2 antibody, was granted conditional approval by the NMPA for the 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, followed by myeloablative therapy and stem cell transplantation, as well as patients with a history of R/R neuroblastoma with or without residual disease. We began commercializing QARZIBA in December 2021.

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

POBEVCY® (BAT1706)

POBEVCY is a biosimilar to Avastin (bevacizumab) developed 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, NSCLC, glioblastoma, ovarian, fallopian tube or primary peritoneal, and cervical cancers.

POBEVCY was approved by the NMPA in China in November 2021 and launched in late 2021 for the treatment of patients with advanced, metastatic or recurrent NSCLC, metastatic colorectal cancer, recurrent glioblastoma, epithelial ovarian, fallopian tube, or primary peritoneal cancer and cervical cancer.

We have acquired the right to develop, manufacture and commercialize POBEVCY in China, including Hong Kong, Macau, and Taiwan.

We commercialize the following product in China under an exclusive license from Luye Pharma:

BAITUOWEI® (goserelin microspheres for injection)

Baituowei (Goserelin Microspheres for Injection), developed by Luye Pharma, is the world's first and only approved microsphere formulation of Goserelin. With its innovative microsphere formulation, Baituowei is able to ensure efficacy and safety while significantly improving patient experience. Baituowei was approved by the NMPA in China in June 2023 for the treatment of patients with prostate cancer requiring androgen deprivation therapy and included in the NRDL in 2023 and was approved by the NMPA in China in September 2023 for treating breast cancer in premenopausal and perimenopausal women that can be treated with hormones and included in the NRDL in 2024.

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 U.S., there are also private payors such as private health insurers and health systems. As of December 31, 2024, we have commercialized our products in over 60 markets.

In the U.S., 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. There is no central list of covered pharmaceuticals in the U.S., as there is no single payer system. As such, the prices paid for pharmaceuticals in the U.S. can vary.

We offer patient assistance programs in the U.S. under our myBeiGene program. This program seeks to enhance access to BRUKINSA and TEVIMBRA 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 TEVIMBRA and their approved indications, nurse advocates, and connecting patients to sources of support such as support groups and transportation/lodging assistance.

In China, there is one main payor, the government's national health care coverage system, which provides Basic Medical Insurance to the majority (greater than 95%) of China's approximately 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 or 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, 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 reimbursement rate that is used can be modified at the provincial level. Innovatively, in the 2022 NRDL, a price bidding process for non-exclusive drugs was undertaken on the C list to set the national reimbursement price benchmark. As additional indications are included in the NRDL, the price of the medicine is reduced to reflect increased patient demand as a result of NRDL inclusion.

Several of our medicines are listed on the NRDL. In the latest NRDL list announced in November 2024, the following medicines and indications have been included in the NRDL, effective January 1, 2025:

- Tislelizumab in thirteen of its eligible approved indications:
  - As a first-line treatment for patients with unresectable or metastatic HCC (approved in December 2023 and included in the NRDL at the end of 2024);
  - In combination with etoposide and platinum chemotherapy as the first-line treatment for patients with extensive-stage small cell lung cancer (ES-SCLC) (approved in June 2024 and included in the NRDL at the end of 2024);
  - In combination with fluoropyrimidine and platinum chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma (approved in April 2024 and included in the NRDL at the end of 2024)[1];
  - In combination with paclitaxel plus platinum- or fluoropyrimidine- and platinum-based chemotherapy, for the first-line treatment of patients with unresectable locally advanced, recurrent or metastatic ESCC (approved in May 2023 and included in the NRDL at the end of 2023);
  - For the treatment of adult patients with locally advanced or metastatic non-squamous NSCLC with EGFR genomic tumor aberrations negative and ALK genomic tumor negative and have progressed after or did nottolerate prior platinum-based chemotherapy; and of adult patients with locally advanced or metastatic squamous NSCLC, with EGFR and ALK negative or unknown, that have progressed after or did not tolerate of prior platinum-based chemotherapy (approved in December 2021 and included in the NRDL at the beginning of 2023);
  - For the treatment of adult patients with advanced unresectable or metastatic MSI-H or dMMR solid tumors: patients with advanced colorectal cancer (CRC) who had been treated fluoropyrimidines, oxaliplatin and irinotecan; patients with other advanced solid tumors who develop disease progression after prior treatment and have no satisfactory alternative treatment options (approved in March 2022 and included in the NRDL at the beginning of 2023);
  - For the treatment of patients with locally advanced or metastatic ESCC who have disease progression following or are intolerant to first-line standard chemotherapy (approved in April 2022 and included in the NRDL at the beginning of 2023);
  - In combination with Gemcitabine and cisplatin, as first-line treatment in patients with recurrent or metastatic NPC (approved in June 2022 and included in the NRDL at the beginning of 2023);
  - For use in combination with pemetrexed and platinum chemotherapy as a first-line treatment in patients with unresectable, locally advanced or metastatic non-squamous NSCLC, with EGFR genomic tumor aberrations negative and ALK genomic tumor negative (approved in June 2021 and included in the NRDL in 2021);

[1] The indication is an expansion of the previous indication "In combination with fluoropyrimidine- and platinum-based chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma with high PD-L1 expression", which was approved in February 2023 and included in the NRDL at the end of 2023.

- For the treatment of patients with HCC who have been previously received Sorafenib, Lenvatinib or systemic chemotherapy containing Oxaliplatin (conditionally approved in June 2021 and included in the NRDL in 2021);
- For use in combination with paclitaxel and carboplatin as a first-line treatment in patients with unresectable, locally advanced or metastatic squamous NSCLC (approved in January 2021 and included in the NRDL in 2021);
- 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 (conditionally approved in April 2020 and included in the NRDL in 2020); and
- For the treatment of patients with cHL who have received at least two prior therapies (conditionally approved in December 2019 and included in the NRDL in 2020).

• BRUKINSA in all four of its approved indications:

- In combination with obinutuzumab, for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior lines of systemic therapy (approved in May 2024 and included in the NRDL at the end of 2024);
- For the treatment of patients with CLL or SLL (approved in April 2023 and included in the NRDL at the end of 2023)[1];
- For the treatment of patients with WM (approved in April 2023 and included in the NRDL at the end of 2023)[2]; and
- For the treatment of adult patients with MCL who have received at least one prior therapy (conditionally approved in June 2020 and included in the NRDL in 2020).

• BAITUOWEI in both of its eligible approved indication:

- For the treatment of patients with breast cancer in premenopausal and perimenopausal women that can be treated with hormone therapy (approved in September, 2023 and included in the NRDL at the end of 2024);
- For the treatment of patients with prostate cancer requiring androgen deprivation therapy (approved in June 2023 and included in the NRDL at the end of 2023).

• KYPROLIS successfully renewed its approved indication in October 2024:

- In combination with dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who have received at least two lines of therapy, including proteasome inhibitor and immunomodulator (approved in July 2021 and included in the NRDL at the beginning of 2023).

In 2018, China started a new program to centrally purchase non-exclusive medicines for the nation's health care system called "volume-based procurement," or "group purchasing organization" or "4+7" 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 generic quality consistency evaluation, which in turn requires passing a bioequivalence comparison to the reference listed drug ("RLD"). 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 is won and at what price are also evolving.

It is common in China for pharmaceutical companies to employ patient assistance programs to help patients afford their innovative medicines. These programs have typically 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.

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[1] The indication included "both treatment-naïve patients and adult patients with CLL/SLL who have received at least one prior therapy". "For the treatment of adult patients with CLL/SLL who have received at least one prior therapy" was conditionally approved in June 2020 and included in the NRDL in 2020.

[2] The indication included "both treatment-naïve patients and adult patients with WM who have received at least one prior therapy". "For the treatment of adult patients with WM who have received at least one prior therapy" was conditionally approved in June 2021 and included in the NRDL in 2021; converted to regular approval in 2023.

Our Pipeline Products

The following table summarizes our pipeline as of February 27, 2025:

Phase 1

Sonrotoclax — BCL2i
- 101 B-cell malignancies
- 102 B-cell malignancies
- 103 AML/MDS
- 105 MM t(11;14)
- 108 Dose ramp-up

BGB-43395 — CDK4i
- 101/102 BC & Solid tumors

BGB-53038 — PanKRASi
- 101 Solid tumors

BG-C9074[1] — B7H4 ADC
- 101 Solid tumors

BG-60366 — EGFR CDAC
- 101 Solid tumors

BG-58067 — MTA Coop. PRMT5i
- 101 Solid tumors

BG-89894[2] — MAT2Ai
- 101 Solid tumors

BGB-45035 — IRAK4 CDAC
- 101 Immunology & Inflammation

BG-68501[3] — CDK2i
- 101 BC & Solid tumors

BG-C354 — B7H3 ADC
- 101 Solid tumors

BG-C477 — CEA ADC
- 101 Solid tumors

BG-C137 — FGFR2b ADC
- 101 Solid tumors

BG-T187 — EGFR x MET TsAb
- 101 Solid tumors

BGB-16673 — BTK CDAC
- 101 B-cell malignancies
- 102 B-cell malignancies
- 104 B-cell malignancies

BGB-21447 — BCL2i 2G
- 101 B-cell malignancies
- 102 Metastatic breast cancer

Xaluritamig[4] — STEAP1 x CD3 XmAb®
- 20180146 mCRPC

BGB-R046 — IL-15 prodrug
- 101 Solid tumors

BGB-B2033 — GPC3 x 4-1BB BsAb
- 101 Solid tumors

BGB-B3227 — MUC1 x CD16A BsAb
- 101 Solid tumors

BGB-15025 — HPK1i
- 101 Solid tumors

BGB-26808 — HPK1i
- 101 Solid tumors

BGB-30813 — DGKζi
- 101 Solid tumors

BGB-A3055 — CCR8 mAb
- 101 Solid tumors

BGB-24714 — SMAC mimetic
- 101 Solid tumors

Tislelizumab — PD1 mAb
- 103 SubQ formulation

BGB-B455 — CLDN6 x CD3 BsAb
- 101 Solid tumors†

Phase 2

Zanubrutinib — BTKi
- 215 B-cell malignancies
- 218 CD79B R/R DLBCL

BGB-16673 — BTK CDAC
- 101 R/R CLL
- 102 R/R CLL

Sonrotoclax — BCL2i
- 201 R/R MCL
- 202 R/R CLL
- 203 R/R WM
- 204 TN CLL/SLL

Blinatumomab[4] — CD3 x CD19 BiTE®
- 20190359 Pediatric R/R BP-ALL

LBL-007[5] — LAG3 mAb
- 201 MSS-CRC
- 202 1L ESCC

BGB-A445 — OX40 mAb
- 201 Melanoma, UC

Umbrella Studies — IO Combos
- LC-201 1L NSCLC
- LC-202 Neoadj NSCLC
- HNSCC-201 1L HNSCC

Tarlatamab[4] — DLL3 x CD3 BiTE®
- 20230273 3L SCLC

Phase 3

Zanubrutinib — BTKi
- 306 TN MCL
- 308 R/R MZL, R/R FL
- 309 pMN

Sonrotoclax — BCL2i
- 301 TN CLL
- 302 R/R MCL†

Tislelizumab — PD1 mAb
- 310 1L UBC
- 314 R/R cHL

Pamiparib — PARPi
- 302 2L MTx gBRCAm PSOC

Ociperlimab — TIGIT mAb
- 302 1L NSCLC PDL1-high

Zanidatamab[6] — HER2 BsAb
- 301 1L HER2+ GEA

Tarlatamab[4] — DLL3 x CD3 BiTE®
- 20210004 2L SCLC
- 20200041 1L ES-SCLC
- 20230016 LS-SCLC

Registration

Zanubrutinib — BTKi
- 114 Tablet formulation (US, EU, Others)

Tislelizumab — PD1 mAb
- 312 1L ES-SCLC (EU)
- 315 Neo/adj NSCLC (EU)
- 306 1L ESCC (US, JP)
- 302 2L ESCC (JP)
- 302 2L ESCC alt dosing (US)
- 309 1L NPC (EU)

Zanidatamab[6] — HER2 BsAb
- 203 HER2+ 2L BTC (CN)

● Heme ● Breast / Gyn ● Pan-Tumor / Other
● Lung ● GI ● Non-Oncology

Registration includes select accepted submissions in major markets.
† Trial is listed on clinicaltrials.gov but may not have subjects enrolled.
1) DualityBio collaboration, 2) CSPC collaboration, 3) Ensem collaboration, 4) Amgen collaboration, 5) Leads Biolabs collaboration, 6) Zymeworks/Jazz collaboration.

The following table summarizes the status of our in-licensed drug candidates as of February 27, 2025:

Partner	Molecule / Asset	Indications	Phase	Commercial Rights
Amgen	Tarlatamab ^	SCLC	Phase 3	China
	Xaluritamig	Prostate cancer	Phase 1	China
Zymeworks	Zanidatamab † + chemo + Tislelizumab	GEA	Phase 3	Asia, Australia, New Zealand
	Zanidatamab † (monotherapy)	BTC	Phase 2	Asia, Australia, New Zealand
SpringWorks	BGB-3245[1]	Solid tumors	Phase 1	Ex-Asia plus Japan
Pfizer	SEA-CD70	MDS, AML	Phase 1	Asia, Australia, New Zealand
DualityBio	BG-C9074/DB1312	BC, EC, OC, CCA, sqNSCLC	Phase 1a	Global
Ensem	CDK2i	Breast cancer and other solid tumors	Phase 1	Global
CSPC	MAT2Ai	Solid tumors	Phase 1	Global

^ Half-life extended BiTE®; † ZW25; [1] By MapKure, a JV with SpringWorks

Abbreviations: AML = acute myelogenous leukemia; BC = breast cancer; BTC = biliary tract cancers; GEA = gastroesophageal adenocarcinoma; MDS = myelodysplastic syndromes; NSCLC = non-small cell lung cancer; SCLC = small cell lung cancer; EC = endometrial cancer; OC = ovarian cancer; CCA = cholangiocarcinoma

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"), the Stock Exchange of Hong Kong Limited ("HKEx"), and the Shanghai Stock Exchange ("SSE"), copies of which are available on the Investors section of our website.

Hematology

BRUKINSA (zanubrutinib), a BTK Inhibitor

We are currently evaluating zanubrutinib in a broad pivotal clinical program globally to treat a number of B-cell malignancies. Zanubrutinib has demonstrated sustained 24-hour BTK occupancy in both the peripheral blood, bone marrow and lymph node compartments in patients. Zanubrutinib is the only BTK inhibitor to demonstrate superior progression-free survival in R/R CLL versus IMBRUVICA® (ibrutinib), an approved BTK inhibitor.

Clinical Development Updates and Regulatory Status

The global BRUKINSA clinical development program includes over 7,100 patients enrolled in more than 30 countries and regions across more than 35 trials. BRUKINSA is approved in more than 70 markets, and more than 180,000 patients have been treated globally.

Five-year follow-up results from cohort 1 of the Phase 3 SEQUOIA study showed sustained PFS benefit (54-month PFS rate of 80%) with BRUKINSA in an all-comer population of patients with treatment-naïve ("TN") CLL or SLL, with no new safety signals observed; detailed data were presented at the annual ASH 2024 conference.

Five-year follow-up data of BOVen (zanubrutinib, obinutuzumab, venetoclax) study in TN CLL demonstrated frequent unmeasurable minimal residual disease ("uMRD") in peripheral blood (96%) and bone marrow (92%), and uMRD was durable with a median MRD-free survival of 34 months; detailed data were presented at the ASH 2024 conference.

Based on the clinical data to date, we believe that BRUKINSA has a best-in-class profile, we have initiated broad global pivotal programs in multiple indications, which led to regulatory approvals of five indications globally. Current ongoing Phase 3 studies include:

- MANGROVE: A Randomized Global Study Comparing Zanubrutinib Plus Rituximab vs. Bendamustine Plus Rituximab in subjects With Previously Untreated Mantle Cell Lymphoma Who Are Ineligible for Stem Cell Transplantation (MCL) (NCT04002297).
- MAHOGANY: Zanubrutinib Plus Obinutuzumab vs Lenalidomide plus Rituximab in Relapsed/ Refractory Follicular Lymphoma (FL) (NCT05100862).

We are also investigating zanubrutinib in several combination studies in MCL, MZL and CLL/SLL, including a Phase 3 trial in combination with sonrotoclax in front-line CLL/SLL. We continue to examine opportunities for zanubrutinib combinations with both sonrotoclax and our BTK-CDAC (BGB-16673).

We continue to pursue regulatory approvals for BRUKINSA globally, including regulatory approval of a new tablet formulation, providing patients with more convenience and flexibility.

Sonrotoclax (BGB-11417), a Small Molecule Bcl-2 Inhibitor

Our differentiated BCL2 inhibitor, sonrotoclax, was intentionally designed to have higher potency and selectivity compared to venetoclax, with a shorter half-life and no accumulation. We believe that efficacy signals and safety data from more than 1,800 patients enrolled by December 2024 in different indications and in different combinations continue to support the pre-clinical best-in-class promise.

Multiple trials with registration potential have completed enrollment or are nearing complete enrollment. Single-arm Phase 2 trials of sonrotoclax monotherapy in R/R MCL (NCT05471843) and R/R CLL/SLL (NCT05479994) have completed enrollment. Enrollment for Phase 2 trial in R/R WM (NCT05952037) is ongoing.

Our first Phase 3 randomized study in TN-CLL, CELESTIAL-TN CLL (NCT06073821), investigating sonrotoclax + BRUKINSA vs. venetoclax + obinutuzumab completed enrollment in Q1 2025. A Phase 2 study (NCT06637501) investigating sonrotoclax + BRUKINSA vs. BRUKINSA to support TN-CLL registration for contribution of components has also started enrollment.

Clinical data of a Phase 1 trial investigating TN-CLL/SLL (NCT04277637) was presented at ASH 2024. Sonrotoclax in combination with BRUKINSA continued to show very promising efficacy signals and a generally favorable safety profile in patients with TN CLL/SLL, especially deep and durable levels of undetectable MRD, and no laboratory or clinical tumor lysis syndrome ("TLS"), which is a key differentiator for our combination.

With these encouraging results, our BCL2 inhibitor sonrotoclax program is steadily progressing at the pivotal stage. Additional pivotal development activities in R/R MCL and R/R CLL are under way.

BGB-16673, a BTK-targeted CDAC

BGB-16673 is an orally available, brain-penetrating BTK targeting chimeric degradation activation compound ("CDAC") designed to promote the degradation, or breakdown, of both wildtype and mutant forms of BTK, including those that commonly result in resistance to BTK inhibitors in patients who experience progressive disease. BGB-16673 is the most advanced BTK degrader in the clinic, with more than 500 patients treated to date across the global clinical development program. The FDA granted Fast Track Designation to BGB-16673 for the treatment of adult patients with R/R CLL/SLL who have been previously treated with at least two prior lines of therapy, including BTKi and BCL2 inhibitor, and adult patients with R/R MCL.

Data from the Phase 1/2 CaDAnCe-101 CLL study (NCT05006716) was presented at ASH 2024 and demonstrated that treatment with BGB-16673 was generally well tolerated in this heavily pretreated population of patients. Promising antitumor activity was observed in patients with high-risk features, including in patients with BTK inhibitor-resistant mutations and those previously exposed to covalent BTK inhibitors, noncovalent BTK inhibitors, and BCL2 inhibitors. No atrial fibrillation was observed in either the CLL/SLL or WM cohorts.

- From the cohort of CLL/SLL patients, BGB-16673 demonstrated an ORR of 94% at the 200mg dose. Furthermore, amongst all doses delivered, 2 patients achieved a complete remission/complete remission with incomplete count recovery (CR/CRi). Grade ≥3 TEAEs were reported in 57% of patients. The most common grade ≥3 TEAEs (≥10%) were neutropenia/neutrophil count decreased (20%) and pneumonia (10%). (Abstract 885)
- From the cohort of Waldenström's macroglobulinemia patients, BGB-16673 demonstrated a 93% disease control rate (DCR) and 26% very good partial response (VGPR). Grade ≥3 TEAEs were reported in 45% of patients. The most common grade ≥3 TEAE (≥20%) was neutropenia/neutrophil count decreased. (Abstract 860)

Phase 2 expansion in R/R CLL with pivotal intent has commenced and a confirmatory Phase 3 study is planned for early 2025. In addition, we have announced intent to conduct a study comparing BGB-16673 to pirtobrutinib (ncBTKi with accelerated approval in R/R MCL and R/R CLL/SLL) and will work with health authorities to initiate this Phase 3 study.

Solid Tumors

TEVIMBRA (tislelizumab), an anti-PD-1 Antibody

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

Clinical Development Updates and Regulatory Status

We have completed more than fourteen registration-enabling clinical trials in lung, liver, lymphoma, urothelial carcinoma, and nasopharyngeal cancer globally, including ten Phase 3 randomized trials and four Phase 2 trials supporting regulatory submissions globally. We have three active studies in lymphoma, urothelial carcinoma, and solid tumors:

- A Phase 3 confirmatory trial in China comparing tislelizumab to salvage chemotherapy in patients with relapsed or refractory classical Hodgkin Lymphoma (cHL; NCT04486391).
- A Phase 3 confirmatory trial in China in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977).
- A Phase 2 trial in China in patients with MSI-H/dMMR solid tumors (NCT03736889).

As of December 2024, we had enrolled over 14,000 subjects in clinical trials of tislelizumab monotherapy or in combination in more than 35 countries, including 4,700+ subjects outside of China. These studies include eight multi-regional registrational trials that are designed for global regulatory approvals. Data from our trials thus far have suggested that tislelizumab was generally well-tolerated and exhibited anti-tumor activity in a variety of tumor types. In 2024, we terminated a Phase 3 trial in China of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590).

Lung Cancer

Ociperlimab (BGB-A1217), an anti-TIGIT Antibody

Ociperlimab (BGB-A1217) is an investigational humanized IgG1-variant monoclonal antibody directed against TIGIT. An immune checkpoint molecule, ociperlimab is currently being investigated in a global Phase 3 trial, AdvanTIG-302 (NCT04746924), in combination with tislelizumab in NSCLC. As of December 2024, more than 2,000 patients have been enrolled across the ociperlimab development program.

We have completed patient enrollment in AdvanTIG-302 and will evaluate data when available to inform future development opportunities for ociperlimab.

BG-60366, an EGFR-targeted CDAC

BG-60366 is an investigational EGFR-targeting CDAC being evaluated in a Phase 1 clinical trial (NCT06685718) as monotherapy in patients with EGFR-mutant Non-Small Cell Lung Cancer.

BG-89894 (SYH2039), a MAT2A Inhibitor

BG-89894 (SYH2039) is an investigational MAT2A inhibitor being evaluated in a Phase 1 clinical trial (NCT06568614) as monotherapy in patients with advanced or metastatic solid tumors. We licensed this asset from CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd in December 2024.

BGB-58067, an MTA-Cooperative PRMT5 Inhibitor

BGB-58067 is an investigational MTA-Cooperative PRMT5 inhibitor being evaluated in a Phase 1 clinical trial (NCT06568614) as monotherapy in patients with MTAP deficiency advanced or metastatic solid tumors.

BG-T187, an anti-EGFRxMET trispecific antibody

BG-T187 is an investigational anti-EGFRxMET trispecific antibody being evaluated in a Phase 1 clinical trial (NCT06598800) as monotherapy or in combination with other therapeutic agents in patients with advanced solid tumors.

BGB-26808, a HPK-1 Inhibitor

BGB-26808 is a second-generation HPK-1 inhibitor with a different scaffold from BGB-15025 being evaluated in a Phase 1 clinical trial (NCT05981703) as monotherapy or in combination with tislelizumab in patients with advanced solid tumors.

BGB-C354, an anti-B7H3 ADC

BGB-C354 is an investigational antibody drug conjugate targeting B7H3 being evaluated in a Phase 1 clinical trial (NCT06422520) as monotherapy or in combination with tislelizumab in patients with advanced solid tumors.

Gastro-Intestinal Cancer

Zanidatamab, a bispecific HER2-targeted antibody

Zanidatamab, a novel investigational ZIIHERA® bispecific antibody targeting HER2, is currently in late-stage clinical development with Zymeworks Inc./Jazz Pharmaceuticals plc. We have development and commercial rights to zanidatamab in Asia (excluding Japan), Australia, and New Zealand. We are participating in one ongoing clinical study with zanidatamab, a global Phase 3 clinical trial (NCT05152147) examining zanidatamab in combination with chemotherapy with and without tislelizumab in HER2-positive gastroesophageal cancer.

The Phase 2b study in patients with advanced or metastatic HER2-amplified biliary tract cancers ("BTC") in which zanidatamab is being used as monotherapy have been completed. We are also participating with Jazz in a confirmatory study (NCT06282575) for 2L+ BTC. A BLA for the BTC indication is under review by China NMPA as of May 2024 and Orphan Drug Designation ("ODD") was issued by Ministry of Food and Drug Safety in South Korea in December 2024. On November 20, 2024, the FDA granted accelerated approval of ZIIHERA to Jazz for previously treated unresectable or metastatic HER2-positive biliary tract cancer. In July 2024, Jazz announced that the Marketing Authorisation Application or zanidatamab in 2L BTC was validated by the European Medicines Agency.

BG-C137, an anti-FGFR2b ADC

BG-C137 is an investigational antibody drug conjugate targeting FGFR2b being evaluated in a Phase 1 clinical trial (NCT06625593) as monotherapy in patients with advanced solid tumors.

BGB-53038, a Pan-KRAS Inhibitor

BGB-53038 is an investigational Pan-KRAS inhibitor being evaluated in a Phase 1 clinical trial (NCT06585488) as monotherapy and in combinations in patients with advanced or metastatic solid tumors with KRAS mutations or amplifications.

BGB-B2033, an anti-GPC3x4-1BB bispecific antibody

BGB-B2033 is an investigational anti-GPC3x4-1BB bispecific antibody being evaluated in a Phase 1 clinical trial (NCT06427941) as monotherapy or in combination with tislelizumab in patients with selected advanced or metastatic solid tumors.

BGB-B3227, an anti-MUC1xCD16A bispecific antibody

BGB-B3227 is an investigational anti-MUC1xCD16A bispecific antibody being evaluated in a Phase 1 clinical trial (NCT06540066) as monotherapy or in combination with tislelizumab in patients with advanced or metastatic solid tumors.

BG-C477, an anti-CEA ADC

BG-C477 is an investigational antibody drug conjugate targeting CEA being evaluated in a Phase 1 clinical trial (NCT06596473) as monotherapy in patients with selected advanced solid tumors.

Breast/Gynecologic Cancer

BGB-43395, a CDK4 Inhibitor

BGB-43395 is an investigational CDK4 inhibitor being evaluated in a Phase 1 clinical trial (NCT06120283) as monotherapy or in combination with either fulvestrant or letrozole in patients with hormone receptor positive ("HR+") and human epidermal growth factor 2 negative ("HER2-") breast cancer ("BC") and other advanced solid tumors.

BG-68501, a CDK2 Inhibitor

BG-68501 is an investigational CDK2 inhibitor being evaluated in a Phase 1 clinical trial (NCT06257264) as monotherapy or in combination with fulvestrant with or without BGB-43395 (CDK4i) in patients with HR+ and HER2- BC and other advanced solid tumors. BG-68501 is licensed from Ensem Therapeutics, Inc.

BG-C9074, an anti-B7H4 ADC

BG-C9074 is an investigational antibody drug conjugate targeting B7H4 being evaluated in a Phase 1 clinical trial (NCT06233942) as monotherapy or in combination with tislelizumab in patients with advanced solid tumors. BG-C9074 is licensed from Duality Biologics (Suzhou) Co., Ltd.

BGB-21447, a Bcl-2 Inhibitor

BGB-21447 is an investigational Bcl-2 inhibitor being evaluated in a Phase 1 clinical trial (NCT05828589) as monotherapy in BC and other solid tumors. In preclinical studies, BGB-21447 shows additional potency and selectivity, with a longer half-life than sonrotoclax. We believe the differentiated profiles of sonrotoclax and BGB-21447 may lead to unique development options for these programs.

I&I

BGB-45035, an IRAK4-targeted CDAC

BGB-45035 is an investigational IRAK4-targeting chimeric degradation activation compound ("CDAC") being evaluated in a Phase 1 clinical trial (NCT06342713) as monotherapy in healthy participants.

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 30 clinical stage assets, including three internally-developed molecules that have been approved by regulatory bodies in the U.S., EU, China, and other markets, 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. Currently, we have over 70 preclinical programs and we believe the majority have best-in-class or first-in-class potential.

We anticipate advancing many of 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/clinical 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 in some cases with the help 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 ("cGMP") regulations conditions. cGMP 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 or in-licensed products. In July 2024, we opened our flagship U.S. campus for clinical R&D and biologics manufacturing in New Jersey.

Our U.S. flagship manufacturing and clinical R&D facility is located on a 42-acre site at the Princeton West Innovation Park in Hopewell, New Jersey. The Hopewell facility is positioned strategically in the Interstate 95 corridor of New Jersey, with a deep and rich talent pool, and has more than one million square feet of developable real estate for potential future expansion to cover our existing medicines and pipeline. This site has 8,000 liters of large molecule biologics manufacturing capacity.

Our manufacturing facility in Suzhou is 52,000 square meters and consists of a manufacturing base for small molecule drug products with an annual production capacity of about 600 million tablets and capsules. The facility meets or exceeds design criteria of the U.S., E.U., and China regulatory requirements, and has been in operation for clinical product supply since the beginning of 2024, with commercial supply expected to be put into operation in mid-2025. The biologics manufacturing business at the former site in Suzhou will conclude at the end of February 2025, with some quality control testing continuing until Q3 2025.

Our state-of-the-art commercial-scale manufacturing facility of large molecule biologics in Guangzhou is approximately 158,000 square meters. Phases 1 and 2 of the facility were completed in September 2019 and December 2020, respectively, with 24,000 liters of single use disposable capacity. Additionally, total committed capacity has been increased to 64,000 liters, with 8 x 5,000L bioreactors in Phase 3 qualified in 2024. Phase 1 and 2 are currently approved for the end-to-end commercial production of tislelizumab for the China market. In April 2024, we opened a new campus equipped with a state-of-the-art ADC production facility and 2 x 500 liters biologics clinical capacity while reserving additional land for the next phase of expansion to support our growing pipeline of large molecule medicines and drug candidates. With the 2 x 500 liters biologics clinical capacity expansion, our Guangzhou manufacturing facility now has a total biologics capacity of 65,000 liters.

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.

With our internal manufacturing capabilities and continued partnership with global contract manufacturers, we continue to diversify our global supply network and do not anticipate any disruption to supply on account of our established strategy to maintain sufficient safety stock of our products. We have commercial supply and related agreements with our manufacturing service providers. The FDA has approved an ex-China active pharmaceutical ingredients ("API") source in January 2025, with EMA approval pending. For our commercial and clinical stage products in-licensed from Amgen, BMS and others, we rely on the licensors and their manufacturing facilities or their CMOs for the supply of those medicines and drug candidates.

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. Our outsourced suppliers procure raw materials themselves. 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 APIs 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. 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 (as amended, 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 clinical 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 $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 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 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 received 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.

In connection with our ongoing assessment of the Amgen Collaboration Agreement cost-share contributions, we determined that our further investment in the development of AMG 510 was no longer commercially viable for us. As a result, in February 2023, we entered into an amendment to the Amgen Collaboration Agreement to (i) stop sharing costs with Amgen for the further development of AMG 510 during the period starting January 1, 2023 and ending August 31, 2023; and (ii) cooperate in good faith to prepare a transition plan with the termination of AMG 510 from the Amgen Collaboration Agreement.

BeiGene, Ltd. has 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 (as amended, the "Share Purchase Agreement"), we issued to Amgen 206,635,013 ordinary shares in the form of 15,895,001 ADSs of the Company on January 2, 2020, representing approximately 20.5% of our then outstanding shares, for an aggregate purchase price of $2.78 billion, or $13.45 per ordinary share, or $174.85 per ADS.

Pursuant to the Share Purchase Agreement, Amgen 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 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. The lock-up has since expired and under the terms of the Share Purchase Agreement, Amgen now has specified registration rights. 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 had 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 was exercisable on a monthly basis, but only if Amgen's interest in our outstanding shares at the monthly reference date was less than 20.4%. The Direct Purchase Option (i) was 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) was 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 terminated on December 1, 2023.

On January 30, 2023, BeiGene, Ltd. and Amgen entered into an Amendment No. 3 to the Share Purchase Agreement, pursuant to which Amgen elected to relinquish its right to appoint a designated director to the Company's board of directors on account of the Company's global growth. The Company has retained Anthony C. Hooper, who was Amgen's director designee on the Company's board of directors until Amgen relinquished its right to appoint a designated director. Mr. Hooper was most recently re-elected by shareholders in 2022 to serve a three-year term ending 2025.

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 U.S. and other countries and regions, such as Europe and China, 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 sometimes 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. Additionally, in various markets, a period of regulatory exclusivity may be provided for drugs upon approval. The scope and term of such regulatory exclusivity will vary but, in general, the period will run concurrently with the term of any existing patent rights associated with the drug at the time of approval.

As of February 14, 2025, we owned 63 issued U.S. patents, 15 issued European patents, 28 issued Japanese patents, 70 issued China patents, a number of pending patent applications in the U.S., Europe, Japan and China, and corresponding issued patents and pending patent applications internationally.

The key patents for our medicines and late-stage clinical drug candidates as of February 14, 2025, are summarized below:

Molecule	Territory	General Subject Matter	Expiration[1]
BRUKINSA® (zanubrutinib)	U.S.	Composition of matter	2034
	U.S.	Pharmaceutical composition	2034
	U.S.	Method of treatment	2034
	U.S.	Crystalline forms	2037
	U.S.	Crystalline forms	2037
	U.S.	Crystalline forms	2037
	U.S.	Method of treatment	2037
	U.S.	Method of treatment	2037
	U.S.	Combination use	2039
	U.S.	Method of treatment	2043
	U.S.	Method of treatment	2043
	U.S.	Method of treatment	2043
	Europe	Composition of matter	2034[2]
	Europe	Combination use	2037[3]
	Japan	Composition of matter	2034
	Japan	Crystalline forms	2037
	Japan	Crystalline forms	2037
	China	Composition of matter	2034
	China	Crystalline forms	2037
	China	Combination use	2037
TEVIMBRA® (tislelizumab)	U.S.	Composition of matter	2033[4]
	U.S.	Composition of matter	2033
	U.S.	Composition of matter	2033
	U.S.	Polynucleotide	2033
	U.S.	Method of treatment	2033
	Europe	Composition of matter for antibodies	2033[5]
	Japan	Composition of matter	2033
	China	Composition of matter	2033
	China	Composition of matter	2033
	China	Composition of matter	2033
	China	Composition of matter for antibodies	2033
	China	Polynucleotide	2033
	China	Method of treatment	2033
PARTRUVIX® (pamiparib)	China	Composition of matter	2031
Ociperlimab	U.S.	Composition of matter	2038
	Japan	Composition of matter	2038
	China	Composition of matter	2038
Sonrotoclax	U.S.	Composition of matter	2039
	Japan	Composition of matter	2039
	China	Composition of matter	2039

1. Unless otherwise indicated, the expected expiration does not include any potential additional term for patent term extension ("PTE"), supplemental protection certificate ("SPC") or pediatric exclusivity.

2. SPCs have been filed in various European countries and have been granted at least in France, Germany, Italy, Spain and the United Kingdom, extending the original patent term in those countries to 2036.

3. This patent is the subject of a pending opposition proceeding at the European Patent Office (EPO).

4. An application for PTE has been filed and if granted, will extend the original patent term to 2038.

5. SPCs have been pending or have been granted in various European countries, extending the original patent term in those countries, where granted, to 2038.

Under our collaboration with Amgen, we have the right to commercialize three medicines in China. The key patents for them in China as of February 14, 2025 are summarized below:

Product	Territory	General Subject Matter	Expiration
BLINCYTO® (blinatumomab)	China	Use for the treatment of pediatric acute lymphoblastic leukemia	2029
KYPROLIS® (carfilzomib)	China	Compound and Composition	2025

We have one in-licensed medicine in China from Shandong Luye Pharmaceutical Co., Ltd ("Luye"). The key patent for it in China as of February 14, 2025 is summarized below:

Product	Territory	General Subject Matter	Expiration
BAITUOWEI® (goserelin microsphere)	China	Formulation	2034

Under our license agreement with Amgen, they retain the responsibility, but are not obligated, to prosecute, defend and enforce the patents for the corresponding in-licensed products. Under our license agreement with Luye, Luye retains the responsibility, but is not obligated, to prosecute the in-licensed patents for the corresponding in-licensed product, and we retain the responsibility, but is not obligated, to defend and enforce the patents for the corresponding in-licensed product.

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.

Competition

We operate in a highly competitive global landscape, with our marketed products facing strong competition in regulated markets worldwide. Our primary competitors include a diverse array of entities, from leading global research-based biopharmaceutical companies to agile regional and local firms. These competitors are actively engaged in the development, production, and marketing of therapeutic products aimed at treating diseases similar to those in our current portfolio or pipeline. This global competition underscores the breadth and depth of our industry, requiring us to maintain a robust and agile approach to R&D and excel in the commercialization of our innovative medicines across international markets.

The following table lists our key competitors for our principal products by competitor, product and territory, though it is not exhaustive.

Product	Competitor	Competitor-marketed product	Territory
BRUKINSA	AbbVie & Janssen	IMBRUVICA	U.S., Europe, Asia Pacific & China
	AstraZeneca	CALQUENCE	U.S., Europe, Asia Pacific & China
	Eli Lilly	JAYPIRCA	U.S., China & Japan
	Innocare	YINUOKAI	China
TEVIMBRA	Merck	KEYTRUDA	U.S., Europe, Asia Pacific & China
	Bristol Meyers Squibb	OPDIVO	U.S., Europe, Asia Pacific & China
	AstraZeneca	IMFINZI	U.S., Europe, Asia Pacific & China
	Roche	TECENTRIQ	U.S., Europe, Asia Pacific & China
	Merck KGaA	BAVENCIO	U.S., Europe, Asia Pacific & China
	Regeneron & Sanofi	LIBTAYO	U.S., Europe, Asia Pacific & China
	GSK	JEMPERLI	U.S., Europe, Asia Pacific & China
	Junshi	LOQTORZI	U.S., Europe & China
	Henlius	HANSIZHUANG	U.S., China & South Asia
	Various Chinese companies	10+ products including PD-1/L1, PD-1xCTLA-4	China

In addition, we have several promising candidates in the pivotal development stage, including sonrotoclax, a BCL-2 inhibitor, and BGB-16673, a BTK-targeted degrader compound ("CDAC"). These products are in various stages of clinical trials conducted globally and show potential in addressing unmet medical needs.

The following table lists our key competitors for our late-stage pipeline products by competitor, asset, latest development stage, and clinical trial territory, although it is not exhaustive.

Asset	Competitor	Competitor-asset	Latest development stage	Territory
Sonrotoclax	AbbVie & Roche	VENCLEXTA	Approved	Global
	Ascentage Pharma	Lisaftoclax	Phase 3	Global
BGB-16673	Eli Lilly (Loxo Oncology)	JAYPIRCA	Approved	Global
	Nurix Therapeutics	NX-5948	Phase 1	U.S.
	AbbVie	ABBV-101	Phase 1	Global

Furthermore, we are advancing several promising candidates through pivotal programs, including novel antibody-drug conjugates ("ADCs"), multispecific antibodies, and targeted therapies for lung, breast, and gastrointestinal cancers. To our knowledge, Roche, AstraZeneca, Pfizer, and Merck are also developing new therapeutic options with similar mechanisms. Our candidates are well-positioned in the market to offer first-in-class and/or best-in-class profiles, particularly in addressing the limitations of existing treatments and offering new alternatives to patients.

Many of the larger companies we compete with are well-capitalized and dedicate a significant number of financial resources to support their research and development, while using business development to supplement their internal pipelines as well as investing heavily in commercialization capabilities. As a result, we must continuously invest and gain experience in the development, acquisition, and marketing of innovative and branded medicines and drug candidates to compete effectively in both current and future markets. This requires us to devote substantial funds and resources to develop and generate evidence that prevents the erosion of existing products and delivers revenue from the next waves of innovation.

The main forms of competition include efficacy, safety, and cost. The long-term success of our products depends on our ability to effectively demonstrate the value to physicians, patients, and third-party payers. This requires a much greater use of a direct sales force and promotion to realize significant revenues. We also have, and will continue to enter into, co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or sufficiently well-aligned to achieve maximum market penetration. Furthermore, robust compliance approaches, science-based promotion model, and integrated management will also be competitive advantages in the industry in the long run, in which we invest significant effort to establish and grow.

Government Regulation

Government authorities in the U.S., Europe, China and other jurisdictions extensively regulate the research and clinical development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of drugs like those we are developing and commercializing. Some jurisdictions also regulate drug pricing. Generally, for a new drug to be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. Regulation

U.S. Government Regulation and Product Approval

In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations, and biologics under the FDCA, its implementing regulations, and the Public Health Service Act ("PHSA"), and its implementing regulations.

U.S. Drug and Biologics Product Development

The process required by the FDA before a drug or biologic may be marketed in the U.S. generally involves the following:

- completion of preclinical laboratory tests and animal studies according to Good Laboratory Practices ("GLP") guidance;
- completion of extensive chemistry, manufacturing, and control ("CMC") studies;
- submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practice ("GCP"), to establish the safety and efficacy of the proposed drug or safety, purity and potency of the proposed biologic, for the intended use;
- preparation and submission to the FDA of an NDA for a small molecule drug or a BLA for a biologic;
- a determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP;
- review of the product candidate by an FDA advisory committee, where appropriate and if applicable;
- payment of user fees for FDA review of the NDA or BLA (unless a fee waiver applies);
- FDA audits of some clinical trial sites to ensure compliance with GCPs; and
- FDA review and approval of the NDA or licensing of the BLA.

Preclinical Studies and Clinical Trials

Once a product candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as *in vitro* and animal studies. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The results of preclinical testing, along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol are reviewed by the FDA as part of an IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to the proposed clinical trial and places the trial on a full clinical hold. The FDA may also impose full or partial clinical holds at any time before or during clinical trials due to safety concerns or noncompliance and may be imposed on all products within a certain class of products.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. Further, an institutional review board ("IRB") must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the trial and may recommend halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

Each new clinical protocol and any amendments to the protocol must be filed with the FDA as an IND amendment and submitted to the IRBs for approval.

A sponsor who wishes to conduct a clinical trial outside of the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or BLA. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- **Phase 1.** The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients with the target disease or condition.

- **Phase 2.** Involves clinical trials in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

- **Phase 3.** Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population. These clinical trials are intended to evaluate the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected AEs, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator's brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product. The FDA, IRB, or the sponsor may suspend or terminate, or a data safety monitoring board may recommend the suspension or termination of, a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk.

U.S. Expanded Access

Expanded access, sometimes called "compassionate use," is the use of investigational products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. There is no requirement for a company to provide expanded access to its investigational products. However, if a company decides to make one of its investigational products available for expanded access, the FDA reviews each request for expanded access and determines if treatment may proceed. We make available on our website our contact information for requesting access to our investigational drugs and expected timeline for us to acknowledge receiving such requests.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the CMC, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new small molecule drug or a BLA for a biologic, requesting approval to market the product. The submission of an NDA or BLA is subject to the payment of a substantial user fee, although a waiver of such fee may be obtained under certain limited circumstances. The sponsor of an approved NDA or BLA is also subject to an annual prescription drug product program fee.

The FDA may request additional information rather than accept an NDA or BLA for filing. In this event, the NDA or BLA must be re-submitted with the additional information and the re-submitted application is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use, and a BLA to determine whether the biologic is safe, pure, and potent for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Before approving an NDA or BLA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities comply with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

The approval process can be lengthy and difficult, and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA or BLA in its present form. The complete response letter describes the specific deficiencies identified in the NDA or BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, withdraw the application or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, require post-approval studies, including Phase 4 clinical trials, to further assess a product's safety and effectiveness, or may require testing and surveillance programs to monitor the safety of approved products. The FDA may also approve an NDA or BLA with a Risk Evaluation and Mitigation Strategy program to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Regulation of Combination Products in the U.S.

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities in certain jurisdictions, and in the U.S. by different centers at the FDA. These products are known as combination products. Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the "primary mode of action" of the combination product. We are developing combination products using our own drug candidates and third-party drugs.

Regulation of Companion Diagnostics in the U.S.

If safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. For novel drugs, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product's labeling. Once cleared or approved, the companion diagnostic must adhere to post-marketing requirements including the requirements of FDA's quality system regulation, medical device reporting, recalls and corrections along with product marketing requirements and limitations. Companion diagnostic manufacturers are subject to unannounced FDA inspections at any time during which the FDA will conduct an audit of the product(s) and the company's facilities for compliance with its authorities.

Expedited Programs

The FDA may employ one of several tools to expedite the development and review of a medicine, including fast track designation, breakthrough therapy designation, priority review designation and accelerated approval. Fast track designation is designed to facilitate the development and review of a medicine that treats a serious or life-threatening disease or condition and fills an unmet medical need. Breakthrough therapy designation is intended to expedite the development and review of a medicine that treats a serious or life-threatening disease or condition and preliminary clinical evidence indicates substantial improvement over existing therapies. Priority review designation means the FDA's goal is to take action on an application within six months of filing. The FDA may grant priority review designation to a medicine that would provide significant improvement in the safety or effectiveness of a treatment, diagnosis or prevention of a serious condition.

A product may also be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful therapeutic benefit over available therapies. In addition, such product must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM") that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trials to confirm the effect on IMM or other clinical benefit. If the FDA concludes that a drug or biologic shown to be effective can be safely used only if distribution or use is restricted, it will require such post-marketing restrictions, as it deems necessary to assure safe use of the product. Under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"), the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Additionally, under FDORA, the FDA has increased authority for expedited procedures to withdraw its accelerated approval for such drug or biologic if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or that the time period for FDA review or approval may not be shortened. Furthermore, fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval.

Pediatric Information

Under the Pediatric Research Equity Act of 2003, all marketing applications for new active ingredients, indications, dosage forms, dosing regimens or routes of administration must contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred or inapplicable.

Under the Best Pharmaceuticals for Children Act, a product may be eligible for pediatric exclusivity, which adds six months to existing exclusivity periods and patent terms. This exclusivity may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued written request for such a study.

Post-Approval Requirements

Any products for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Manufacturers and other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory requirements and test each product batch or lot prior to its release. Additionally, manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and notify the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the U.S.

The FDA may withdraw a product approval, revoke a biologics license or implement restrictions on such product if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, untitled or warning letters, holds on clinical trials, product seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties. We may undertake or be required to undertake a product recall.

Patent Term Restoration and Regulatory Exclusivity

In certain circumstances, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA or BLA, plus the time between the submission date of an NDA or BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, if available, we intend to apply for restorations of patent term for some of our patents beyond their current expiration dates, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA or BLA; however, there can be no assurance that any such extension will be granted to us.

Data exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. During the exclusivity period, the FDA may not accept for review an abbreviated NDA ("ANDA") or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of data exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA.

Regulatory exclusivity in the U.S. can also include pediatric exclusivity and orphan drug exclusivity. Pediatric exclusivity, if granted, provides an additional six months of exclusivity for all formulations, dosage forms, and indications of the active moiety and, for drugs, patent terms. This exclusivity may be granted based on the voluntary completion of a pediatric trial, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. Orphan drug exclusivity is described below under "Orphan Drugs."

Biosimilars and Exclusivity

The PHSA includes an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

A reference biologic is granted 12 years of exclusivity from the time of first licensure of the product. The FDA may approve multiple "first" interchangeable products so long as they are all approved on the same first day of marketing. This exclusivity period, which may be shared amongst multiple first interchangeable products, lasts for the lesser of (i) one year after the first commercial marketing, (ii) 18 months after approval if there is no legal challenge, (iii) 18 months after the resolution in the applicant's favor of a lawsuit challenging the biologic's patents if an application has been submitted, or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

Orphan Drugs

Orphan drugs are defined by the FDA as products intended to treat a rare disease or condition that affects less than 200,000 persons in the U.S. or that affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that costs of research and development of the product for the indication can be recovered by sales of the product in the U.S. A company must request orphan drug designation prior to filing and, if granted, the FDA will not approve another sponsor's marketing application for the same drug for the same indication for seven years. Orphan drug exclusivity will not bar approval of another medicine for the same indication if it is shown to be clinically superior.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs and biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pharmaceutical Coverage, Pricing, and Reimbursement

In the U.S. and in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors, including government authorities, managed care providers, private health insurers and other organizations. Patients generally rely on third-party payors to reimburse all or part of the associated healthcare costs and no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor.

Additionally, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list which might not include all of the FDA-approved products for a particular indication. Moreover, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. If third-party payors do not consider a product to be cost-effective or medically-necessary compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

In some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, 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. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the EU do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

The U.S. government and state legislatures have implemented cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Such adoption of government controls and tightening of restrictive policies could limit payments for pharmaceuticals. For example, the Affordable Care Act (the "ACA") contains provisions that may reduce the profitability of drug products, including increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, Congressional, and Executive challenges. As a result, it is unclear how such efforts to challenge, repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. For example, the Bipartisan Budget Act of 2018 amended the ACA by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D from 50% to 70% and closing the coverage gap in most Medicare drug plans. In addition, the Budget Control Act of 2011 and the Bipartisan Budget Act of 2015 led to aggregate reductions of Medicare payments to providers of up to 2% per fiscal year that will remain in effect through 2031 unless additional Congressional action is taken. Further, the American Taxpayer Relief Act reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

The Inflation Reduction Act of 2022 ("IRA") was enacted containing provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D; allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the U.S. Department of Health and Human Services ("HHS") rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

In addition, former President Biden issued multiple executive orders seeking to reduce prescription drug costs. President Trump reversed some of President Biden's executive orders including rescinding Executive Order 14087 entitled "Lowering Prescription Drug Costs for Americans." President Trump may issue new executive orders designed to impact drug pricing. Congress and the Trump administration have indicated that they will continue to seek new legislative measures to control drug costs.

The Centers for Medicare and Medicaid Services ("CMS") published a final rule that gives states greater flexibility 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. CMS also published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs.

There has also been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products.

The HHS implemented a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers ("PBMs"), unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between PBMs and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation until January 1, 2032. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and PBM service fees are currently under review by the Biden administration and may be amended or repealed.

In addition, there have been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. In 2023, the U.S. District Court of South Carolina issued an opinion in Genesis Healthcare Inc. v. Becerra et al. that may lead to an expansion of the scope of patients eligible to access prescriptions at 340B pricing. The outcome of this judicial proceeding is currently uncertain.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. While much of the focus of state pricing policies is limited to Medicaid, we cannot assess the impact that these and other measures such as state transparency policies will have on our business.

Other U.S. Healthcare Laws and Compliance Requirements

We are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our sales, marketing and education programs. In addition, we may be subject to patient privacy, cybersecurity, trade, and national security regulation by both the federal government and the states in which we conduct our business prior to and after receiving regulatory approval of our product candidates. Some of the laws that may affect our ability to operate are detailed below:

- The federal healthcare Anti-Kickback Statute (“AKS”), which prohibits, among other things, knowingly and willfully soliciting, receiving, providing, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation or arrangement of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person or entity can be found guilty of violating the AKS without actual knowledge of the statute or specific intent to violate it. Violations of the AKS carry potentially significant civil fines and criminal penalties, including imprisonment, fines, administrative federal civil monetary penalties, and exclusion from participation in federal healthcare programs. This law applies to our marketing practices, educational programs, pricing policies and relationships with healthcare providers. We continue to evaluate what effect, if any, these rules will have on our business.

- The federal civil and criminal false claims and civil monetary penalty laws, such as the federal False Claims Act ("FCA"), which impose criminal and civil penalties and authorize civil whistleblower or qui tam actions, against individuals or entities for, among other things: knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent; knowingly making or causing a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal AKS constitutes a false of fraudulent claim for purposes of the FCA. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Companies that submit claims directly to payors may also be liable under the FCA for the direct submission of such claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs. Our marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products and any future product candidates are subject to scrutiny under this law.

- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal AKS, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.

- As further amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), HIPAA and their respective implementing regulations impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their respective business associates who perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, made civil and criminal penalties directly applicable to business associates, and gave state attorneys authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA laws and seek attorneys' fees and costs. In addition, there may be other federal, state and non-U.S. laws which govern the privacy and security of health and other personal information and which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

- The federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to Centers for Medicare & Medicaid Services information related to payments or other transfers of value made to physicians, certain other licensed health care practitioners and teaching hospitals. Manufacturers are also required to disclose ownership and investment interest held by physicians and their immediate family members.

- Federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics in an accurate and timely manner to government programs.

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

- The Foreign Corrupt Practices Act, which prohibits companies and their intermediaries from making, or offering or promising to make, improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment.

- Executive Order 14117 on Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern prohibits transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict investment agreements, employment agreements and vendor agreements involving such data and countries of concern. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions, and may result in exclusion from participation in federal and state programs.

Similarly, state privacy laws may be broader and require greater protections than HIPAA. These data privacy and security laws may differ from each other and often are not pre-empted by HIPAA, which may complicate compliance efforts. For example, certain states have passed privacy laws that grant consumers rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. Several states have passed laws specifically regulating consumer health data, which impose detailed consent requirements for uses and disclosures of such data. These laws provide for civil penalties for violations, and key concepts in such laws have not yet been tested, leading to significant uncertainty concerning the application of such laws to our practices. In addition, several of these laws allow for private claims, which could lead to litigation risks even where we believe we are in compliance.

Additionally, we are subject to state equivalents of each of the healthcare laws described above, 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.

In the U.S., to help patients afford our approved product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In addition, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS also requires individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. Furthermore, the Office of Inspector General ("OIG") of the HHS has warned manufacturers that they may be subject to sanctions under the federal AKS and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

Third-party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

EU and UK Data Protection Laws

In the EU, the General Data Protection Regulation ("GDPR") governs the processing of personal data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, such as including requirements relating to having legal basis for processing personal data relating to identifiable individuals and transferring such information outside the European Economic Area ("EEA"), including to the U.S., providing details to those individuals regarding the processing of their personal data, implementing safeguards to keep personal data secure, having data processing agreements with third parties who process personal data in countries not deemed adequate by the EU and the UK, responding to individuals' requests to exercise their rights in respect of their personal data, obtaining consent of the individuals to whom the personal data relates if there is no legal basis for processing, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to €20,000,000 or 4% of total annual global revenue, whichever is greater. In addition, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. We are required to implement certain safeguards detailed in these regulations when conducting restricted data transfers under the EU and UK GDPR and regulators retain authority to further restrict or prohibit transfers to certain countries where applicable laws would undermine the privacy safeguards provided by the GDPR.

PRC Regulation

In the PRC, we operate in an increasingly complex legal and regulatory environment. We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section summarizes the principal PRC laws, rules and regulations that we believe are relevant to our business and operations.

PRC Drug Regulation

Introduction

China heavily regulates the development, approval, manufacturing and distribution of drugs, including biologics. The legal framework for the administration of pharmaceutical products in China was established by the Drug Administration Law of the PRC (the "DAL"). The DAL provides a framework for regulating pharmaceutical manufacturers, pharmaceutical trading companies, medical institutions, and the research, development, manufacturing, distribution, packaging, pricing, and advertisement activities related to pharmaceutical products. The Implementing Measures of the Drug Administration Law provides detailed implementation regulations for the DAL.

The DAL

The DAL embodies a regulatory trend to strengthen the life-cycle management of drugs, to balance the development of innovative drugs and generic drugs, and to enhance drug review and enforcement. It established the Marketing Authorization Holder (the "MAH") system, and subject to approval by the NMPA, MAHs will be allowed to transfer their marketing authorizations. However, to date, it remains uncertain whether the transferability of MAH will offer more flexibility in structuring cross-border transactions. In addition, the implementation of the MAH system was accompanied by a range of new requirements for the MAHs. For example, a MAH must establish a quality assurance system and be responsible for the whole process and all aspects of preclinical research, clinical trials, manufacturing and distribution, post-marketing research, adverse drug reaction monitoring and reporting. A foreign MAH is required to engage a local agent to fulfill the MAH's obligations and the foreign MAH is subject to joint and several liability in the event of any wrongdoing. On November 13, 2024, the NMPA issued the Interim Provisions for the Management of Domestic Responsible Persons Designated by Foreign Drug Marketing Authorization Holders (the "Interim Provisions"), which will come into effect on July 1, 2025. The Interim Provisions explicitly require foreign MAHs to designate local delegates and authorize them to undertake important post-marketing responsibilities together with the drug MAHs, including post-marketing change management, pharmacovigilance, and product quality complaint handling. As of July 1, 2025, the name, address and contact information of the domestic responsible person shall be listed in the package insert and detailed requirements of implementation shall be subject to further practical guidance and interpretation rules from the relevant government authorities.

The DAL requires drug manufacturers and drug distributors to comply with current GMP and GSP requirements. Pursuant to the DAL, NMPA and its local counterparts are directed to strengthen their surveillance of drug manufacturers and distributors, including through regular site inspections and unannounced checks, to ensure their compliance. The NMPA has also been strengthening its regulation of clinical trial institutions by collaborating with the National Health Commission (the "NHC"), the chief healthcare regulator in China. The Measures for the Administration of Drug Clinical Trial Institutions jointly issued by the NMPA and the NHC provides detailed requirements on how drug clinical trial institutions should comply with GCP, including, among others, that all drug clinical trial institutions are required to be registered on an online system and disclose their key information essential for compliance with GCP.

The DAL also requires MAHs, manufacturers, distributors, and medical institutions to establish and implement drug track and trace systems. The Measures for the Quality Supervision of Drug Commercialization and Use established the requirements and standards for the drug track and trace system. A drug pharmacovigilance system will also be established to monitor, identify, evaluate and control adverse drug reactions and other possible drug-related problems. The Good Pharmacovigilance Practices provides detailed requirements on MAH's pharmacovigilance obligations.

The DAL creates an expanded access pathway for investigational drugs under which a company sponsor of a clinical trial in China can apply to establish an expanded access treatment program for patients with life-threatening disease who otherwise do not satisfy the inclusion criteria of a clinical trial. To quality for expanded access: (1) the drug must be used for life-threatening diseases that lack effective treatment; (2) the drug must have demonstrated its potential efficacy based on medical observations; (3) such use is in line with ethical principles; (4) such expanded use has been reviewed and approved (although the approval pathway not clear), and has obtained patients' informed consent; and (5) the drug must be used within the clinical trial institution and used on patients with similar conditions.

The DAL provides heavy penalties for violations. Depending on various types of violations, the DAL imposes different penalties, including warnings, confiscation of illegal gains, fines of up to RMB5 million (about $725,000) or up to 30 times of illegal gains, revocation of required business and operating licenses, certificates or approval documents for drugs, suspension of business, temporary (10 years) or permanent debarment of companies, institutions and responsible persons, and criminal liabilities in the case of serious violations.

The interpretation and implementation of the DAL have been evolving overtime. We plan to closely monitor the implementation of the DAL and its impact on our operations in China.

Regulatory Authorities and Government Reorganization

In China, the NMPA is the primary regulator for pharmaceutical products and businesses. It is a sub-agency of the State Administration for Market Regulation (the "SAMR"), which is responsible for, in addition to drug regulation, consumer protection, advertising, anticorruption, antitrust, fair competition and intellectual property.

The NMPA regulates almost all of the key stages of the life cycle of pharmaceutical products, including nonclinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations). The CDE, which remains under the NMPA, conducts the technical evaluation of each drug and biologic application for safety and efficacy.

The NHC is China's chief healthcare regulator. It is primarily responsible for overseeing the operation of medical institutions (including clinical trial sites) and regulating the licensure of hospitals and other medical personnel.

The NHSA is the primary regulator overseeing national medical insurance and related drug reimbursement schemes, including, among others, the National Drug Reimbursement Price Negotiations, which have significant impact on innovative drugs' prices in China. The NHSA and its local counterparts at or below the provincial level of local government also oversee and organize public medical institutions' centralized bidding and procurement programs for pharmaceutical products. This is the primary way that public hospitals and their internal pharmacies procure drugs.

Preclinical and Clinical Development

The NMPA requires preclinical data to support registration applications for new drugs. Preclinical work, including safety assessment studies, must meet the GLP's standards. The DAL requires the NMPA to accredit GLP labs, and that nonclinical studies of chemical drug substances and preparations and biologics that are not yet marketed in China be conducted in GLP-certified labs. There are no approvals required from the NMPA to conduct preclinical studies.

A Certificate for Use of Laboratory Animals is required for performing experimentation on animals under the Regulations for the Administration of Affairs Concerning Experimental Animals, the Administrative Measures on Good Practice of Experimental Animals, and the Administrative Measures on the Certificate for Experimental Animals (Trial). Applicants for this certificate must satisfy a number of conditions, including (1) the environment and facilities for lab animals' living and propagating must satisfy national requirements; (2) lab animals must be qualified and sourced from institutions with Certificates for Production of Lab Animals; and (3) the animals' feeding and experimentation must be conducted by professionals, specialized and skilled workers, or other trained personnel.

Registration Categories

Prior to engaging with the NMPA on research and development and approval, an applicant will need to determine the registration category for its drug candidate (which will ultimately need to be confirmed with the NMPA), which will determine the requirements for its clinical trial and marketing application. There are five categories for small molecule drugs: Category 1 (innovative drugs) refers to drugs that have a new chemical entity that has not been marketed anywhere in the world, Category 2 (improved new drugs) refers to drugs with a new indication, dosage form, route of administration, combination, or certain formulation changes not approved in the world, Categories 3 and 4 are for generics that reference an innovator drug (or certain well-known generic drugs) marketed either abroad or in China, respectively, and Category 5 refers to innovative or generic drugs that have already been marketed abroad but are not yet approved in China (i.e., imported drugs).

Expedited Programs

Priority Evaluation and Approval Programs to Encourage Innovation

The NMPA has adopted several expedited review and approval mechanisms that are intended to encourage innovation. Applications for these expedited programs can be submitted after the clinical trial application is admitted for review by the CDE. The NMPA's Drug Registration Rules ("DRR") provide certain categories of drugs that may be eligible for priority status, among which, the following may be particularly relevant for us: (1) drugs that are clinically and urgently needed but insufficient in supply; (2) innovative drugs and improved new drugs for prevention and treatment of major contagious diseases and rare diseases; (3) new pediatric drugs, (4) drugs designated as breakthrough therapies, and (5) drugs that satisfy the conditional approval criteria. If admitted to one of these expedited programs, an applicant will be entitled to more frequent and timely communication with reviewers at the CDE, expedited review and approval, and more agency resources throughout the approval process.

Conditional Approval

NMPA also permits conditional approval of certain medicines based on early phase data. The agency has done this for medicines that meet unmet medical needs for life-threatening illnesses and also for medicines that treat orphan indications. Under the DRR, drugs that meet one of the three criteria might be eligible for conditional approval: (1) drugs that treat life threatening illnesses for which there are no effective treatment or preventive methods, but their clinical trials already have the data to prove efficacy and their clinical value is predictable, (2) drugs that are urgently needed for public health reasons, and their clinical trials already have the data to prove efficacy and their clinical value is predictable; or (3) vaccines that are urgently needed for major public health emergencies or otherwise deemed by the NHC to be urgently needed, and it is concluded upon evaluation that their benefits outweigh their risks. Following approval, the MAH is required to take risk mitigation measures and complete a post-market study as required by the NMPA within a prescribed timeline.

Breakthrough Therapy Designation

Breakthrough therapy designation ("BTD") is a process designed to expedite the development and review of clinical stage, innovative or improved new drugs that meet the following criteria: (1) they are intended to treat life threatening conditions or conditions that have serious negative impact on the quality of life, and (2) there are no effective treatment or preventive methods available, or there is preliminary clinical evidence indicating that they may demonstrate substantial improvement over available therapies. Applicants of drugs designated as breakthrough therapies will be entitled to direct communications with CDE at key states during the clinical trials and may seek CDE's opinion on study progress.

Policies on Expediting Approval of Imported Oncology Drugs

The PRC government continues to establish measures and incentives to promote the development and swifter approval of marketing for oncology and other innovative drugs. Beginning in May 2018, the PRC eliminated tariffs on a significant number of imported innovative drugs, including oncology drugs, making the importation process more efficient. The PRC government has also stated that it will explore ways to expand access to reimbursement under the state health plans for innovative drugs (particularly for urgently needed oncology drugs).

Clinical Trials and Marketing Approval

Upon completion of preclinical studies and preliminary CMC studies, a sponsor typically needs to conduct clinical trials in China for registering a new drug. The materials required for this application and the data requirements are determined by the registration category. The NMPA has taken a number of steps to increase efficiency for approving clinical trial applications, and it has also significantly increased monitoring and enforcement of GCP to ensure data integrity.

Clinical Trial Approval

All clinical trials conducted in China for the purpose of seeking marketing approvals must be approved by the NMPA and conducted at hospitals satisfying GCP requirements. In addition to a standalone China trial to support development, imported drug applicants may include Chinese clinical sites as part of an international multicenter trial ("IMCT"). Domestically manufactured drugs are not subject to foreign approval requirements and the NMPA permits those drugs to conduct development via an IMCT as well.

The DAL has now also adopted an implied approval system for clinical trials of new drugs. Trials can proceed if after 60 business days, the applicant has not received any objections from the CDE, as opposed to the lengthier previous clinical trial pre-approval process in which the applicant had to wait for affirmative approval. The DAL also expands the number of trial sites by abolishing the GCP accreditation system and requiring trial sites to follow a more simplified notification procedure.

Clinical Trial Register

Clinical trials conducted in China must be registered and published through the Drug Clinical Trial Information Platform (http://www.chinadrugtrials.org.cn). Applicants are required to pre-register the trial information within one month after obtaining the clinical trial approval to obtain the trial's unique registration number and to complete registration of certain follow-up information before the first subject's enrollment in the trial. If the foregoing pre-registration and registration is not obtained within three years, the clinical trial approval automatically expires.

Human Genetic Resources Regulation

The Regulation on the Administration of Human Genetic Resources ("HGR Regulation") applies to all human genetic resources ("HGR")-related activities for R&D purposes, including sampling, biobanking, use of HGR materials and associated data in China, and the provision or sharing of such materials or data with non-PRC parties. As BeiGene, Ltd. is a Cayman Islands company, we and our activities in China are subject to the HGR Regulation. Such non-PRC parties seeking access to China's HGRs for scientific research, including clinical trials intended to support marketing approval of drugs and medical devices in China, must do so only through collaborations with Chinese parties, such as Chinese hospitals. The HGR Regulation prohibits non-PRC parties from independently sampling or biobanking any China HGR in China and requires approval for the sampling of certain HGR and biobanking of all HGR by Chinese parties. Any cross-border transfer of the HGR materials, either under an international collaboration or as a direct export, must be on an as-needed basis and requires approval. In addition, providing HGR data to non-PRC parties requires a record filing.

The HGR Regulation provides a record-filing procedure for international collaborations on clinical trials intended to support marketing approval of drugs in China that do not transfer HGR materials abroad, while the advance approval requirement still applies if such trials involve export of HGR materials or the collection, testing, analysis or disposal of HGR samples during the trials are not solely conducted at the clinical trial sites. Companies conducting global clinical trials may benefit little from this record filing procedure because those trials would often require cross-border transfer of HGR materials and the advance approval requirement would still apply.

The HGR Regulation requires parties to jointly apply for and own the patent rights arising from the results generated from international collaborations that utilize China HGR. Subject to approval, the parties may contractually agree on how to dispose of their patent rights and non-patent proprietary rights arising from the collaboration. As the joint ownership requirement is rather broad, it is unclear how this requirement will be implemented in practice.

The HGR Regulation also imposes severe penalties for various violations, including warnings, disgorgement of illegal gains, confiscation of illegal HGR, fines up to RMB10 million ($1,450,000) or 5-10 times of illegal gains in the event such illegal gains exceed RMB1 million ($145,000), and temporary (1-5 years) or permanent debarment of companies, institutions and responsible persons from future HGR projects regulated by the HGR Regulation.

The Implementing Rules for the HGR Regulation (the "HGR Implementing Rules") provide several critical clarifications. HGR data is narrowed down to cover only the data derived from HGR materials and gene-irrelevant clinical data, image data, protein data, and metabolic data are expressly excluded. The use of the term non-PRC parties is also further clarified by elaborating that (1) "actual control" by non-PRC entities/individuals is interpreted to include not only being controlled through equity interests but also investment or contractual arrangements, which may cover variable interest entities ("VIEs"), and (2) companies incorporated in Hong Kong Special Administration Region ("SAR") and Macau SAR but essentially controlled by Chinese domestic entities are not viewed as non-PRC parties. The industry guidance provides more clarifications from practice perspective. Notably, among others, (1) the non-PRC entity operating the electronic data capture system for an in-China trial is no longer regarded as a non-PRC party, (2) for gene-related scientific studies, if non-PRC entities do not substantively participate in such studies, nor obtain any study data, then such studies are no longer subject to the HGR regulation; and (3) human urine, feces, blood plasma, and blood serum are expressly excluded from the scope of HGR materials.

Trial Exemptions and Acceptance of Foreign Data

The NMPA may be flexible on the requirements of trials and data generated in China, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and stated that it will accept data generated abroad (even if not part of a global study), including early phase data, that meets its requirements. The NMPA issued the Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data (the "Guidance Principles"), as one of the implementing rules for the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (the "Innovation Opinion"). According to the Guidance Principles, data from foreign clinical trials must meet authenticity, completeness and accuracy requirements and such data must be obtained in compliance with the relevant requirements under the GCP of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

The NMPA permits drugs approved outside of China to be approved in China on a conditional basis without the need for pre-approval clinical trials in China. Specifically, in 2018, the NMPA established a program permitting drugs that have been approved within the last ten years in the U.S., EU or Japan to be approved in China without local clinical trials if they (1) prevent or treat orphan diseases, (2) prevent or treat serious life-threatening illnesses for which there is either no effective therapy in China, or for which the foreign-approved drug would have clear clinical advantages. Applicants for such conditional approvals will be required to establish a risk mitigation plan and may be required to complete trials in China after the drug is approved. The CDE has developed a list of drugs that meet these criteria.

Clinical Trial Process and Good Clinical Practices

As in other parts of the world, clinical trials in China typically have three phases. Phase 1 refers to the initial clinical pharmacology and human safety evaluation studies. Phase 2 refers to the preliminary evaluation of a drug candidate's therapeutic efficacy and safety for target indication(s) in patients. Phase 3 (often the pivotal study) refers to clinical trials to further verify the drug candidate's therapeutic efficacy and safety on patients with target indication(s) and ultimately provide sufficient evidence for the review of a drug registration application. The NMPA requires that the different phases of clinical trials in China receive ethics committee approval (with exemptions for certain specific circumstances, such as studies utilizing public information or anonymized data) and comply with GCP. The NMPA conducts inspections on clinical trials conducted in China to assess GCP compliance and may refuse to approve the drug if it finds substantial issues in the trials. In addition, upon granting the drug registration certificate, NMPA may, at its sole discretion, require a Phase 4 trial to be conducted by MAH within a specified period of time so as to further monitor and obtain safety and efficacy data of the drug.

Generic small molecule drugs are required to conduct a bioequivalence trial, in vitro studies or in some cases a clinical trial to demonstrate therapeutic equivalence to an innovator drug marketed either in China or abroad or an internationally accepted generic drug. The NMPA has released catalogues of reference products, and it released first installment of a Marketed Drug List (China's "Orange Book") with information about drugs that may serve as reference products.

Pursuant to GCP, sponsors of clinical trials are responsible for proper packaging and labeling of drugs used for clinical trials, and in double-blinded clinical trials, the investigational drugs shall be consistent with the control drug or placebo in appearance, odor, packaging, labeling, and certain other features. Pharmaceutical packaging must comply with national and professional standards. If there is no national or professional standard available, companies may formulate and implement their own standards after obtaining the approval of the provincial administration for medical products or bureau of standards. Changes in such approved packaging standards need to be re-approved. Drugs of which the packaging standards are not approved shall not be released or marketed in China, except for those specifically supplied to the military.

New Drug Application ("NDA") and Approval

Upon completion of clinical trials, a sponsor may submit clinical trial data to support marketing approval for the drug. For domestically manufactured drugs, NDA sponsors must submit data derived from the submitted drugs in support of their approval. Under the DAL, upon approval of the registration application, the NMPA will issue a drug registration certificate to the applicant which is in fact the marketing approval of the drug, and the applicant is no longer required to be equipped with relevant manufacturing capability.

Manufacturing and Distribution

All facilities that manufacture drugs in China must receive a Drug Manufacturing License ("DML") with an appropriate "scope of manufacturing" from the local drug regulatory authority. This license must be renewed every five years, and the manufacturing facility is also required to comply with GMP. MAHs holding a Type B DML are allowed to contract manufacturing and must undertake the quality management obligations. NMPA has been increasing its regulatory oversight and control over contract manufacturing activities in China by way of imposing more specific and higher regulatory compliance requirements in terms of personnel, quality management system, and oversight of CMOs on MAHs. For instance, NMPA released a Guidance on Onsite Inspection of Contract Manufacturing Activities by Drug MAHs in October 2023, in which over 60 inspection items are set for issuing and maintaining Type B DML.

Similarly, to conduct sales, importation, shipping and storage, a company must obtain a Drug Distribution License ("DDL") from the local drug regulatory authority, subject to renewal every five years. As with GMPs, companies are required to comply with GSP. One exception is that the DAL and relevant implementation rules allow the MAH to conduct wholesales of its drugs directly without holding a separate DDL for wholesale, however, a retail DDL would still be required if the MHA intends to conduct direct retail to patients.

China has developed a "Two-Invoice System" to control distribution of prescription drugs. This system generally requires that no more than two invoices may be issued throughout the distribution chain, with one from the manufacturer to a distributor and another from the distributor to the end-user hospital. This excludes the sale of products invoiced from the manufacturer to its wholly-owned or controlled distributors, or for imported drugs, to their exclusive distributor, or from a distributor to its wholly-owned or controlled subsidiary (or between the wholly-owned or controlled subsidiaries). However, the system still significantly limits the options for companies to use multiple distributors to reach a larger geographic area in China. Compliance with the Two-Invoice System is a prerequisite for pharmaceutical companies to participate in procurement processes with public hospitals, which currently provide most of China's healthcare. Manufacturers and distributors that fail to implement this system may lose their qualifications to participate in the bidding process or be blacklisted from engaging in drug sales to public hospitals in a locality.

Post-Marketing Surveillance

Under the DAL, the MAH of a drug is ultimately responsible for pharmacovigilance, including quality assurance, adverse reaction reporting and monitoring, and product recalls. Distributors and user entities (e.g., hospitals) are also required to report, in their respective roles, adverse reactions of the products they sell or use, and assist the MAH with any product recalls. A MAH for a drug that is currently under the new drug monitoring period has to report all adverse drug reactions (as opposed to just serious adverse reactions) for that period.

Advertising and Promotion of Pharmaceutical Products

China has a strict regime for the advertising of approved medicines. No unapproved medicines may be advertised. The definition of an advertisement is very broad and does not expressly exclude scientific exchange. It can be any media that directly or indirectly introduces the product to end users. There is no clear line between advertising and any other type of promotion. An enterprise seeking to advertise a prescription drug may do so only in medical journals jointly approved by NMPA and the NHC, and each advertisement requires approval from a local drug regulatory authority. The content of an approved advertisement may not be altered without filing a new application for approval.

Prescription drug advertisements are subject to strict content restrictions, which prohibit recommendations by doctors and hospitals and guarantees of effectiveness. Advertising that includes content that is outside of the drug's approval documentation (off-label content) is prohibited. False advertising can result in civil suits from end users and administrative liability, including fines. In addition to advertisements, non-promotional websites that convey information about a drug must go through a separate approval process by a local drug regulatory authority.

Regulatory Intellectual Property Protections

The amendments to the PRC Patent Law (the "Amended PRC Patent Law") provides a cause of action to allow a patent holder to initiate a declarative action during the regulatory review process of a generic drug application to determine whether the drug falls within the patent scope, which may be comparable to the patent linkage system in the U.S. The system requires that the NMPA continue to review the potentially infringing generic application during any lawsuit by the innovator. However, the NMPA may not approve the generic application pending resolution of the patent litigation in favor of the generic filer or for a specified period of time, whichever is shorter. The Amended PRC Patent Law also provides patent term extension ("PTE") for the patent term lost during the regulatory review process of a new drug upon the patent holder's request. The extended term shall not exceed five years, and the total patent term after approval of the drug shall not exceed 14 years. On December 21, 2023, the final versions of Rules for Implementation of the Patent Law was published, and the China National Intellectual Property Administration ("CNIPA") published new version of Patent Examination Guidelines accordingly. The Implementation Rules and Patent Examination Guidelines introduced detailed rules and examination guidelines on PTE, and took effect on January 20, 2024.

Reimbursement and Pricing

China regulates drug prices mainly by establishing a consolidated procurement mechanism, restructuring medical insurance reimbursement standards and strengthening regulation of medical and pricing practices, as discussed below.

National Reimbursement Drug List

China's national medical insurance program currently consists of two fundamental sub-programs: (1) the basic medical insurance program for urban employees, under which urban employers are required to enroll their employees in the program and the insurance premium is jointly contributed by the employers and employees; and (2) the basic medical insurance program for urban and rural residents, which allows urban and rural residents who do not have employers to voluntarily participate in the basic medical insurance program and the insurance premium is jointly contributed by the participants and the government. Participants of the national medical insurance program and their employers, if any, are required to contribute to the payment of insurance premiums on a monthly basis. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the NRDL. A pharmaceutical product listed in the NRDL must be clinically needed, safe, effective, reasonably priced, easy to use, and available in sufficient quantity.

Factors that affect the inclusion of a pharmaceutical product in the NRDL include whether the product is used in large volumes and commonly prescribed for clinical use in the PRC and whether it is considered to be important in meeting the basic healthcare needs of the general public. Historically, special consideration has been given to, among others, innovative drugs with high clinical value and drugs for serious diseases. In addition, the government has also been negotiating with manufacturers of exclusive drugs with high clinical demands and proven effectiveness for price cuts in exchange for inclusion into the NRDL. The version of the NRDL released in 2024 (effective from January 1, 2025) covers approximately 3,159 drugs in total, including 91 new drugs listed for which the prices were determined through negotiations between the drug companies and government. China has been pursuing a policy of expediting the addition of innovative oncology drugs to this list. REVLIMID has been included in the NRDL since 2017. VIDAZA has been included in the NRDL since 2018. BRUKINSA (zanubrutinib), tislelizumab, and XGEVA (120-mg denosumab) have been included in the NRDL since 2020. PARP inhibitor PARTRUVIX (pamiparib) has been included in the NRDL since 2021. KYPROLIS has been included in the NRDL since 2022. SYLVANT and BAITUOWEI have been included in the NRDL since 2024.

Centralized Procurement and Tenders

Under current regulations, public medical institutions owned by the government or owned by state-owned or controlled enterprises are required to purchase pharmaceutical products through centralized online procurement processes. There are exceptions for drugs on the National List of Essential Drugs, which must comply with their own procurement rules, and for certain drugs subject to the central government's special control, such as toxic, radioactive and narcotic drugs, and traditional Chinese medicines.

The centralized procurement process takes the form of public tenders that are typically conducted once every year by provincial or municipal-level government agencies. The bids are assessed by a committee randomly selected from a database of experts. The committee members assess the bids based on a number of factors, including bid price, product quality, clinical effectiveness, product safety, level of technology, the manufacturer's qualifications and reputation, after-sale services and innovation.

Since 2018, the government implemented a “zero markup” policy on all drugs among all public healthcare institutions nationwide. In addition, some local governments have begun to allow medical institutions to collectively negotiate with manufacturers for a second price to further lower the already agreed bid price. The Two-Invoice System, described above, is also designed to reduce price mark-ups brought about by multi-tier distribution chains.

Since 2019, the government adopted a volume-based, centralized drug procurement program to optimize the pricing of drugs. Drugs are selected from generic brands for volume-based, centralized drug procurement. The selected drugs must pass the bio-equivalence evaluation on quality and efficacy. All approved enterprises that produce drugs on the procurement list in China may participate. Clinical effects, adverse reactions, and batch stability of the drugs will be considered, and their consistency will be the main criteria for evaluation, while production capacity and stability of the supplier will also be considered.

In recent years, China has gradually improved its mechanism for centralized medicine procurement. On November 18, 2024, the NHSA together with the NHC jointly issued Notice on Improving Working Mechanism of Centralized Drug Procurement and Implementation. The new notice sets forth ten improvements to strengthen the management of the whole process of centralized drug procurement based upon existing policies.

Other PRC National and Provincial Laws and Regulations

Pharmaceutical companies operating in China are subject to changing regulations under many other laws and regulations administered by governmental authorities at the national, provincial and municipal levels, some of which are or may become applicable to our business. For example, regulations controlling the confidentiality of patient medical information and the circumstances under which patient medical information may be released for inclusion in our information systems or released by us to third parties. The privacy of human subjects in clinical trials is also protected by privacy laws such as the Personal Information Protection Law. These laws and regulations governing both the disclosure and the use of confidential patient medical information may become more restrictive in the future, including restrictions on transfer of healthcare data. The Cybersecurity Law designates healthcare as a priority area that is part of critical information infrastructure, and China’s cyberspace administration has been working to finalize the regulatory regime on cross-border transfer of personal information.

PRC Regulation of Foreign Investment

The Foreign Investment Law of the PRC (the “Foreign Investment Law”) and its implementing rules (the “Implementing Rules”) establish a basic framework for access to, and the promotion and administration of foreign investments in China. The Foreign Investment Law establishes a pre-entry national treatment and negative list system for the administration of foreign investments. “Pre-entry national treatment” means that the treatment afforded to foreign investors at the market access stage shall be no less favorable than that afforded to domestic investors. “Negative list” refers to the special administrative measures for foreign investors’ access to specific fields or industries. Foreign investments outside of the negative list will be granted national treatment. Foreign investors shall not invest in the prohibited fields as specified in the negative list, and foreign investors who invest in the restricted fields shall comply with certain special requirements including the shareholding percentage and citizenship of senior executives. The current industry entry clearance requirements governing foreign investment activities in the PRC are set out in two categories, namely the Special Entry Management Measures for the Access of Foreign Investment (Negative List) (2024 version), and the Encouraged Industry Catalogue for Foreign Investment (2022 version) (the “2022 Encouraged Industry Catalogue”). Industries not listed in these two categories are generally deemed “permitted” for foreign investments unless specifically restricted by other applicable PRC laws or regulations. Pursuant to the 2022 Encouraged Industry Catalogue, the research, development and manufacture of innovative oncology drugs, cell therapies, and certain other types of pharmaceutical products belongs to the encouraged industries for foreign investment. In September 2024, the Ministry of Commerce, the National Health Commission and the National Medical Products Administration jointly issued the Notice on Carrying out a Pilot Program for Expanding Opening-up in the Medical-related Field, which further allows foreign invested enterprises to engage in the technology development and application of human stem cell, gene diagnosis and treatment in four designated pilot free trade zones of China for the registration, marketing and production of products, and allow the establishment of wholly foreign-owned hospitals in selected cities and regions, which will further optimize foreign investment environment and attract foreign investment to propel the high-quality development of healthcare sector in China.

PRC Antitrust Regulation

China’s anti-trust regulatory regime is founded on the Anti-Monopoly Law (the “AML”) (last amended in 2022) and supplemented by several implementation rules. The AML in general restricts monopolistic practices including concentration of undertakings, horizontal and vertical monopolistic agreements, and certain activities of market dominance abuse.

The AML provides heavy penalties for violations, including warnings, confiscation of illegal gains, a fine ranging up to 50% of the preceding year’s turnover, revocation of required business and operating licenses, suspension of business, and even criminal liabilities.

The SAMR is the chief regulator of anti-trust law in China, and the pharmaceutical sector has been one of its focused enforcement area for years. For example, in 2021, a local drug company was found to have engaged in resale price maintenance ("RPM") practices and fined up to RMB 764 million, and in 2023, SAMR announced seven administrative penalty decisions on monopoly agreement reached and/or abuse of market dominance in pharmaceutical industry, among which, a local drug company was fined RMB 12.64 million for RPM.

Regulations Relating to Product Liability

Under current law, a defective product which causes property damage or physical injury to any person may subject the manufacturer or vendor of such product to civil liability for such damage or injury. Additionally, China's Product Quality Law provides that manufacturers are liable for the quality of products produced by them, and sellers are required take measures to ensure the quality of the products sold by them. A manufacturer is liable for compensating for any bodily injury or property damage resulting from product defects unless the manufacturer is able to prove that: (1) the product was not distributed; (2) the defects causing injury or damage did not exist at the time that the product was distributed; or (3) science and technology at the time that the product was distributed was at a level incapable of detecting the defects. A seller is liable for compensating for any bodily injury or property damage of others caused by the defects in the product if such defects are attributable to the seller. A seller is required to pay compensation if it fails to indicate either the manufacturer or the supplier of the defective product. A person who is injured or whose property is damaged by the defects in the product may claim compensation from the manufacturer or the seller.

Regulations Relating to Technology Export Control

Import and export of technologies for civilian use are regulated under the PRC Administrative Regulations on Technology Import and Export (the "TIER"). Technology export is broadly defined under Chinese law to encompass any cross-border transfer of technologies from a Chinese entity to overseas – whether by way of patent assignments, patent licenses, software licenses, transfers of technical know-how, or the provision of technical services, or by any other means. TIER divides technology export into the categories of (1) "prohibited" technologies, which cannot be exported outside China (2) "restricted" technologies, which requires approvals from the relevant Chinese authority, and (3) "unrestricted" technologies, which requires filing of proper transaction documents with the authority. The "prohibited" and "restricted" technologies are defined by the Catalogue of Technologies Prohibited or Restricted from Export (the "Catalogue"). The latest Catalogue, which was issued on December 21, 2023, included "cell cloning and gene editing technologies used in humans" into the prohibited list. It still remains unclear how the Chinese government would eventually enforce such prohibition on technology control. We plan to closely monitor China's legislative and regulatory evolvement in this area and its potential impact on our operations in China.

Regulations Relating to Commercial Bribery

Pharmaceutical companies involved in a criminal investigation or administrative proceeding related to bribery are listed in the Adverse Records of Commercial Briberies by the provincial health commissions. If a pharmaceutical company or its agent is listed, public medical institutions located in the local provincial level region are prohibited from making any purchase from the company for two years. Where a pharmaceutical company or its agent is listed in the adverse records on two or more occasions within five years, all public medical institutions in China are not permitted to purchase any products from that company for two years.

Regulations Relating to Foreign Exchange

The Foreign Exchange Administration Regulations govern foreign currency exchange in China. Under these regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the State Administration of Foreign Exchange ("SAFE") by complying with certain procedural requirements. In contrast, approval from or registration with appropriate government authorities or designated banks is required when RMB is to be converted into a foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

Under current regulations, the capital of a foreign-invested enterprise and capital in RMB obtained by the foreign-invested enterprise from foreign exchange settlement must not be used for the following purposes: directly or indirectly for payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; directly or indirectly for investment in securities or certain other financial products, unless otherwise provided by relevant laws and regulations; extending loans to non-related parties, unless permitted by the scope of business and located in the designated area; or paying expenses related to the purchase of residential real estate that is not for self-use, except for real estate enterprises. Regulations have relaxed the restrictions on foreign exchange inflow to further enhance trade and investment facilitation and enhance genuineness and compliance verification of cross-border transactions and cross-border capital flows. Furthermore, in 2019, SAFE issued the Circular of the State Administration of Foreign Exchange on Further Promoting the Facilitation of Cross-border Trade and Investment ("Circular 28") which allows non-investment foreign-invested enterprises to use their capital funds to make equity investments in China, provided that such investments do not violate the effective Special Entry Management Measures for the Access of Foreign Investment (Negative List) and the target investment projects are genuine and in compliance with laws. The interpretation and implementation of Circular 28 in practice are subject to substantial uncertainty.

Regulations Relating to Dividend Distributions

Foreign-invested companies may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. Both PRC domestic companies and foreign invested PRC companies are required to allocate at least 10% of their respective accumulated after-tax profits each year, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of the registered capital of the companies. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

Labor Laws and Social Insurance

Under Chinese law, employers must execute written labor contracts with their full-time employees and must comply with local minimum wage standards. Employers must establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety, and to truthfully inform prospective employees of the job description, working conditions, location, occupational hazards and status of safe production as well as remuneration and other conditions. Violations of these requirements may result in the imposition of fines and other administrative and criminal liability in the case of serious violations. In addition, employers must provide employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, medical insurance and housing funds. These payments are made to local administrative authorities, and any employer who fails to contribute may be fined and ordered to pay the deficit amount within a stipulated time limit.

Regulations Relating to Overseas Listing

In 2023, the China Securities Regulatory Commission (the "CSRC") released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic (the "Overseas Listing Trial Measures"), and related guidelines requiring Chinese domestic companies' overseas offerings and listings of equity securities be filed with the CSRC.

The Overseas Listing Trial Measures clarify the scope of overseas offerings and listings by Chinese domestic companies which are subject to the filing and reporting requirements thereunder, and provide that Chinese domestic companies that have already directly or indirectly offered and listed securities in overseas markets shall fulfil their filing obligations and report relevant information to the CSRC within three working days after conducting a follow-on offering of equity securities on the same overseas market, and follow the relevant reporting requirements within three working days upon the occurrence of any specified circumstances provided thereunder. According to the Overseas Listing Trial Measures, if we were deemed as an indirect overseas listed Chinese domestic company but fail to complete the filing procedures with the CSRC for any of our follow-on offerings or follow any other reporting requirements required thereunder, we may be subject to penalties, sanctions and fines imposed by the CSRC and relevant departments of the State Council.

Rest of World Regulation

For other countries outside of the U.S. and the PRC, the requirements governing the conduct of preclinical studies, clinical trials, drug licensing, manufacturing, pricing and reimbursement, and other matters impacting our business vary from country to country. In all cases, clinical trials must be conducted in accordance with GCP requirements, applicable regulatory requirements, and the ethical principles having their origin in the Declaration of Helsinki.

Status under Holding Foreign Companies Accountable Act

The Holding Foreign Companies Accountable Act (as amended, the "HFCAA") includes requirements for the SEC to identify issuers who file annual reports with audit reports issued by independent registered public accounting firms located in foreign jurisdictions that the Public Company Accounting Oversight Board ("PCAOB") is unable to inspect or investigate completely because of a position taken by a non-U.S. authority in the accounting firm's jurisdiction ("Commission-Identified Issuers"). The HFCAA also requires that, to the extent that the PCAOB has been unable to inspect an issuer's independent registered public accounting firm for two consecutive years since 2021, the SEC shall prohibit the issuer's securities registered in the U.S. from being traded on any national securities exchange or over-the-counter markets in the U.S.

Under the HFCAA, each Commission-Identified Issuer is required to submit documentation to the SEC annually on or before its annual report due date that establishes that it is not owned or controlled by a government entity in its public accounting firm's foreign jurisdiction and require additional specified disclosures by "foreign issuers" as defined in Rule 3b-4 promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The SEC identifies an issuer as a Commission-Identified Issuer after the issuer files its annual report and on a rolling basis. To end an initial or subsequent trading prohibition, a Commission-Identified Issuer must certify that it has retained a registered public accounting firm that the PCAOB has determined it is able to inspect or investigate by filing financial statements that include an audit report signed by such a registered public accounting firm.

On March 30, 2022, the SEC added BeiGene, Ltd. to its conclusive list of issuers identified under the HFCAA. Ernst & Young Hua Ming LLP, located in the PRC, served as our independent registered public accounting firm from 2014 to 2021, including for our annual report on Form 10-K for the year ended December 31, 2021. However, as our global business has expanded, we have built substantial organizational capabilities outside of the PRC and have evaluated, designed and implemented business processes and control changes. Therefore, on March 23, 2022, following a review process carried out by our audit committee, Ernst & Young Hua Ming LLP resigned as our independent registered public accounting firm for the audits of our financial statements and internal control over financial reporting to be filed with the SEC. On the same day, our audit committee approved the engagement of Ernst & Young LLP (U.S.) as the Company's independent registered public accounting firm for the audits of our financial statements and internal control over financial reporting for the fiscal year ending December 31, 2022. Ernst & Young LLP (U.S.) has continued to serve as our independent registered public accounting firm for the fiscal year ending December 31, 2023 and those thereafter. No changes were made to the accounting firms who audit our financial statements filed with the Shanghai Stock Exchange and the Hong Kong Stock Exchange, which remain Ernst & Young Hua Ming LLP, located in Beijing, PRC, and Ernst & Young, located in Hong Kong, PRC, respectively.

In December 2022, the PCAOB announced that it has secured complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong and confirmed that until such time as the PCAOB issues any new determination, there are no Commission-Identified Issuers at risk of having their securities subject to a trading prohibition under the HFCAA.

Given that Ernst & Young LLP (U.S.) has served as the principal accountant to audit our consolidated financial statements to be filed with the SEC since 2022, we believe this should preclude the delisting of our American Depositary Shares from Nasdaq under HFCAA. For a detailed description of risks related to our doing business in China and status under the HFCAA, see "Item 1A. Risk Factors—Risks Related to Our Doing Business in the PRC."

Doing Business in the PRC

As a result of our operations in the PRC, the PRC government may exert influence over our operations at any time, which could result in a material change in our operations and/or the value of our ADSs, ordinary shares, or RMB Shares. For example, the PRC government has recently published policies that significantly affected certain industries such as the education and internet industries, and we cannot rule out the possibility that it will in the future release regulations or policies regarding any industry that could adversely affect the business, financial condition and results of operations of our company.

Furthermore, the PRC government has also indicated an intent to exert more oversight and control over securities offerings and other capital markets activities that are conducted outside of China and over foreign investment in China-based companies. Any such action, once taken by the PRC government, could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or in extreme cases, become worthless. The PRC government initiated a series of regulatory actions and statements to regulate business operations in China, including enforcement actions against illegal activities in the securities market, enhancing supervision over China-based companies listed outside of China using the variable interest entity structure, adopting new measures to extend the scope of cybersecurity reviews, and expanding the efforts in anti-monopoly enforcement. For example, in July 2021, the relevant PRC government authorities made public the Opinions on Intensifying Crack-Down on Illegal Securities Activities (the "Securities Opinions") which emphasized the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and proposed to take measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies. In September 2024, the State Council released the Administrative Regulations on Cyber Data Security, which require, among others, a prior cybersecurity review for cyber data processing activities which affect or may affect national security. In March 2023, the Overseas Listing Trial Measures, and five relevant guidelines issued by the CSRC took effect, requiring the Chinese domestic companies' overseas offerings and listings of equity securities be filed with the CSRC.

The Chinese government may further promulgate relevant laws, rules and regulations that may impose additional and significant obligations and liabilities on overseas listed PRC companies regarding data security, cross-border data flow, anti-monopoly and unfair competition, and compliance with China's securities laws. It is uncertain whether or how these new laws, rules and regulations and the interpretation and implementation thereof may affect us, but among other things, our ability to obtain external financing through the issuance of equity securities in the U.S., Hong Kong or other markets could be negatively affected, and as a result, the trading prices of our ADSs, ordinary shares and RMB Shares could significantly decline or become worthless. For a detailed description of risks related to our doing business in China, please see the section of this Annual Report titled "Item 1A. Risk Factors—Risks Related to Our Doing Business in the PRC."

Flow of Funds with our Operations including the PRC

We are a holding company incorporated in the Cayman Islands with operations primarily conducted through direct and indirect subsidiaries in the U.S., China, the UK, Switzerland and Australia. The intercompany flow of funds within the organization is effected through capital contributions, intercompany loans, intercompany transfers of products and intellectual property, and cost reimbursements. Since formation in 2010, BeiGene, Ltd. has raised over $10.8 billion in various public and private stock offerings and from various borrowings. Of this amount, (1) $2.1 billion and RMB18.9 billion have been transferred as capital contributions to its operating subsidiaries and (2) $1.5 billion and RMB1.9 billion are outstanding intercompany loans due from its operating subsidiaries as of December 31, 2024. All biopharmaceutical patents previously owned by BeiGene, Ltd. have been transferred to operating subsidiaries for further development and commercialization. As of December 31, 2024, BeiGene, Ltd. held $400 million in cash and cash equivalents which are available for future investment in its programs and operating subsidiaries, of which $216 million is to be used in China pursuant to the obligations under the Company's offering on the STAR Market. The Company's subsidiaries outside of China have cash and cash equivalents of $1.1 billion that may be permanently transferred to BeiGene, Ltd. in the form of dividends and distributions or temporarily in the form of intercompany loans or advances without consent of a third-party; however, to date, BeiGene, Ltd. has not received any dividends or distributions from its operating subsidiaries. As of December 31, 2024, the Company has established a deferred tax liability of $24 million associated with potential withholding taxes in the U.S. and Canada on unremitted earnings that are no longer indefinitely reinvested. The amount of actual cash taxes associated with potential future distributions will depend on the timing of cash outflows at the parent and availability and use of cash in other jurisdictions that are not subject to withholding taxes. Please see the section of this Annual Report titled "Liquidity and Capital Resources" for further discussion.

Further, our board of directors 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 amended and restated articles of association, any future determination to pay dividends will be made at the discretion of our board of directors 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 our board of directors may deem relevant. This dividend policy reflects our board of directors' 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.

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 of association and the accounting standards and regulations in the PRC.

We may rely on dividends and other distributions on equity paid by our PRC subsidiaries or as noted above on dividends and distributions from our U.S, Canadian and other 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 from those subsidiaries in the PRC but not from our subsidiaries in the U.S., Canada and others. 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, 2024, these restricted assets totaled $1.7 billion.

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. However, conversion of RMB to other currencies are permitted for the purpose of dividends according to the PRC's regulations on foreign exchange control. The PRC government may, in accordance with applicable laws and regulations, impose limitations on access to foreign currencies for current account transactions and if this occurs in the future, we may not be able to pay dividends in foreign currencies to our shareholders. 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. As a result, and principally due to the restriction in China, our subsidiaries' restricted net assets (as defined in Rule 5-04 of Regulation S-X) exceeds 25% of our consolidated net assets and thus we have provided the stand-alone financial statements of BeiGene, Ltd. in Item 15 as Schedule 1.

The PRC Enterprise Income Tax 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 reduced withholding rate arrangement and such non-PRC resident enterprises constitute the beneficiary of such income.

Pursuant to an arrangement between Mainland China and the Hong Kong Special Administrative Region and relevant tax regulations of the PRC, subject to certain conditions, a reduced withholding tax rate of 5% 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." We own the PRC subsidiaries through BeiGene (Hong Kong) Co., Limited ("BeiGene HK"). 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.

Permissions Required from the PRC Authorities for Our Operations and Securities Offerings

We conduct our business in the PRC through our PRC subsidiaries. Our operations in the PRC are governed by PRC laws and regulations. As of the date of this annual report, our PRC subsidiaries have obtained all requisite licenses and permits from the PRC government authorities that are material for their business operations in the PRC, including, among others, business licenses issued by local counterparts of the SAMR, drug manufacturing licenses, drug trade license, clinical trial applications, drug registration certificates, licenses for use of experimental animals, pollutant discharge licenses and permits for urban sewage discharge into drainage pipe network. No material permissions have been denied to us by relevant government authorities in China. As of the date of this Annual Report, we do not operate our businesses in China or elsewhere through variable interest entities, or VIEs, and therefore are not subject to risks associated with contractual arrangements with VIEs. As of the date of this annual report, we have not received any inquiry, notice, warning, or sanctions regarding our business operations and corporate structure from the CSRC, the Cyberspace Administration of China (the "CAC"), or any other PRC governmental agency that would have a material impact on our business, results of operations or financial condition. However, given the uncertainties of interpretation and implementation of relevant laws and regulations and the enforcement practice by government authorities, we cannot assure you that we have obtained all permits or licenses required for conducting our business in the PRC. If (i) we have inadvertently concluded that such permissions, approvals, licenses or permits have been acquired or are not required, or (ii) applicable laws, regulations, or interpretations change and we are required to obtain such permissions, approvals, licenses or permits in the future, then we may have to expend time and costs to procure them. If we are unable to do so on commercially reasonable terms or in a timely manner, it could cause significant disruption to our business operations and damage our reputation, which would in turn have a material adverse effect on our business, results of operations and financial condition.

In connection with our previous issuance of securities to foreign investors in stock markets outside the PRC, under current PRC laws, regulations and regulatory rules, as of the date of this Annual Report, we and our PRC subsidiaries, (i) are not required to obtain permissions from the CSRC, (ii) are not required to go through cybersecurity review by the Cyberspace Administration of China, or the CAC, and (iii) have not received or were denied such requisite permissions by any PRC authority. In 2023, the CSRC released the Overseas Listing Trial Measures and five relevant guidelines. The Overseas Listing Trial Measures require the Chinese domestic companies' overseas offerings and listings of equity shares, depositary receipts, convertible bonds, preferred shares or other equity securities be filed with the CSRC. See "Item 1. Business—Government Regulation—PRC Regulation—Regulations Relating to Overseas Listing". If we were deemed as an indirect overseas listed Chinese domestic company subject to the filing requirements under the Overseas Listing Trial Measures, our offering of equity securities on Nasdaq or Hong Kong Stock Exchange in the future would be required to be filed with the CSRC within three working days after the offering is completed.

As of the date of this Annual Report, we have not received any inquiry, notice, warning or sanction regarding obtaining approval, completing filing or other procedures in connection with offering our equity securities in overseas stock markets from the CSRC or any other PRC governmental or regulatory authorities that have jurisdiction over our operations. However, there remains significant uncertainty as to the interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities, including the Overseas Listing Trial Measures. Although we intend to fully comply with the then effective relevant laws and regulations applicable to any securities offerings we may conduct, there are uncertainties with respect to whether we will be able to fully comply with requirements to obtain any permissions and approvals from, or complete any reporting or filing procedures with, PRC authorities that may be in effect in the future. If we, for any reason, are unable to complete, or experience significant delays in completing the requisite filing or other procedure(s), we may face sanctions by the CSRC or other Chinese regulatory authorities as applicable. These regulatory authorities may impose fines and penalties on our operations in the PRC, limit our ability to pay dividends outside of China, limit our operations in the PRC, delay or restrict the repatriation of funds into the PRC or take other actions that could have a material adverse effect on our business, financial condition, results of operations and prospects, as well as the trading price of our ADSs, ordinary shares and RMB Shares.

Cash Management Policies and Procedures

The frequency and amount of intercompany transfers of funds is determined based on the working capital needs of our subsidiaries and intercompany transactions, and is subject to internal approval processes and funding arrangements. Our management reviews and monitors our cash and working capital needs and external debt repayment and borrowing needs, of our subsidiaries on a regular basis. In addition, capital contributions and intercompany loan arrangements are subject to local jurisdiction and banking regulations.

BeiGene, Ltd. and its subsidiaries hold cash in demand deposits, time deposits and money market funds for the operating needs of each entity, including from intercompany transactions. As needed, cash to fund both short-term operating needs (such as investments in inventory or sales and marketing capabilities) and long-term investment needs (such as for property, plant and equipment) can be transferred from BeiGene, Ltd. or between subsidiaries to supply additional liquidity using capital contributions, intercompany advances or loans, as follows:

- Cash may be transferred between BeiGene HK and its operating subsidiaries in mainland China through intercompany loans and capital contributions. Cash generated from BeiGene HK is used to fund operations of its subsidiaries, and no funds were transferred from BeiGene HK's subsidiaries in mainland China to fund operations of other BeiGene subsidiaries outside of mainland China for the years ended December 31, 2024 and 2023. For the years ended December 31, 2024 and 2023, the amount of cash transferred between BeiGene HK and its subsidiaries in mainland China was $106 million and $295 million, respectively.

- Cash may be transferred between BeiGene UK, Ltd. ("BeiGene UK") and/or BeiGene Switzerland and their respective operating subsidiaries through intercompany fund advances and capital contributions. There are currently no restrictions on transferring funds between BeiGene UK or BeiGene Switzerland and their respective operating subsidiaries. Cash generated from BeiGene UK and BeiGene Switzerland may be used to fund operations of their respective subsidiaries, and no funds were transferred from BeiGene UK's subsidiaries or from BeiGene Switzerland's subsidiaries to fund operations of other BeiGene subsidiaries (such as BeiGene HK and its subsidiaries in mainland China) for the years ended December 31, 2024 and 2023. For the years ended December 31, 2024 and 2023, the amount of cash transferred between BeiGene UK to its respective subsidiaries was $142 million and $270 million, respectively. For the years ended December 31, 2024 and 2023, the amount of cash transferred between BeiGene Switzerland to its respective subsidiaries was nil.

Human Capital Resources

We are committed to attracting and retaining exceptional, passionate people to work with a clear purpose: creating impactful, affordable and accessible medicines to help more patients around the world live better. To this end, we provide opportunities for employees to grow and develop in their careers, supported by competitive compensation, benefits, health and wellness programs, and by programs that build connections among our employees worldwide.

We believe that the success of our business is fundamentally connected to the well-being of our employees. Hence, we take a holistic view of well-being – one that considers financial, physical, and social-emotional health – we are working to cultivate a community and culture where our colleagues can find balance both professionally and personally. Accordingly, we offer our employees and their families innovative, flexible and convenient health and wellness programs, that are tailored to the region of the world where they work.

Our competitive compensation and benefits programs help meet the needs of our employees. In addition to base salaries, these programs include potential annual discretionary bonuses, equity awards, a 401(k) plan in the U.S. and pension plans in other jurisdictions, healthcare and insurance benefits, health savings, life and disability insurances, and flexible spending accounts, paid time off, family leave, and flexible work schedules, among others. In addition to our broad-based equity award programs, we have used equity-based grants with vesting conditions to facilitate retention of key personnel. In addition to compensation and benefits, we provide our employees opportunities for growth through challenging job assignments, performance management and training opportunities. We seek to remain competitive in our compensation and benefits by routinely benchmarking against industry peers.

Our worldwide teams are united by a common mission. We are committed to encouraging a culture of open communication where employees can ask questions, raise concerns, and contribute creative solutions. Our management team routinely makes themselves available to all employees, including in regular town hall events that encourage open dialogue. Fostering a culture of accountability and compliance is also important, and all of our employees complete trainings on applicable corporate policies including our Global Code of Conduct which covers conflicts of interest; Harassment, Discrimination, and Retaliation Policy; Insider Trading Policy; and Anti-Corruption Policy.

At BeiGene, empowering our people begins with our culture and values: Bold Ingenuity, Collaborative Spirit, Driving Excellence, and most importantly, Patients First. As a global entity with many remote workers, we have been able to build a team of talented professionals with a wide range of experiences, regardless of their location. We are an equal opportunity employer. We do not discriminate on the basis of race, religion, color, sex, gender identity, sexual orientation, age, physical or mental disability, national origin, veteran status or any other basis covered by applicable law. All employment is decided on the basis of qualifications, merit, and business need. Further, we have policies in place that prohibit harassment and retaliation and a 24/7 ethics hotline where concerns can be raised on an anonymous basis. We maintain a culture where all voices are welcomed, heard, and respected.

As of February 14, 2025, we had over 11,000 full-time employees worldwide, across six continents, with approximately 1,700 employees in the U.S. and the balance outside of the U.S. We have also engaged and may continue to engage contingent workers to assist us with our operations. None of our employees are represented by a labor union or covered by a collective bargaining agreement, except as required by local laws such as in some European countries and Brazil. We also track voluntary and involuntary turnover rates and we consider our relations with our employees to be good.

Responsible Business & Sustainability

As a global organization focused on providing innovative medicines to more patients around the world, our Responsible Business & Sustainability ("RB&S") efforts are aligned with our corporate strategy. We believe: broad patient access and sustainable profitability are achievable through cost and speed efficiencies in drug discovery and development; the discovery of novel solutions is enabled by engaged colleagues with varied experiences and perspectives and an inclusive culture; and operational resilience is supported by our efforts to identify and mitigate risk in our operations and in our value chain. As such, our RB&S strategy is focused on the following key areas:

1. *Advancing Global Health* - We are focused on developing impactful medicines that will be accessible to far more patients around the world.
2. *Empowering Our Colleagues* - We are committed to fostering a culture of innovation and building a global workforce that enables our colleagues to thrive.
3. *Innovating Sustainably* - We aim to assess and mitigate our impact on the environment and ensure business continuity.
4. *Operating Responsibly* - We operate with integrity, transparency, and discipline to ensure we are meeting the expectations of our stakeholders.

Within each focus area, we have identified key strategic priorities against which we have set targets. Our targets are aspirational and may change; statements regarding these priorities and targets are not guarantees or promises that they will be met. We report our progress in late April of each year, and our reports can be found on our corporate website.

Financial Information

The financial information required under this Item 1 is incorporated herein by reference from the section of this Annual Report titled "Part II-Item 8-Financial Statements and Supplementary Data." For financial information regarding our business, please see the section of this Annual Report titled "Part II-Item 7-Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report and our consolidated audited financial statements and related notes included elsewhere in this Annual Report.

Corporate Information

We are an exempted company incorporated on October 28, 2010 in the Cayman Islands with limited liability. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. Our current registered office in the Cayman Islands is located at the offices of Mourant Governance Services (Cayman) Limited, 94 Solaris Avenue, Camana Bay, Grand Cayman KY1-1108, Cayman Islands. Our website address is www.beigene.com. We do not incorporate the information on or accessible through our website into this Annual Report, and you should not consider any information on, or that can be accessed through, our website as part of this Annual Report.

We own various registered trademarks, trademark applications and unregistered trademarks and service marks, including the name "BeiGene" and our corporate logo. All other trade names, trademarks and service marks of other companies appearing in this Annual Report are the property of their respective holders. Solely for convenience, some of the trademarks and trade names in this document are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Available Information

We make available on or through the Investor section of our website certain reports and amendments to those reports that we file with or furnish to the SEC, in accordance with the Exchange Act. These include our annual reports on Form 10-K, our quarterly reports on Form 10-Q, and our current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% shareholders pursuant to Section 16 under the Exchange Act. Additionally, we make available on our website our securities filings with the HKEx and the Shanghai Stock Exchange. We make this information available on or through our website free of charge as soon as reasonably practicable after we electronically file the information with, or furnish it to, the SEC, the HKEx, and the SSE.

From time to time, we may use the Investors section of our website at www.beigene.com, our X (formerly known as Twitter) account at x.com/BeiGeneGlobal, our LinkedIn account at linkedin.com/company/BeiGene, our Facebook account at facebook.com/BeiGeneGlobal, and our Instagram account at instagram.com/BeiGeneGlobal to disclose material information and to comply with our disclosure obligations under Regulation FD. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website, our X posts, our LinkedIn posts and our Instagram posts are not incorporated into, and does not form a part of, this Annual Report.

Item 1A. Risk Factors

The following section includes material 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 "Part II-Item 7-Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding to invest in our ADSs, ordinary shares, or RMB 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, ordinary shares, and RMB 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. Please refer to the explanation of the qualifications and limitation on forward-looking statements set forth on page 1 hereof.

Summary of Risk Factors

Below is a summary of the material factors that make an investment in our ADSs listed on Nasdaq, our ordinary shares listed on the Stock Exchange of Hong Kong Limited, and our ordinary shares issued to permitted investors in China and listed and traded on the Science and Technology Innovation Board of the Shanghai Stock Exchange in Renminbi ("RMB Shares") speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, are set forth herein and should be carefully considered, together with other information in this Annual Report and our other filings with the U.S. Securities and Exchange Commission ("SEC"), before making an investment decision regarding our ADSs, ordinary shares or RMB shares.

- 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.
- We face substantial competition, which may result in others discovering, developing, or commercializing competing medicines before or more successfully than we do.
- The market opportunities for our future medicines may be limited to those patients who are ineligible for or have failed prior treatments and may be small.
- 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 levels of reimbursement or are subject to unfavorable pricing regulations, our commercial success and business operations could be adversely affected.
- 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.
- 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 U.S., China, Europe and other comparable regulatory authorities are lengthy, time consuming, costly, and inherently unpredictable. If we experience delays or 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.
- We have historically incurred significant net losses and may incur net losses in the future.
- 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, we may lose market exclusivities in our medicines.
- 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 comply with manufacturing regulations, provide us with insufficient quantities of product or provide product at unacceptable quality levels or prices.

- 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 fail to maintain an effective distribution channel for our medicines, our business and sales could be adversely affected.
- 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 the collection and transfer of personal data. These laws and regulations can be 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. Failure to comply with regulatory requirements could result in sanctions being imposed against us and delays in 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 U.S. or other governments and the significant oversight and discretion the PRC government has over the conduct of the business operations of our PRC subsidiaries 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 PRC government may intervene or influence our operations at any time, and has the ability to exert significant oversight and control over any offering of securities conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in our operations and limit or completely hinder our ability to offer or continue to offer securities to investors, and may cause the value of such securities to significantly decline or be worthless.
- There are uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, and rules and regulations in China can change quickly with little advance notice.
- Filing or other procedures with the China Securities Regulatory Commission ("CSRC") or other Chinese regulatory authorities may be required in connection with issuing our equity securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to complete such filing or other procedures. If we fail to complete a filing with the CSRC, our future offering application may be impacted and we may be subject to penalties, sanctions and fines imposed by the CSRC and relevant departments of the State Council.
- The trading prices of our ordinary shares, ADSs, and/or RMB Shares can be volatile, which could result in substantial losses to you.
- Your rights as a shareholder will change as a result of the Continuation.
- As a result of increased shareholder voting requirements upon completion of the Continuation, we will have less flexibility with respect to certain aspects of capital management than previously.
- The Continuation will result in additional direct and indirect costs whether or not completed.

Risks Related to Clinical Development and 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. If our medicines do not achieve and maintain an adequate level of market acceptance, the sales of our medicines may be limited 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 safe and effective; government agencies, professional societies, practice management groups, insurance carriers, physicians' groups, private health and science foundations recommending our medicines; the perceived advantages and relative cost of alternative treatments; the prevalence and severity of any side effects; product labeling, including limitations or warnings, or product insert requirements of regulatory authorities; the timing of market introduction of our medicines as well as competitive medicines; the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities; and the effectiveness of our sales and marketing efforts.

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, 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 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 three of BMS's approved cancer therapies, in the People's Republic of China ("PRC" or "China"). In October 2019, we entered into a collaboration with Amgen for its commercial-stage oncology products and a portfolio of clinical- and late-preclinical-stage oncology pipeline products. We received the first approvals for our internally developed drug candidates in late 2019 in the United States ("U.S."), in 2020 in China, and in 2021 in Europe. Given this, we have limited experience in commercializing our internally developed and in-licensed medicines, including building and managing a commercial team, conducting a comprehensive market analysis, obtaining state licenses and reimbursement, and managing distributors and a sales force for our medicines. 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.

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, 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 whether they will have effective sales forces. 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. 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.

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 medicines 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, BRUKINSA®, tislelizumab, and pamiparib 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 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.

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, management and marketing personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The market opportunities for our future 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, may prove to be inaccurate and new studies may change the estimated incidence or prevalence of these cancers. 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.

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 levels of reimbursement or are subject to unfavorable pricing regulations, 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 from government health administration authorities, private health insurers and other organizations. In the U.S. and 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 medicines will depend substantially, 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. For additional information, please see the section of this Annual Report titled "Part I—Item 1—Business—Government Regulation—Pharmaceutical Coverage, Pricing, and Reimbursement."

In the U.S., 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. Coverage may be more limited than the purposes for which the medicine is approved by the U.S. Food and Drug Administration ("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 medicines. 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.

In China, drug prices are typically lower than in the U.S. and Europe, and until recently, the market has been dominated by generic drugs. Government authorities regularly review the inclusion or removal of medicines from China's 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 medicine will be classified, both of which affect the amounts reimbursable to program participants for their purchases of those medicines. Products included in the NRDL have typically been generic and essential drugs. BRUKINSA, tislelizumab, PARTRUVIX®, XGEVA® and KYPROLIS® have been included in the NRDL. While the demand for these medicines has generally increased after inclusion in the NRDL, there can be no assurance that demand will continue to increase and 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. We prepare for the NRDL negotiations in China for our eligible medicines/indications annually. If any of these medicines/indications are not included in the NRDL or included at a significantly lower price, the revenues for such medicines could be limited, which could have a material adverse effect on our business, financial condition and results of operations in China.

The government in China also has a program for volume-based, centralized drug procurement with minimum quantity commitments to negotiate lower prices from drug manufacturers and reduce the price of drugs. The Chinese government awards contracts to the bidders who can satisfy the quality and quantity requirements, with price being a significant factor in the procurement decisions. The successful bidders are guaranteed a sale volume for at least a year, which gives an opportunity to gain or increase market share. 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 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. Also in 2020, VIDAZA® and its generic forms were included for bidding in the program. We did not win the bid for VIDAZA, which 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. This 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 in China.

Countries in Europe provide options to restrict the range of medicinal products for which their national health insurance systems provide reimbursement. 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. Countries 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. Furthermore, some countries require approval of the sale price of a medicine 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 medicine in a particular country, but then be subject to price regulations that delay our commercial launch of the medicine and negatively impact our revenues 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 medicines 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 medicines. Moreover, eligibility for reimbursement does not imply that any medicine 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 medicines, 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 medicine and the clinical setting in which it is used, may be based on payments allowed for lower cost medicines that are already reimbursed, and may be incorporated into existing payments for other services. Net prices for medicines 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 medicines from countries where they may be sold at lower prices than in the U.S. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private 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.

We have operations in the U.S., China, Europe, and other markets 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 medicines in international markets, including China, Europe and other markets outside of the U.S., 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:

- 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, including tariffs that have been or may in the future be imposed by the U.S. or other countries, trade barriers and regulatory requirements, including the loss of normal trade status between China and the U.S. or actions taken by U.S. or China governmental authorities on companies with significant operations in the U.S. and China, such as us, and protectionist or retaliatory measures taken by the U.S.or China;
- economic weakness;
- compliance with tax, employment, immigration and labor laws for employees traveling internationally;
- 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;
- business interruptions resulting from geo-political actions, including trade disputes, war and terrorism, public health crises or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires;
- economic and political instability; and
- international military conflicts and related sanctions.

For example, on February 1, 2025, the U.S. imposed a 25% tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10% additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. These and other risks, including the risks described in “Risks Related to Our Doing Business in the PRC”, 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 medicines, which do not meet our or our collaborators' rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit medicine 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 medicines 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.

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, patient adherence to the dosing regimen 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.

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 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, or ethics committees may not authorize us to conduct a clinical trial or may require us or our investigators to suspend or terminate clinical research or not rely on the results of our clinical research for various reasons, including noncompliance with regulatory requirements; our inability to reach agreements on acceptable terms with contract research organizations ("CROs") and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly; manufacturing issues, including problems with supply quality, compliance with good manufacturing practice ("GMP"), or obtaining sufficient quantities of a drug candidate for use in a clinical trial; 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 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 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; 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 or other materials necessary to conduct clinical trials may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if they raise safety concerns, we may be delayed in obtaining regulatory approval for our drug candidates, or not obtain regulatory approval at all; obtain approval for 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 or obtain reimbursement at a commercially viable level for use of the drug.

Significant clinical trial 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 crises.

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 enroll in a trial being conducted by a competitor. 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 sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such 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.

Risks Related to Regulatory Approval and 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.

We are currently focusing our pharmaceutical-industry activities in the major markets of the U.S., China, Europe, and other select countries and regions. These 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 that make for a more complex and costly regulatory compliance burden. Additionally, the China National Medical Products Administration's ("NMPA") reform of the medicine 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. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. From time to time, laws may be passed that significantly change the statutory provisions governing the approval, manufacturing, and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect the manner in which pharmaceutical products are regulated and marketed.

The process of obtaining regulatory approvals and compliance with laws and regulations require the expenditure of substantial time and financial resources. Failure to comply with 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, in 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China previously supplied to us by BMS, and the drug was subsequently recalled by BMS. This suspension was based on inspection findings at BMS's contract manufacturing facility in the U.S. In any event, the receipt of regulatory approval does not assure the success of our commercialization efforts for our medicines.

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, 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 our approved products. 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. For additional information, please see the section of this Annual Report, titled "Part I—Item 1—Business—Government Regulation—Other U.S. Healthcare Laws and Compliance Requirements."

In addition, the approval and commercialization for our medicines and drug candidates outside the U.S. subjects us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws. Some of these non-U.S. laws may be broader in scope and subject to the discretion of non-U.S. law enforcement authorities, including Chinese authorities who recently increased anti-bribery efforts to reduce improper payments and other benefits received by physicians, staff and hospital administrators in relation to sales, marketing and purchase of pharmaceuticals. 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.

In the past, we have made grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations and we expect to make such grants in the future. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws or regulations in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Furthermore, there has been increased scrutiny of company-sponsored patient assistance programs, including co-pay assistance programs, and donations to third-party charities that provide such assistance. There has also been enhanced scrutiny by governments of reimbursement support offerings, clinical education programs and promotional speaker programs. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance.

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. Furthermore, 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.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate Program, the 340B program, the U.S. Department of Veterans Affairs, Federal Supply Schedule ("FSS") pricing program, and the Tricare Retail Pharmacy program, which require us to disclose average manufacturer pricing, and, in the future may require us to report the average sales price for certain of our drugs to the Medicare program. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts. Furthermore, regulatory and legislative changes, and judicial rulings relating to these programs and policies (including coverage expansion), have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation. For example, in the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements increase our costs and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and give rise to an obligation to refund entities participating in the 340B program for overcharges during past quarters impacted by a price recalculation.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. Additionally, our agreement to participate in the 340B program or our Medicaid drug rebate agreement could be terminated, in which case federal payments may not be available under Medicaid or Medicare Part D for our covered outpatient drugs. Additionally, if we overcharge the government in connection with our arrangements with FSS or Tricare Retail Pharmacy, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Further, legislation may be introduced that, if passed, would, among other things, further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting, and any additional future changes to the definition of average manufacturer price or the Medicaid rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations. Additionally, certain pharmaceutical manufacturers are involved in ongoing litigation regarding contract pharmacy arrangements under the 340B program. The outcome of those judicial proceedings and the potential impact on the way in which manufacturers extend discounts to covered entities through contract pharmacies remain uncertain.

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

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 U.S., 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 comprehensive information regarding the chemistry, manufacturing and controls ("CMC") for the drug candidate. If we submit an NDA or BLA to the FDA, we cannot be certain that a submission will be accepted for filing and review by the FDA.

Regulatory authorities outside of the U.S., such as the NMPA and European Medicines Agency ("EMA"), also have requirements for approval of medicines for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements, approval processes and review periods can vary 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. Seeking regulatory approvals outside of the U.S. could require additional nonclinical studies or clinical trials, which could be costly and time consuming. For all of these reasons, we may not obtain regulatory approvals on a timely basis, if at all.

The processes required to obtain approval by the FDA, the NMPA, the EMA, and other comparable regulatory authorities are complex, costly, unpredictable and typically take many years following the commencement of preclinical studies and clinical trials and depend on numerous factors, including the substantial discretion of the regulatory authorities. Regulatory approval is never guaranteed. Furthermore, we have limited experience in obtaining regulatory approvals for our drug candidates, including preparing the required materials for regulatory submission and navigating the regulatory approval process. As a result, our ability to successfully 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.

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;
- a delay in or the inability of health authorities to complete regulatory inspections of our development activities, regulatory filings or manufacturing operations, whether as a result of a public health crisis, government shutdown, resource shortages or other reasons, or our failure to satisfactorily complete such inspections;
- 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.

For example, in 2022, the FDA extended the Prescription Drug User Fee Act goal date for the supplemental new drug application ("sNDA") for BRUKINSA as a treatment for adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma by three months, to allow time to review additional clinical data submitted by us, which was deemed a major amendment to the sNDA. In 2022, the FDA deferred action on the BLA for TEVIMBRA® as a second-line treatment for patients with unresectable or metastatic ESCC, citing only the inability to complete inspections due to COVID-19 related restrictions on travel. In 2024, the FDA deferred approval for tislelizumab in first-line unresectable, recurrent, locally advanced, or metastatic ESCC on account of a delay in scheduling clinical site inspections.

Our development activities, regulatory filings and manufacturing operations also could be harmed or delayed by a shutdown of the U.S. government, including the FDA, or governments and regulatory authorities in other jurisdictions. If the FDA or other health authorities are delayed or unable to complete required regulatory inspections of our development activities, regulatory filings or manufacturing operations due to government shutdowns, public health crises, or other reasons, or we do not satisfactorily complete such inspections, our business could be materially harmed. Currently, federal agencies in the U.S. are operating under a continuing resolution that is set to expire on March 14, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted.

Delays in the completion of a clinical trial of any of our drug candidates 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.

We are currently conducting and may in the future conduct clinical trials for our drug candidates outside the U.S., and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are currently conducting and may in the future conduct clinical trials for our drug candidates outside the U.S., including in China. The acceptance of data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. The FDA will generally not consider the data from a foreign clinical trial not conducted under an IND unless (i) the trial was well-designed and well-conducted in accordance with good clinical practice ("GCP") requirements, including requirements for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected, and (ii) the FDA is able to validate the data from the trial through an on-site inspection, if necessary. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering must be met. Many foreign regulatory authorities have similar approval requirements. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in drug candidates that we may develop not receiving approval for commercialization in the applicable jurisdictions.

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 U.S. 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.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, NMPA, EMA and comparable regulatory authority requirements, including, in the U.S., 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, BLA or 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, in 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China previously supplied to us by BMS, and the drug was subsequently recalled by BMS. This suspension was based on inspection findings at BMS's contract manufacturing facility in the U.S.

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 medicine's commercial potential or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the medicine or drug candidate. Failure to exhibit due diligence when conducting post-marketing requirements could result in withdrawal of approval for products. The FDA, NMPA, EMA or comparable regulatory authorities may also require a Risk Evaluation Mitigation Strategy ("REMS") program or comparable program as a condition of approval of our drug candidates or following approval. 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 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;
- 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 U.S. 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 accelerated approval of BRUKINSA in the U.S. and China and certain approvals of tislelizumab, PARTRUVIX, XGEVA, BLINCYTO®, KYPROLIS and QARZIBA® 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. If we fail to conduct such studies in a timely manner or such studies fail to verify clinical benefit, such approval may be withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval. For example, the FDA generally requires that all advertising and promotional materials be submitted to the FDA for review prior to dissemination or publication for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product.

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.

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 medicine;
- regulatory authorities may withdraw approvals or revoke licenses of the medicine, 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 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. For additional information, please see the section of this Annual Report titled *"Risks Related to Our Reliance on Third Parties—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 comply with manufacturing regulations, provide us with insufficient quantities of product or provide product at unacceptable quality levels or prices."*

Recently enacted and future legislation and regulations 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 U.S., China, Europe 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. For example, the Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act), requires sponsors of approved new drug applications and biologics license applications to provide sufficient quantities of product samples on commercially reasonable, market-based terms to entities developing generic drugs and biosimilar biological products. The law establishes a private right of action allowing developers to sue application holders that refuse to sell them product samples needed to support their applications. If we are required to provide product samples or allocate additional resources to respond to such requests or any legal challenges under this law, our business could be adversely impacted.

In addition, proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. For example, by Executive Order, the FDA works with states and Indian Tribes that propose to develop importation programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. In January 2024, the FDA issued to Florida the first approval for a state importation plan and several states have pending applications with the FDA. If successfully implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability. 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. For additional information, please see the section of this Annual Report titled “Part I—Item 1—Business—Government Regulation—Healthcare Reform.”

Furthermore, changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. We cannot predict the initiatives or changes that may be adopted in the future or the impact, if any, they may have on our business. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for our product candidates, if we obtain regulatory approval; our ability to set a price that we believe is fair for our approved products; our ability to generate revenue and achieve or maintain profitability; the level of taxes that we are required to pay; and the availability of capital.

Risks Related to Our Financial Position and Need for Additional Capital

We have historically incurred significant net losses and may incur net losses in the future.

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 most periods since our inception, other than periods when we were profitable due to revenue recognized from up-front license fees from collaboration agreements or the settlement of legal proceedings. As of December 31, 2024, we had an accumulated deficit of $8.6 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.

Although we expect to achieve positive GAAP operating income for full year 2025 as product sales growth exceeds expense growth, we may incur losses in the future. We expect expenses to continue to increase as we continue to 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 $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 in-licensed. In addition, we will continue to incur costs associated with operating as a public company. The size of any 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 if promising 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. To the extent 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 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 $0.1 billion, $1.2 billion and $1.5 billion of net cash during the years ended December 31, 2024, 2023 and 2022, respectively. We recorded negative net cash flows from operating activities in 2024, 2023 and 2022 primarily due to our net losses of $0.6 billion, $0.9 billion and $2.0 billion, respectively. We cannot assure you that we will be able to generate positive cash flows from operating activities in the future.

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 yet 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 and cash equivalents to meet our projected operating requirements for at least the next 12 months. However, our existing cash and cash equivalents and potential future 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.

Furthermore, our debt is primarily short-term in nature. As a result, we do not have many long-term commitments for funding. Our current debt also contains numerous financial and non-financial covenants, some of which include cross-default provisions that could require acceleration of repayment of loans in the event of default. Any acceleration may impact the Company's ability to refinance debt obligations if an event of default occurs.

Our liquidity and financial condition may be materially and adversely affected by negative net cash flows and our current debt structure, 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 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. Fluctuations in currencies may be affected by, among other things, changes in political and economic conditions and the foreign exchange policies proposed or adopted by certain governments. 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. Fluctuations 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 the RMB and the U.S. dollar or any other currencies in the future. There remains significant international pressure on 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.

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 approval from or registration with appropriate government authorities or designated banks 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 or by actual events or concerns involving the liquidity, default, or non-performance of financial institutions, including the U.S. government, and an impairment in the carrying value of any 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.

Furthermore, actual events involving reduced liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any such events, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023, Silvergate Bank, La Jolla, California, announced its decision to voluntarily liquidate its assets and wind down operations, Silicon Valley Bank, Santa Clara, California ("SVB"), was closed by the California Department of Financial Protection and Innovation, and Signature Bank, New York, New York, was closed by the New York State Department of Financial Services, and, in each case the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. Since then, additional financial institutions have experienced similar failures and have been placed into receivership. These events lead to volatility and declines in the market for bank stock and questions regarding confidence in depository institutions. There is no guarantee that the federal government will guarantee depositors in the event of a future bank closure. Investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could adversely impact our ability to meet our operating expenses or result in breaches of our financial or contractual obligations which could have material adverse impact on our liquidity and our projected business operations, financial condition and results of operations.

As a result of uncertain political, credit and financial market conditions, including the potential of the U.S. government to default on the payment of its obligations for a period of time due to federal debt ceiling limitations or other unresolved political issues, investments in financial instruments issued or guaranteed by the U.S. government pose credit default and liquidity risks. A payment default or delay by the U.S. government, or continued uncertainty surrounding the U.S. debt ceiling, could result in a variety of adverse effects for financial markets, market participants and U.S. and global economic conditions. In addition, U.S. debt ceiling and budget deficit concerns have increased the possibility a downgrade in the credit rating of the U.S. government and could result in economic slowdowns or a recession in the U.S. No assurance can be made that losses or significant deterioration in the fair value of our U.S. government issued or guaranteed investments will not occur. At December 31, 2024, we had approximately $1.0 billion invested in government money market funds. Downgrades to the U.S. credit rating could affect the stability of securities issued or guaranteed by the U.S. government and the valuation or liquidity of our portfolio of such investment securities.

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 no short-term investments, cash and cash equivalents of $2.6 billion and restricted cash of $11.3 million as of December 31, 2024, most of which are deposited in financial institutions outside of China. As required by the PRC securities laws, the net proceeds from our offering on the STAR Market of the Shanghai Stock Exchange (the "STAR Offering") must be used in strict compliance with the planned uses as disclosed in the PRC prospectus for the STAR Offering as well as our proceeds management policy for the STAR Offering approved by our board of directors. 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, 2024, we held no short-term investments. To the extent we invest in U.S. Treasury securities as short-term investments in the future, although we believe that such 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.

Failure to meet responsible business and sustainability expectations or standards or achieve our corporate strategy goals could adversely affect our business, results of operations, financial condition or stock price.

There has been focus from global regulators and stakeholders on responsible business and sustainability matters, including greenhouse gas emissions and climate-related risks; human capital management; responsible sourcing and supply chain; human rights and social responsibility; and corporate governance and oversight. As part of our long-term strategy and in-line with safeguarding sustainable value growth, we actively manage these issues. We have identified key strategic priorities and set goals that reflect our current plans and aspirations and cannot guarantee that we will be able to achieve them. Evolving stakeholder expectations and our efforts and ability to manage these issues and goals present numerous operational, regulatory, reputational, financial, legal, and other risks, any of which may be outside of our control or could have a material adverse impact on our business, including on our stock price. Further, there is uncertainty around the accounting standards and climate-related disclosures associated with emerging sustainability laws and reporting requirements and the related costs to comply with the emerging regulations. Our failure or perceived failure to achieve our sustainability goals or comply with sustainability-related regulations could expose us to increased scrutiny from the investment community and enforcement authorities. Our reputation also may be harmed by the perceptions that our stakeholders have about our action or inaction on these sustainability issues.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our medicines and drug candidates, we may lose market exclusivities in our medicines.

Our success depends in large part on our ability to protect our valuable innovations including medicines, drug candidates and proprietary technologies by obtaining, maintaining and enforcing our intellectual property rights, including patent rights. We seek to protect our innovations that we consider commercially important by filing patent applications in the U.S., the PRC, Europe and other territories, or relying on trade secrets or regulatory exclusivities.

However, filing, prosecuting and maintaining patents/patent applications in all countries worldwide could be prohibitively expensive. As the patent laws of different countries vary, our patent applications may not be granted in all countries and the issued patents may have various scope and enforceabilities. In addition, different countries may provide varying regulatory exclusivities to pharmaceutical drugs, and some countries provide no regulatory exclusivities. Consequently, we may not have the same patent protection or exclusivities to our medicines or drug candidates in all countries worldwide. Further, 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 length of exclusivities to our medicines or drug candidates. 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 “Part I—Item 1—Business—Intellectual Property” of this Annual Report. Upon expiration, we may no longer have exclusivities on the corresponding medicines or drug candidates.

Moreover, issued patents may be invalidated for a number of reasons, including but not limited to known or unknown prior art, deficiencies in the patent applications or the lack of novelty or inventive step of the underlying invention or technology.

Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

We have been and may further 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, unenforceable or not infringed by a court or government patent authorities.

Third parties may infringe, misappropriate or otherwise violate our intellectual property rights. Litigation may be necessary to enforce or defend our intellectual property rights or to protect our trade secrets. This can be expensive and time consuming. The third parties may also challenge the validity or enforceability of our patents.

When a generic drug company files an Abbreviated New Drug Application (“ANDA”) with the FDA seeking approval to market a generic version of any of our products before the expiration of Orange Book listed patents (“OB Patents”) covering such products, this will most likely trigger ANDA litigation. For example, on March 8, 2024, our subsidiaries, BeiGene USA, Inc. and BeiGene Switzerland GmbH, filed patent infringement suits against Sandoz Inc. (“Sandoz”), and MSN Pharmaceuticals, Inc. and MSN Laboratories Private Ltd. (collectively “MSN”), in the U.S. District Court for the District of New Jersey, in response to Sandoz’s and MSN’s notices informing their filings of ANDAs with the FDA regarding BRUKINSA. For additional information on this litigation, please see the section of this Annual Report titled “Legal Proceedings”. The success of ANDA litigation depends on the strength of the OB Patents and our ability to prove infringement. The outcome of ANDA litigation is inherently uncertain and may result in potential loss of market exclusivity for our products which may have a significant financial impact on product revenue.

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. As such, any issued patents may not protect us from generic or biosimilar competition for these medicines. Specifically, in patent litigation, defendants often challenge the validity and/or enforceability of the asserted patents, and there are numerous potential grounds upon which a patent can be found invalid and/or unenforceable. The validity of a patent can also be challenged before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our medicines or drug candidates. The outcome of such proceedings is inherently uncertain and may result in losing the patent protection on our medicines or drug candidates. Such a loss of patent protection could have a material adverse impact on our business.

Lawsuits alleging infringing of intellectual property rights of third parties could be costly and time consuming and could prevent or delay us from developing or commercializing our medicines or drug candidates.

We respect third parties' valid intellectual property rights and diligently manage any freedom to operate risks associated with our medicines and drug candidates. Nevertheless, we bear the risk that we may be sued by third parties for patent infringement. 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 be issued 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.

For example, on June 13, 2023, Pharmacyclics LLC ("Pharmacyclics") filed a complaint in the U.S. District Court for the District of Delaware against us and one of our subsidiaries, alleging that BRUKINSA infringes a Pharmacyclics' patent issued on June 13, 2023. For additional information on this litigation, please see the section of this Annual Report titled "Legal Proceedings". 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.

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.

Even in the absence of litigation, we may seek to obtain licenses from third parties to mitigate freedom to operate risks and as a result, could impose costly royalty and other fees and expenses on us.

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

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 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.

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 executed proprietary rights, non-disclosure and in some cases non-competition agreements in connection with their previous employment. Our employees may also have access to trade secrets of our collaboration partners. Although we try our best 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 misappropriated trade secrets or other proprietary information, of any such employees' former employers. For example, in September 2024, AbbVie filed a lawsuit alleging misappropriation of certain trade secrets concerning our Bruton's tyrosine kinase degrader program, including lead compound BGB-16673. Defending against such claims, regardless of their merit, could result in substantial costs and be a distraction to management. If we fail in defending any such claims, we may need to pay monetary damages and lose valuable intellectual property rights.

Risks Related to Our Reliance on Third Parties

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 comply with manufacturing regulations, provide us with insufficient quantities of product or provide product at unacceptable quality levels or prices.

Although we manufacture commercial supply of tislelizumab, zanubrutinib, and pamiparib at our manufacturing facilities in China, and recently opened our commercial-stage biologics manufacturing and clinical R&D center in New Jersey and a new small molecule manufacturing campus in Suzhou, China, we continue to rely on outside vendors to manufacture supplies and process some of 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 generally rely on our collaboration partners and their third-party manufacturers for supply of in-licensed medicines in China. 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.

Our 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;
- 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 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;
- manufacturers are subject to initial and ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the U.S. to ensure strict compliance with GMP requirements, chain of distribution requirements and other government regulations and by other comparable regulatory authorities for corresponding non-U.S. requirements. Manufacturers may be unable to comply with these GMPs which may result in fines and civil penalties, suspension of production, suspension, delay or withdrawal of product approval, product liability claims, product seizure or recall and enforcement actions, including injunctions and criminal or civil prosecution;
- 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;
- 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; and
- manufacturing partners may require us to fund capital improvements to support scale-up of manufacturing and related activities to the extent our drug candidates or medicines become approved for commercial sale.

For example, in March 2020, the NMPA suspended the importation, sales and use of ABRAXANE in China previously supplied to us by BMS, and the drug was subsequently recalled by BMS. This suspension was based on inspection findings at BMS's contract manufacturing facility in the U.S.

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.

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.

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.

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.

For example, 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 2021, we entered into a collaboration and license agreement with Novartis Pharma AG ("Novartis"), granting Novartis rights to develop, manufacture and commercialize our anti-PD-1 antibody tislelizumab in certain territories, but that agreement was terminated in September 2023 and we regained full, global rights to develop, manufacture and commercialize tislelizumab. In December 2021, we entered into an option, collaboration and license agreement with Novartis to develop, manufacture and commercialize our investigational TIGIT inhibitor, ociperlimab, in North America, Europe, and Japan, terminated that agreement in July 2023 and regained full, global rights to develop, manufacture and commercialize ociperlimab. In December 2024, we entered into a global licensing agreement with CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd. for a methionine adenosyltransferase 2A (MAT2A)-inhibitor being explored for solid tumors.

Our strategic collaborations involve numerous risks. We may not achieve the revenue and cost synergies expected from our collaborations, and our management's attention may be diverted from our drug discovery and development business. 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. Additionally, strategic collaborations can be terminated for various reasons, including future acquisitions.

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 for our medicines and drug candidates because they may be deemed to be at too early of a stage of development for collaborative effort. 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.

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;
- 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; 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.
- As a result, we may not be able to realize the benefit of current or future collaborations, licensing arrangements or strategic alliances if we are unable to successfully integrate 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 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 some of our in-licensed approved medicines 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 medicines, 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 medicines in the manner we contemplate. 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.

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. In connection with our ongoing assessment of the collaboration agreement cost-share contributions, we determined that our further investment in the development of LUMAKRAS (sotorasib) ("AMG 510"), a first-in-class KRAS G12C inhibitor, was no longer commercially viable for BeiGene. As a result, in February 2023, we entered into an amendment to the collaboration agreement to (i) stop sharing costs with Amgen for the further development of AMG 510 during the period starting January 1, 2023 and ending August 31, 2023; and (ii) cooperate in good faith to prepare a transition plan with the termination of AMG 510 from the Amgen Collaboration Agreement. Additionally, for the period between 2020 and 2022, we were advised by Amgen 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 were 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 the previous HGRAC delay to affect the conduct of the clinical trials in China for our drug candidates. 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.

We may 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 to some extent upon third-party CROs to monitor and manage data and provide other services for our ongoing preclinical and clinical programs. We may 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.

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 2024, we had approximately 10,500 employees, and we ended the year with over 11,000 employees, an increase of approximately 5%. As of the date of this Annual Report, we had over 11,000 employees. 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 U.S., 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; and improving our operational, financial and management controls, reporting systems and procedures. 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.

Additionally, we have invested, and are investing significant time, resources and capital into the expansion of our facilities, including the creation of additional capacity at our Guangzhou and Suzhou manufacturing facilities and the construction of our Hopewell facility. If actual demand for our medicines does not meet our future projections, we will likely incur increased costs related to idle capacity including, but not limited to, acceleration of the timing of depreciation or impairment charges, which may adversely affect our financial condition and results of operations.

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

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 and Chief Operating Officer; Aaron Rosenberg, our Chief Financial Officer; and the other principal members of our management and scientific teams play a critical role in the Company's operations and development. 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.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. 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.

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.

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 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 ("HGR" and, such regulation, the "HGR Regulation") applies to activities that involve sampling, biobanking, use of HGR materials and associated data, in China, and provision of such materials to non-PRC parties. The HGR Regulation prohibits both onshore or offshore entities established or actually controlled by non-PRC 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 HGR material is required, and transfer of China HGR data by Chinese parties to non-PRC 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 non-PRC parties ensure the full participation of Chinese parties in international collaborations and all records and data must be shared with the Chinese parties. The Implementing Rules for the HGR Regulation and additional issued guidance has clarified many areas of the HGR Regulation. For information about applications under the HGR Regulation for clinical studies in China that may affect the Amgen collaboration, see the risk factor titled *"If we are not able to successfully develop and/or commercialize Amgen's oncology products, the expected benefits of the collaboration will not materialize."*

Additionally, the Cyberspace Administration of China ("CAC") released the final Measures of Cross-Border Data Transfer Security Assessment, effective as of September 2022, under which any transfer of certain "important data" out of China triggers a security assessment to be conducted by the Chinese government. The term "important data" is a broadly defined term under the Cybersecurity Law and Data Security Law, and further clarifications need to be put in place by the Chinese government. However, under the latest draft Information Security Technology – Guideline for Identification of Critical Data, HGR data is classified as "important data," and if the guidance is finalized as is, it can be expected that this new cross-border data transfer rule may create considerable additional regulatory burdens on international companies' human gene-involved R&D activities in China.

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 from initiating new clinical trials in China. So far, the HGR administration has disclosed a number of HGR violation cases.

To further enhance the administration of China HGR, in 2021, the Chinese government adopted amendments to the Criminal Code, 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 non-PRC parties or entities established or actually controlled by them without going through security review and assessment. Also in 2021, the PRC Biosecurity Law became effective. The PRC Biosecurity Law establishes an integrated system to regulate biosecurity-related activities in China, including the security regulation of HGR and biological resources. The PRC Biosecurity Law for the first time expressly declared 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 the National Health Commission, China's major regulatory authority of HGR, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for Chinese HGR will continue to evolve and become even more rigorous. In addition, the interpretation and application of data protection laws in China 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. Failure to comply with regulatory requirements could result in sanctions being imposed against us and delays in 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 multiple manufacturing facilities in China. We recently opened our commercial-stage biologics manufacturing and clinical R&D center in New Jersey and a new small molecule manufacturing campus in Suzhou, China. These facilities may encounter unanticipated delays and expenses in startup operations due to a number of factors, including regulatory requirements. If 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.

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. Historically, some manufacturing facilities in China have had difficulty meeting the FDA's, NMPA's or EMA's standards. 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 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, as well as shortages of qualified personnel, raw materials or key contractors.

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.

To supply commercial quantities for our marketed products, produce our medicines 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 medicines in a sufficient quantity to meet future demand. Furthermore, 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.

If our manufacturing facilities or the equipment in them is damaged or destroyed, we may not be able to quickly or inexpensively restore our manufacturing capacity or restore 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 medicines manufactured at that facility. 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 medicines 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 listed in the U.S., Hong Kong and Shanghai, 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 Global Select Market ("Nasdaq"), The Stock Exchange of Hong Kong Limited (the "HKEx") and the STAR Market of the Shanghai Stock Exchange (the "SSE"), 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, CSRC, SSE or other applicable regulatory authorities, and our business could be harmed.

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, including applicable antitrust and trade regulation laws in the relevant U.S. and foreign jurisdictions in which we or the operations or assets we seek to acquire carry on business; 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 our transaction with Amgen, we issued to Amgen a total of 206,635,013 ordinary shares in the form of ADSs in 2020, representing 20.5% of the then 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.

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"), have 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, under the Anti-Monopoly Law of the PRC and the Provisions on Thresholds for Prior Notification of Concentrations of Undertakings issued by the State Council, a transaction by way of merger, acquisition or contractual arrangement that allow one market player to take control of or to exert decisive impact on another market player requires advanced notice to the State Administration for Market Regulation (the "SAMR") when such threshold is crossed and shall not be implemented without the clearance of prior notification. In addition, the Measures for Security Review of Foreign Investment and the Regulations on Implementation of Security Review System for the Merger and Acquisition of Domestic Enterprise by Foreign Investors (the "Security Review Rules") 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 prohibit any activities attempting to bypass a security review by structuring the transaction through, among other things, trusts, entrustment or contractual control arrangements. Furthermore, according to the Overseas Listing Trial Measures, if a Chinese overseas listed company issues overseas listed securities to acquire assets, such issuance would be subject to filing requirements with the CSRC. We may also be subject to similar review and regulations in other jurisdictions, such as the laws and regulations on foreign investment in the U.S. under the jurisdiction of the Committee on Foreign Investment in the United States ("CFIUS") and other agencies, including the Foreign Investment Risk Review Modernization Act.

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 or filing processes, including obtaining approval from or filing with CFIUS, the SAMR, the MOFCOM, the CSRC 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. Furthermore, CFIUS, SAMR, MOFCOM, CSRC or other government agencies may make further determinations that increase the scrutiny of our future acquisitions in the U.S. or the PRC or prohibits such acquisitions. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

If we fail to comply with 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 U.S. 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 U.S., PRC or other countries' anti-corruption and related laws. 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. 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.

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 such 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.

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 cyberattacks, computer viruses, unauthorized access to systems and data, malicious internet-based activity, online and offline fraud, wrongful conduct by insider employees and vendors, denial-of-service attacks, ransomware attacks, business email compromises, social engineering (including phishing attacks), computer malware, malicious codes, wrongful intrusions, and other similar activities, as well as natural disasters, terrorism, war, and telecommunication and electrical failures, which can compromise the confidentiality, integrity and availability of the systems. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources. Although, to our knowledge, we have not experienced any material cyber incidents or data breaches 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, banking information of our vendors, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems and outsourced vendors. 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, business email compromises, social engineering (including phishing attacks), 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. Like other companies in our industry, we, and our contractors and collaborators, have experienced and will continue to experience cybersecurity threats and incidents relating to our information technology systems and infrastructure, including malicious codes and viruses, phishing, email compromise attacks, ransomware, or other cyber-attacks. Such threats could adversely affect our security, leave us without access to important systems, products, raw materials, components, services or information and expose our confidential data. For example, one of our third-party vendors experienced a business email compromise which resulted in us sending payment to a fraudulent bank account. Funds were successfully recovered in this case, but it is possible that to the extent a similar future event occurs, funds will not be recoverable. In addition, system redundancy may be ineffective or inadequate, and our disaster recovery planning may not be sufficient to cover all eventualities. Significant events could result in a disruption of our operations, damage to our reputation or a loss of revenues.

We could be subject to risks caused by misappropriation, misuse, leakage, falsification 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. 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 provide legal notifications and disclosures, as well as 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. It is possible that the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our remote working environment, which may be less secure and more susceptible to hacking attacks. 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, data 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. Further, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach.

The increasing use of artificial intelligence-based software (including machine learning) and social media platforms may result in reputation harm or liability or could otherwise adversely affect our business.

The use of artificial intelligence-based software is increasingly being used in the biopharmaceutical and global healthcare industries. As with many developing technologies, artificial intelligence-based software presents risks and challenges that could affect its further development, adoption, and use, and therefore our business. For example, algorithms may be flawed; data sets may be insufficient, of poor quality, or contain biased information; and inappropriate or controversial data practices by data scientists, engineers, and end-users could impair results. If the analyses that artificial intelligence applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability, and brand or reputational harm. Furthermore, use of artificial intelligence-based software may lead to the inadvertent release of confidential information which may impact our ability to realize the benefit of our intellectual property.

A growing number of laws and regulations are being adopted focused on enforcement efforts surrounding artificial intelligence and the use of such technologies in compliance with ethical standards and societal expectations. For example, the EU's Artificial Intelligence Act imposes significant obligations on providers and deployers of artificial intelligence systems, and encourages ethical principles in the development and use of these systems. Likewise, in the U.S., several states passed laws to regulate various uses of artificial intelligence. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of artificial intelligence in regulated sectors. The FDA, for example, issued guidance on the use of artificial intelligence in medical devices, requiring detailed risk management and review processes to obtain approvals. We currently use systems that incorporate artificial intelligence, and if we develop or continue to use artificial intelligence systems governed by these laws or regulations, we will need to apply significant resources to design, develop, test and maintain such systems in accordance with applicable law and regulation, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

Additionally, our vendors may incorporate artificial intelligence tools into their offerings, and the providers of these artificial intelligence tools may not meet regulatory standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Relatedly, social media platforms are increasingly being used to communicate about our products and the diseases our medicines and drug candidates are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear and create uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we may fail to monitor and comply with applicable adverse event reporting obligations. There is also a risk of negative or inaccurate posts about us on social media, including criticism regarding our medicines or drug candidates. The immediacy of social media precludes us from having real-time control over postings made regarding our company, medicines or drug candidates. Our reputation could be damaged by negative publicity posted on social media platforms which we may not be able to timely reverse. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

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

In the U.S., Europe, China, and many other jurisdictions where we operate, we are subject to laws and regulations that address privacy, personal information protection, use of artificial intelligence-based software and data security. Numerous laws and regulations, including, without limitation, privacy laws (such as the European Union's General Data Protection Regulation ("GDPR") or similar laws), security breach notification laws (such as Australia's amendment to the Privacy Act), health information privacy laws (such as the United States' Health Insurance Portability and Accountability Act ("HIPAA") and the Human Genetic Resources Administration of China's rules), and consumer protection laws (such as the United States' Federal Trade Commission's unfair or deceptive practices rules, or California's Consumer Privacy Act), govern the collection, use, disclosure and protection of health-related and other personal information. A subset of these laws also have strict requirements governing the cross-border transfer of, or access to, personal information (see the risk factor titled "*Compliance with the Data Security Law of the People's Republic of China (the "Data Security Law"), Cybersecurity Review Measures, Personal Information Protection Law of the People's Republic of China (the "PIPL"), regulations and guidelines relating to the multi-level protection scheme (the "MLPS") and any other future laws and regulations may entail significant expenses and could materially affect our business.*").

The legal and regulatory landscape around data privacy is rapidly changing with countries, states and other localities passing new laws and regulations every year. For example, the U.S. Department of Justice issued regulations implementing Executive Order ("EO") 14117, "Preventing Access to Americans' Bulk Sensitive Personal Data and United Stated Government-Related Data by Countries of Concern," which are expected to become effective in April 2025 and prohibit transactions involving access to bulk sensitive data by countries of concern, such as China (including Hong Kong and Macau), Cuba, Iran, North Korea, Russia, and Venezuela. For example, the regulations prohibit transactions involving human genomic data and biospecimens of more than 100 U.S. individuals, except where necessary for specified exempt activities, such as for regulatory approvals, clinical investigations in support of FDA applications, and post-marketing surveillance. Tracking and complying with these laws and regulations requires significant time and expenses and could materially affect our business. By way of example and without limitation, these laws may require updating of contracts, informed consent forms, clinical trial protocols and privacy notices; changes to company procedures and corporate structures; limiting what personal information we collect, who has access to it and how/where we use it; performing internal assessments; changes to the security and hosting solution of our systems; changes to vendors and other third parties that we work with; specific reporting and remediation efforts in the event of a data breach; and even opening our business up for external assessments by government bodies.

Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may face challenges in implementing all measures required by regulators or courts in their interpretation. Additionally, we may experience a reportable data breach (see the risk factor titled "*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*"). Any failure or perceived failure by us to comply with applicable laws and regulations could subject us to significant administrative, civil or criminal fines or other penalties and negatively impact our reputation and our ability to participate in certain government-supported programs. For severe violations, in some countries these laws even allow courts and government agencies to delay or halt transfer of personal information, require deletion of personal information, or even order we stop collection, use or other processing of personal information in that country. All of these could materially harm our business, prospects, and financial condition or even disrupt our operations.

These laws apply not just to us, but also to those vendors working on our behalf, as well as our business partners. Any actual or perceived failure of them to comply with these laws and regulations could impact the services they provide to us, our collaborations with them and our reputation; additionally, there is a risk of liability flowing to us under certain contractual and/or legal conditions.

Compliance with the Data Security Law of the People's Republic of China (the "Data Security Law"), Cybersecurity Review Measures, Personal Information Protection Law of the People's Republic of China (the "PIPL"), regulations and guidelines relating to the multi-level protection scheme (the "MLPS") and any other future laws and regulations may entail significant expenses and could materially affect our business.

China has implemented extensive data protection, privacy and information security rules and is considering a number of additional proposals relating to these subject areas. We face significant uncertainties and risks related to these laws, regulations and policies, some of which were only recently enacted, and the interpretation of these legal requirements by government regulators as applied to biotechnology companies like us. For example, we collect and maintain de-identified or pseudonymized health data for clinical trials in compliance that could be deemed "personal data" or "important data" by government regulators. With China's growing emphasis of its sovereignty over data derived from China, the outbound transmission of de-identified or pseudonymized health data for clinical trials may be subject to the new national security legal regime, including the Data Security Law, the Cyber Security Law of the People's Republic of China (the "Cyber Security Law"), the PIPL, and various implementing regulations and standards.

China's Data Security Law provides that the data processing activities must be conducted based on "data classification and hierarchical protection system" for the purpose of data protection and prohibits entities in China from transferring data stored in China to foreign law enforcement agencies or judicial authorities without prior approval by the relevant PRC authority. The classification of data is based on its importance in economic and social development, as well as the degree of harm expected to be caused to national security, public interests, or the legitimate rights and interests of individuals or organizations if such data is tampered with, destroyed, leaked, or illegally acquired or used.

The Cyber Security Law requires companies to take certain measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that companies adopt an MLPS, under which network operators are required to perform obligations of security protection to ensure that the network is free from interference, disruption or unauthorized access, and prevent network data from being disclosed, stolen or tampered. Under the MLPS, entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level to which the entity's information and network systems belong, from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cybersecurity. The grading result will determine the set of security protection obligations that entities must comply with and when relevant government authority examination and approval is required.

Under the Cyber Security Law and Data Security Law, we are required to establish and maintain a comprehensive data and network security management system that will enable us to monitor and respond appropriately to data security and network security risks. We are obligated to notify affected individuals and appropriate Chinese regulators of and respond to any data security and network security incidents. Chinese authorities have issued guidance, regulations, and amendments that continue to evolve the required standard of security and potential liabilities for violations. For example, the Network Data Security Management Regulations issued in September 2024 impose detailed and prescriptive requirements for protecting network security. Establishing and maintaining such systems takes substantial time, effort and cost, and we may not be able to establish and maintain such systems as fully as needed to ensure compliance with our legal obligations. Despite our investment, such systems may not adequately protect us or enable us to appropriately respond to or mitigate all data security and network security risks or incidents we may face.

Furthermore, under the Data Security Law, data categorized as "important data," which will be determined by governmental authorities in the form of catalogs, is to be processed and handled with a higher level of protection. The notion of important data is not clearly defined by the Cyber Security Law or the Data Security Law. In order to comply with the statutory requirements, we will need to determine whether we possess important data, monitor the important data catalogs that are expected to be published by local governments and departments, perform risk assessments and ensure we are complying with reporting obligations to applicable regulators. We may also be required to disclose to regulators business sensitive or network security-sensitive details regarding our processing of important data and may need to pass the government security review or obtain government approval in order to share important data with offshore recipients, which can include foreign licensors, or share data stored in mainland China with judicial and law enforcement authorities outside of mainland China. If judicial and law enforcement authorities outside mainland China require us to provide data stored in mainland China, and we are not able to pass any required government security review or obtain any required government approval to do so, we may not be able to meet the non-PRC authorities' requirements and may be unable to share information outside of China which may disrupt the operation of our business. The potential conflicts in legal obligations could have adverse impacts on our operations in and outside of mainland China. PRC regulatory authorities have also enhanced the supervision and regulation of cross-border data transmission. The Data Security Law prohibits entities and individuals in China from providing any foreign judicial or law enforcement authority with any data stored in China without approval from competent PRC authority and sets forth the legal liabilities of entities and individuals found to be in violation of their data protection obligations, including rectification order, warning, fines, suspension of relevant business, and revocation of business permits or licenses. Moreover, the CAC promulgated the Measures for the Security Assessment of Cross-border Data Transmission (effective September 2022) and the Provisions on Promoting and Standardizing Cross-Border Data Flows (effective March 2024), which provide certain clarification and relaxation to the compliance mechanisms for cross-border transfer of personal information, and provide several exemptions from undergoing security assessment, obtaining personal information protection certification, or entering into prescribed agreement for cross-border transfer of personal information for businesses. The provisions also explicitly state that data processors are not required to conduct data security assessment for cross-border important data transfers if the concerning data has not been notified or published as important data by relevant departments or regions. According to these measures, personal data processors are subject to security assessment prior to any cross-border transfer of data if the transfer involves (i) important data; (ii) personal information transferred overseas by operators of critical information infrastructure; (iii) non-sensitive personal data of more than 1 million persons or sensitive personal data of more than 10,000 persons transferred overseas since January 1 of the current year; or (iv) other circumstances as requested by the CAC. Though these measures have already taken effect, substantial uncertainties still exist with respect to the interpretation and implementation of these measures in practice and how they will affect our business operation.

The CAC has taken action against several Chinese internet companies listed on U.S. securities exchanges for alleged national security risks and improper collection and use of the personal information of Chinese data subjects. According to the official announcement, the action was initiated based on the National Security Law of the People's Republic of China (the "National Security Law"), the Cyber Security Law and the Cybersecurity Review Measures. Effective as of February 2022, the CAC, together with 12 other PRC governmental authorities, promulgated the Revised Cybersecurity Review Measures, pursuant to which critical information infrastructure operators procuring network products and services and online platform operators carrying out data processing activities, which affect or may affect national security, shall conduct a cybersecurity review. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review. The relevant competent governmental authorities may also initiate a cybersecurity review against the relevant operators if the authorities believe that the network product or service or data processing activities of such operators affect or may affect national security. There are still uncertainties as to the exact scope of network product or service or data processing activities that will or may affect national security, and the PRC government authorities may have discretion in the interpretation and enforcement of these measures.

Additionally, the State Council published the Administrative Regulations on Cyber Data Security ("Cyber Data Security Regulations", effective January 1, 2025), pursuant to which data processors are required to identify and report important data. Important data processors shall further adopt specific measures to secure the important data, such as designing the personnel and management institution responsible for the network data security, conducting risk assessment for the sharing, entrusted processing and joint processing of important data, and submit the annual risk assessment reports to competent authorities. Furthermore, data processors shall be subject to national security review if their cyber data processing activities affect or may affect national security.

There remain uncertainties as to how widespread the cybersecurity or national security review requirement and the enforcement action will be and what effect they will have on the life sciences sector generally and the Company in particular. China's regulators may impose penalties for non-compliance ranging from fines or suspension of operations, and the imposition of any such penalties on our business could cause a material adverse effect on our business, financial condition, results of operations, prospects and the trading price of our ordinary shares, ADSs and RMB Shares, and could lead to our delisting from Nasdaq. As of the date of this Annual Report, we have not received any notice from any Chinese regulatory authority identifying us as a "critical information infrastructure operator," "online platform operator" or "data processor" requiring us to go through the cybersecurity review procedures pursuant to the Revised Cybersecurity Review Measures or national security review under the Cyber Data Security Regulations. However, there remains uncertainty as to how the regulations if enacted as currently proposed, will be interpreted or implemented and whether the Chinese regulatory authorities will adopt additional regulations. We intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Revised Cybersecurity Review Measures, the Cyber Data Security Regulations or other laws and regulations related to privacy, data protection and information security.

Additionally, the Standing Committee of the National People's Congress of the PRC promulgated the PIPL, which expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in China, and the processing of personal information of persons in China outside of China if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in China. The PIPL also provides that critical information infrastructure operators and personal information processing entities that process personal information meeting a volume threshold are also required to store in China personal information generated or collected in China, and to pass a security assessment for any export of such personal information. Lastly, the PIPL contains proposals for significant fines for serious violations of up to RMB50 million, or 5% of annual revenues from the prior year, and penalties, including that companies found to have violated the PIPL may be ordered to suspend any related activity.

Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with the Cyber Security Law, the Data Security Law and the PIPL could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed by the Cyber Security Law, the Data Security Law and/or related implementing regulations. Any failure on our part to comply with such law or regulation, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by Chinese government authorities and private claims or litigation, any of which could materially adversely affect our business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law and the actions taken by the Chinese government could materially adversely affect our ability, on favorable terms, to raise capital in the U.S. and other markets in the future.

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.

Our financial and operating performance may be adversely affected by government shutdowns, public health crises, natural catastrophes, or other business interruptions outside of our control.

Our global operations and those of our third-party contractors and collaborators expose us to natural or man-made disasters, such as earthquakes, hurricanes, floods, fires, explosions, public health crises, such as epidemics or pandemics, terrorist activity, wars, political uncertainty, or other business interruptions outside of our control. Furthermore, we do not maintain any insurance other than property insurance for some of our buildings, vehicles and equipment. Accordingly, unexpected business interruptions resulting from disasters could disrupt our operations and thereby result in substantial costs and diversion of resources. For example, our Guangzhou manufacturing facility was hit by a typhoon in 2019 and although the typhoon did not cause material damage to the facility, the boundary area and the adjacent land were flooded, causing a power outage for a few days. Afterwards, we fortified the facility to help prevent future interruptions. A significant disruption at our manufacturing facilities, even on a short-term basis, could impair our ability to timely produce products, which could have a material adverse effect on our business, financial position and results of operations.

Our production process requires a continuous supply of electricity. We have encountered power shortages historically in China due to restricted power supply to industrial users during summers when the usage of electricity is high and supply is limited or as a result of damage to the electricity supply network. Because the duration of those power shortages was brief, they had no material impact on our operations. Longer interruptions of electricity supply could result in lengthy production shutdowns, increased costs associated with restarting production and the loss of production in progress. Any major suspension or termination of electricity or other unexpected business interruptions could have a material adverse impact on our business, financial condition and results of operations.

We also rely in part 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 crises or other business interruptions which could cause us to delay or cease development or commercialization of some or all of our medicines and drug candidates. 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. For example, the ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Currently, federal agencies in the U.S. are operating under a continuing resolution that is set to expire on March 14, 2025. Without appropriation of additional funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted.

In particular, the COVID-19 pandemic negatively impacted our business and our financial performance, and future global pandemics or other public health crises could have similar negative impacts, including delays or other disruptions to required regulatory inspections of our development activities, regulatory filings, manufacturing operations, or clinical trial recruitment and progress. 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. Additionally, as seen in connection with the COVID-19 pandemic, public health crises may result in significant governmental measures being implemented to control the spread of a virus, including quarantines, travel restrictions, social distancing and business shutdowns. These measures may negatively affect our business by inducing absenteeism or employee turnover, disrupting our operations, increasing the risk of a cybersecurity incident, or other business disruptions outside of our control.

Climate change manifesting as physical or transition risks, included related environmental regulation, could have a material adverse impact on our business operations, clients and customers.

The long-term effects of climate change are difficult to assess and predict. Our business and the activities of our clients and customers could be impacted by climate change. Climate change could manifest as a financial risk either through changes in the physical climate or from the process of transitioning to a low-carbon economy, including related environmental regulation of companies with respect to risks posed by climate change.

The physical impacts of climate change may include physical risks (such as rising sea levels or frequency and severity of extreme weather conditions), social and human effects (such as population dislocations or harm to health and well-being), compliance costs and transition risks (such as regulatory or technology changes) and other adverse effects. The effects could impair, for example, the availability and cost of certain products, commodities and energy (including utilities), which in turn may impact our ability to procure goods or services required for the operation of our business at the quantities and levels we require. Furthermore, related environmental regulation as a response to climate change could result in additional costs in the form of taxes and investments of capital to maintain complacent with such laws. We bear losses incurred as a result of, for example, physical damage to or destruction of our facilities, loss or spoilage of inventory, and business interruption due to weather events that may be attributable to climate change and could materially adversely affect our business operations, financial position or results of operation.

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 the U.S., China, Europe and other markets, and for 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 medicine, 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 medicines; 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.

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

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 U.S.; 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 U.S. 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 crises on employees, our operations and the global economy; restrictions on international travel and commerce; and significant adverse changes in local currency exchange rates. In addition, in 2017 the United Kingdom Financial Conduct Authority ("UKFCA"), which regulates the London Interbank Offered Rate ("LIBOR"), announced that it would no longer require banks to submit rates for the calculation of LIBOR to the LIBOR administrator. Following June 30, 2023, the UKFCA ceased to publish one month, three month and six month USD LIBOR settings. In the U.S., the Alternative Reference Rate Committee ("ARRC"), a steering committee assembled by the Federal Reserve Board and the Federal Reserve Bank of New York, was tasked with identifying alternative reference rates to replace LIBOR. The AARC selected, and the Federal Reserve Bank of New York has recommended, the Secured Overnight Finance Rate ("SOFR") as an alternative to LIBOR. SOFR is a broad measure of the cost of borrowing cash in the overnight U.S. treasury market. LIBOR and SOFR have significant differences: LIBOR was an unsecured lending rate and SOFR is a secured lending rate, and SOFR is an overnight rate while LIBOR is a forward-looking rate that reflected term rates at different maturities. At this time, it is not possible to predict how markets will respond to SOFR or other alternative reference rates, and 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.

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 intended to address concerns over base erosion and profit shifting ("BEPS") and other perceived international tax avoidance techniques as a result of both coordinated actions by governments, such as the OECD/G20 Inclusive Framework on BEPS, and unilateral measures designed by individual countries. 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.

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 and the significant oversight and discretion the PRC government has over the conduct of the business operations of our PRC subsidiaries 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 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 U.S. or other governments. There is significant uncertainty about the future relationship between the U.S. and China with respect to trade policies, data sharing, treaties, government regulations and tariffs. China's economy differs from the economies of other countries in many respects, including with respect to the level of development, growth rate, amount of government involvement, regulation 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 Chinese 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 regulation 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 manage the pace of economic growth and prevent the economy from overheating. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations.

The PRC government may intervene or influence our operations at any time, and has the ability to exert significant oversight and control over any offering of securities conducted overseas and/or foreign investment in China-based issuers, which could result in a material change in our operations and limit or completely hinder our ability to offer or continue to offer securities to investors, and may cause the value of such securities to significantly decline or be worthless.

The Chinese government may intervene or influence our operations at any time, or may exert control over operations of our business, which could result in a material change in our operations and/or the value of our securities. Any actions by the Chinese government to exert more oversight and control over offerings that are conducted overseas and/or foreign investment in China-based issuers could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless.

For example, the PRC government has indicated its intent to exert more oversight and control over securities offerings and other capital markets activities that are conducted overseas and foreign investment in China-based companies. If the PRC authorities attempt to exercise such control or influence through regulation over our PRC subsidiaries, we could be required to restructure our operations to comply with such regulations or potentially cease operations in the PRC entirely, which could adversely affect our business, results of operations and financial condition. Any such action, once taken by the PRC government, could result in a material change in our operations, and could also significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or in extreme cases, become worthless.

Additionally, the PRC government initiated a series of regulatory actions and statements to regulate business operations in China, including cracking down on illegal activities in the securities market, enhancing supervision over China-based companies listed overseas using the variable interest entity ("VIE") structure, adopting new measures to extend the scope of cybersecurity reviews, and expanding the efforts in anti-monopoly enforcement. For example, in July 2021, the relevant PRC government authorities made public the Securities Opinions, which emphasized the need to strengthen the administration over illegal securities activities and the supervision on overseas listings by China-based companies and proposed to take effective measures, such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas listed companies.

Furthermore, in July 2021, the PRC government provided guidance on China-based companies raising capital outside of China, including through VIE structures. In light of such developments, the SEC has imposed enhanced disclosure requirements on China-based companies seeking to register securities with the SEC. In February 2023, the CSRC released the Overseas Listing Trial Measures and five relevant guidelines which became effective as of March 31, 2023. According to the Overseas Listing Trial Measures, where Chinese companies that have directly or indirectly listed securities in overseas markets conduct follow-on offering of equity securities in such overseas markets, they shall fulfill the filing procedures with and report relevant information to the CSRC. As the Overseas Listing Trial Measures are subject to changes and may continue to evolve, we cannot assure you that we would not be deemed as an indirect overseas listed Chinese company under the Overseas Listing Trial Measures. If we are deemed as an indirect overseas listed Chinese company but fail to complete the filing procedures with the CSRC for any of our follow-on offerings or follow relevant reporting requirements thereunder, we may be subject to penalties, sanctions and fines imposed by the CSRC and relevant departments of the State Council. See also the section of this Annual Report titled "Part I—Item 1—Business—Government Regulation—PRC Regulation—Regulations Relating to Overseas Listing". We are currently evaluating the implications and potential impact of the Overseas Listing Trial Measures and will continue to closely monitor the interpretation and implementation of the Overseas Listing Trial Measures. Due to our operations in China and stock listings in and outside of China, the Overseas Listing Trial Measures and any future PRC, U.S. or other rules and regulations that place restrictions on capital raising could adversely affect our business and results of operations and could significantly limit or completely hinder our ability to offer or continue to offer our ADSs or ordinary shares to investors, and could cause the value of our ADSs or ordinary shares to significantly decline or become worthless.

In February 2023, the CSRC and other PRC governmental authorities jointly issued the revised Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (the "Revised Confidentiality Provisions"), which became effective as of March 31, 2023. According to the Revised Confidentiality Provisions, Chinese companies that directly or indirectly conduct overseas offerings and listings, shall strictly abide by the laws and regulations on confidentiality when providing or publicly disclosing, either directly or through their overseas listed entities, materials to securities services providers. In the event such materials contain state secrets or working secrets of government agencies, the Chinese companies shall first obtain approval from authorities, and file with the secrecy administrative department at the same level with the approving authority; in the event that such materials, if divulged, will jeopardize national security or public interest, the Chinese companies shall comply with procedures stipulated by national regulations. The Chinese companies shall also provide a written statement of the specific sensitive information provided when providing materials to securities service providers, and such written statements shall be retained for inspection. The interpretation and implementation of the Revised Confidentiality Provisions may continue to evolve.

Currently, these statements and regulatory actions have had no impact on our daily business operations or our ability to accept foreign investments and list our securities on a U.S. or other foreign exchange. However, it is highly uncertain how the legislative or administrative agencies will further interpret, modify or implement such laws and regulations, or if they will promulgate any new laws or regulations, and their potential impact on our daily business operations, the ability to accept foreign investments and list our securities on a U.S., Hong Kong, or other stock exchanges. There are still substantial uncertainties as to how PRC governmental authorities will regulate overseas listing in practice and whether we are required to obtain any specific regulatory approvals from PRC governmental authorities for our offshore offerings. If PRC regulatory agencies later promulgate new rules or explanations requiring that we obtain their approvals for our future offshore offerings, we may be unable to obtain such approvals in a timely manner, or at all, and such approvals may be rescinded even if obtained. Any such circumstance could significantly limit or completely hinder our ability to continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. In addition, implementation of industry-wide regulations directly targeting our operations could cause the value of our securities to significantly decline. Therefore, investors of our company face potential uncertainty from actions taken by the government authorities affecting our business. Any intervention by the PRC government in our operations could undermine our business plan and cause the value of an investment in the Company to significantly decline or become worthless.

Historically, there has been legislation implemented which put our ADSs at risk of potential delisting. The delisting of our ADSs, or the threat of their being delisted, may materially and adversely affect the value of your investment.

The Holding Foreign Companies Accountable Act (as amended, the "HFCAA") provides that if the SEC determines an issuer has filed audit reports issued by a registered public accounting firm that has not been subject to inspection by the PCAOB for two consecutive years beginning in 2021, the SEC shall prohibit that issuer's securities from being traded on a national securities exchange or in the over-the-counter trading market in the U.S. Following the filing of our annual report on Form 10-K for fiscal year ended December 31, 2021, which was audited by Ernst & Young Hua Ming LLP, the SEC added us to its list of Commission-Identified Issuers identified under HFCAA.

However, as our global business expanded, we built substantial organizational capabilities outside of the PRC and we evaluated, designed and implemented business processes and control changes which enabled us to engage Ernst & Young LLP, located in Boston, Massachusetts, U.S., as our independent registered public accounting firm for the audits of our financial statements and internal control over financial reporting commencing for the fiscal years ended December 31, 2022 and those thereafter. We believe that this satisfies the PCAOB inspection requirements for the audit of our consolidated financial statements prior to the two-year deadline of the HFCAA. Given that Ernst and Young LLP (U.S.) has served as the principal accountant to audit our consolidated financial statements since 2022, we believe this should preclude the delisting of our ADSs from Nasdaq under HFCAA.

We may be subject to enforcement under 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 U.S., we are currently unable to predict the potential impact on our listing status by any rules that may be adopted by the SEC in the future. If we failed to comply with those rules, it is possible that our ADSs would be delisted. The risk and uncertainty associated with a potential delisting would have a negative impact on the price of our ADSs, ordinary shares and RMB Shares.

There are uncertainties regarding the interpretation and enforcement of Chinese laws, rules and regulations, and rules and regulations in China can change quickly with little advance notice.

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.

Furthermore, China's legal system is still developing. The laws, rules and regulations are subject to interpretation and enforcement by PRC regulatory agencies and courts. In particular, on account of the relatively new implementation of certain laws, rules and regulations, the non-precedential nature of court decisions, and the discretion such laws, rules and regulations give to the relevant regulator in enforcement, the interpretation and enforcement of these laws, rules and regulations involve uncertainties and can be inconsistent. In addition, the legal system is based in part on government policies and rules which may quickly be amended from time to time with little advance notice. 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 its 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 its 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 its implementation 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 Security Review Rules 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 U.S. There are still uncertainties with respect to the interpretation, implementation and enforcement of the Security Review Rules. 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 Security Review Rules on our existing investments or potential investments in China.

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. According to Article 177 of the PRC Securities Law, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the PRC territory, which may increase the difficulties you face in protecting your interests. According to the Revised Confidentiality and Archives Administration Provisions, where overseas securities regulators or relevant competent authorities request to inspect, investigate or collect evidence from Chinese domestic companies concerning their overseas offering and listing or their securities firms and securities service providers that undertake securities business for such Chinese domestic companies, such inspection, investigation and evidence collection must be conducted under the cross-border regulatory cooperation mechanism, and the CSRC or competent authorities of the Chinese government will provide necessary assistance pursuant to bilateral and multilateral cooperation mechanism. 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 Unities States may not be efficient in the absence of a mutual and practical cooperation mechanism. For risks associated with investing in us as a Cayman Islands company, see the risk factor titled *"Because we are a Cayman Islands company, our shareholders may have fewer shareholder rights than they would have under Hong Kong law, Chinese law or U.S. law and may face difficulties in protecting their interests."*

Any administrative and court proceedings in the jurisdictions in which we operate, including 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 difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection. 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.

In addition, the PRC government has announced its plans to enhance its regulatory oversight of China-based companies listed overseas and cross-border law enforcement cooperation. The Securities Opinions called for:

- tightening oversight of data security, cross-border data flow and administration of classified information, as well as amendments to relevant regulation to specify responsibilities of overseas listed China-based companies with respect to data security and information security;
- enhanced oversight of overseas listed companies as well as overseas equity fundraising and listing by China-based companies; and
- extraterritorial application of China's securities laws.

There are uncertainties with respect to the interpretation and implementation of the Securities Opinions and the Overseas Listing Trial Measures. The PRC government may promulgate relevant laws, rules and regulations to impose additional and significant obligations and liabilities on overseas listed China-based companies regarding data security, cross-border data flow, and compliance with China's securities laws. As a company with operations in China and stock listings in and outside of China, it is uncertain whether or how these laws, rules and regulations and their interpretation and implementation may affect us. However, among other things, our ability to obtain external financing through the issuance of equity securities overseas could be adversely affected if restrictions on overseas fundraising are imposed on companies like us.

Filing or other procedures with the CSRC or other Chinese regulatory authorities may be required in connection with issuing our equity securities to foreign investors under Chinese law, and, if required, we cannot predict whether we will be able, or how long it will take us, to complete such filing or other procedures. If we fail to complete a filing with the CSRC, our future offering application may be impacted and we may be subject to penalties, sanctions and fines imposed by the CSRC and relevant departments of the State Council.

Numerous regulations, guidelines and other measures have been or are expected to be adopted in China under the umbrella of or in addition to the Cyber Security Law and Data Security Law. As there are still uncertainties regarding the interpretation and implementation of such regulatory guidance, we cannot assure investors that we will be able to comply with new regulatory requirements relating to our future overseas capital-raising activities outside of China and we may become subject to more stringent requirements with respect to matters including data privacy and cross-border investigation and enforcement of legal claims.

In February 2023, the CSRC released the Overseas Listing Trial Measures and five relevant guidelines, requiring Chinese companies that have already directly or indirectly offered and listed securities in overseas markets to fulfill their filing obligations and report relevant information to the CSRC within three working days after conducting a follow-on offering of equity securities on the same overseas market. The Overseas Listing Trial Measures, the relevant guidelines and their implementation may continue to evolve. We may have to go through this filing process for any follow-on offerings we conduct on Nasdaq or Hong Kong Stock Exchange. If we fail to complete a filing with the CSRC for any of our follow-on offerings, we may be subject to penalties, sanctions and fines imposed by the CSRC and relevant departments of the State Council.

As of the date of this Annual Report, we have not received any inquiry, notice, warning or sanction regarding completing filing or other procedures in connection with offering our equity securities on Nasdaq or Hong Kong Stock Exchange from the CSRC or any other Chinese regulatory authorities that have jurisdiction over our operations. However, there remains uncertainty as to the interpretation and implementation of regulatory requirements related to securities offerings and other capital markets activities outside of China. If it is determined in the future that the filing or other procedure with the CSRC or any other regulatory authority is required for issuing our equity securities on Nasdaq or Hong Kong Stock Exchange, it is uncertain whether we will be able to and how long it would take for us to complete the filing or other procedure, despite our best efforts. If we, for any reason, are unable to complete, or experience significant delays in completing, the requisite relevant filing or other procedure(s), we may face sanctions by the CSRC or other Chinese regulatory authorities. These regulatory authorities may impose fines and penalties on our operations in China, limit our ability to pay dividends outside of China, limit our operations in China, delay or restrict the repatriation of funds into China or take other actions that could have a material adverse effect on our business, financial condition, results of operations and prospects, as well as the trading price of our ADSs, ordinary shares, and RMB Shares. In addition, if the CSRC or other regulatory authorities later promulgate new rules requiring that we obtain their approvals or complete filing or other procedures for any future public offerings on Nasdaq or Hong Kong Stock Exchange, we may be unable to obtain a waiver of such requirements, if and when procedures are established to obtain such a waiver. Any uncertainties and/or negative publicity regarding such a requirement could have a material adverse effect on the trading price of our ADSs, ordinary shares, and RMB Shares.

PRC regulations establish complex procedures for some acquisitions conducted by foreign investors, which could make it more difficult for us to pursue growth through acquisitions in China.

PRC regulations and rules concerning mergers and acquisitions set forth additional procedures and requirements that could make merger and acquisition activities of PRC-based companies by foreign investors more time-consuming and complex. See the risk factor titled "*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*." These rules, among others, 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. Although we believe that our business is not in an industry related to national security, we cannot preclude the possibility that the competent PRC government authorities may publish explanations contrary to our understanding or broaden the scope of such security reviews in the future, in which case our future acquisitions and investment in the PRC, including those by way of entering into contractual control arrangements with target entities, may be closely scrutinized or prohibited. Moreover, according to the Anti-Monopoly Law, the SAMR shall be notified in advance of any concentration of undertaking if certain filing thresholds are triggered. We may grow our business in part by acquiring complementary businesses in China. Complying with the requirements of the laws and regulations mentioned above and other PRC regulations to complete such transactions could be time-consuming, and any required approval processes, including obtaining approval from the SAMR, may delay or inhibit our ability to complete such transactions, which could affect our ability to expand our business or maintain or expand our market share. Our ability to expand our business or maintain or expand our market share through future acquisitions would as such be materially and adversely affected.

In January 2021, the Foreign Investment Security Review Measures promulgated by the NDRC and the MOFCOM came into effect. Pursuant to these measures investments in military, national defense-related areas or in locations in proximity to military facilities, or investments that would result in acquiring the actual control of assets in certain key sectors, such as critical agricultural products, energy and resources, equipment manufacturing, infrastructure, transport, cultural products and services, IT, Internet products and services, financial services and technology sectors, are required to be approved by designated governmental authorities in advance. Official guidance for these measures has not been issued by the designated office in charge of such security review yet, therefore there are great uncertainties with respect to the interpretation and implementation of the Foreign Investment Security Review Measures, including the scope of key sectors. If any of our business operations were to fall under the foregoing categories, we would need to take further actions in order to comply with these laws, regulations and rules, which may materially and adversely affect our current corporate structure, 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 until the liquidation of the enterprise. 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, 2024, these restricted assets totaled $1.7 billion.

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, the People's Bank of China ("PBOC") and China's State Administration of Foreign Exchange ("SAFE") promulgated a series of measures relating to oversight of capital flow in 2016, 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 oversight of capital flow, and more regulations and substantial vetting process may be put forward by the SAFE for cross-border transactions. 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 PRC 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 tax residency has a tax treaty with China that provides for a reduced withholding rate arrangement and such non-PRC resident enterprises constitute the beneficiary of such income.

Pursuant to an arrangement between mainland China and the Hong Kong Special Administrative Region (the "Hong Kong Tax Treaty") and relevant tax regulations of the PRC, subject to certain conditions, a reduced withholding tax rate of 5% will be available for dividends from PRC entities provided that the recipient holds at least 25% shares of the PRC entities and can demonstrate it is a Hong Kong tax resident and it is the beneficial owner of the dividends. The China government has adopted multiple regulations 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." We own the PRC subsidiaries through BeiGene (Hong Kong) Co., Limited ("BeiGene HK"), a company incorporated under the laws of Hong Kong on November 22, 2010 and a wholly owned subsidiary of the Company. 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.

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 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), which may be reduced or exempted according to relevant tax treaties between PRC and the non-PRC resident enterprise/individual ADS holders' or shareholders' tax resident jurisdictions.

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 originally purchased from a stock exchange 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.

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

The PRC government exerts oversight 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. Since a portion of our revenue is denominated in RMB, any existing and future regulations 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 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.

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 medicines. 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 medicines in China.

Chinese authorities have become increasingly active in enforcing laws affecting the pharmaceutical industry. Specifically, the Chinese authorities have recently increased anti-bribery efforts to address improper payments and other benefits received by physicians, staff and hospital administrators in connection with the sales, marketing and purchase of pharmaceuticals products. 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).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.

Risks Related to Our Ordinary Shares, ADSs, and RMB Shares

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

The trading price of our ordinary shares, ADSs, and/or RMB Shares can be volatile and fluctuate widely in response to a variety of factors, many of which are beyond our control, 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; 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, Shanghai or the U.S.; 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, ADSs or RMB Shares; sales or perceived potential sales of additional ordinary shares, ADSs or RMB Shares by us, our executive officers and directors or our shareholders; general economic and market conditions and overall fluctuations in the U.S., Hong Kong or Shanghai equity markets; changes in accounting principles; trade disputes or U.S.-China government relations; and changes or developments in the U.S., PRC, the EU or global regulatory environment.

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, ADSs, and/or RMB Shares, regardless of our actual operating performance.

The characteristics of capital markets in the United States, Hong Kong and Shanghai are different, which may cause volatility in the market price of our ordinary shares, ADSs, and RMB Shares.

Our ordinary shares are listed on the HKEx in Hong Kong under the stock code “06160”, our ADSs are listed on Nasdaq in the U.S. under the symbol “ONC”, and our RMB Shares are listed on the STAR Market in the PRC under the stock code “688235”. Under current PRC laws and regulations, our ADSs and ordinary shares listed on Nasdaq and the HKEx are not interchangeable or fungible with the RMB Shares listed on the STAR Market, and there is no trading or settlement between either Nasdaq or the HKEx on the one hand, and the STAR Market on the other hand. The three markets 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 major differences, the trading prices of our ordinary shares, ADSs, and RMB Shares 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/or RMB Shares, and vice versa. Because of the different characteristics of the U.S., Hong Kong and Shanghai equity markets, the historic market prices of our ordinary shares, ADSs, and RMB 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/or reputational harm 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, ADSs, and/or RMB Shares in the public market could cause the ordinary share, ADS, and/or RMB Share price to fall.

The price of our ordinary shares, ADSs, and/or RMB Shares could decline as a result of sales of a large number of the ordinary shares, ADSs, and/or RMB Shares 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 14, 2025, 1,387,367,704 ordinary shares, par value $0.0001 per share, were outstanding, of which 870,983,672 ordinary shares were held in the form of 66,998,744 ADSs, each representing 13 ordinary shares, and 115,055,260 were RMB Shares.

We filed a registration statement on Form S-3 with the SEC on behalf of certain shareholders on May 9, 2023, registering 298,738,765 ordinary shares, including 222,835,028 ordinary shares in the form of 17,141,156 ADSs to be resold by the selling shareholders identified therein and in any related prospectus supplement from time to time. Amgen also has specified registration rights pursuant to its share purchase agreement. 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, ADSs and/or RMB Shares could decline.

In addition, in the future, we may issue additional ordinary shares, ADSs, RMB Shares, or other equity or debt securities convertible into ordinary shares, ADSs, or RMB Shares 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, ADS, and/or RMB Share price to decline.

The triple listing of our ADSs, ordinary shares and RMB Shares may adversely affect the liquidity and value of our ADSs, ordinary shares and/or RMB Shares and lead to increased compliance obligations and costs.

Our ADSs are traded on Nasdaq, our existing ordinary shares maintained on our Cayman register in Cayman Islands and Hong Kong register in Hong Kong, are traded on the HKEx, and our RMB Shares are traded on the STAR Market. The triple listing of our ADSs, ordinary shares and RMB Shares may dilute the liquidity of these securities in one or all three markets and may adversely affect the maintenance of an active trading market for ADSs in the U.S., the ordinary shares in Hong Kong, and/or the RMB Shares in the PRC. The price of our ADSs, ordinary shares and/or RMB Shares could also be adversely affected by trading of our securities on other markets. We may decide at some point in the future to delist our securities from one or more of the stock exchanges where they are currently traded, subject to our shareholders' approval if required. We cannot predict the effect such delisting of our securities from one or more of the stock exchanges would have on the market price of our securities on the other stock exchanges. Additionally, the listing and trading of our equity securities in multiple jurisdictions and multiple markets has resulted in increased compliance obligations and costs for us, and we may face the risk of significant intervention by regulatory authorities in these jurisdictions and markets, such as inquiries, investigations, enforcement actions and other regulatory proceedings by regulatory authorities. In addition, we may be subject to securities litigation filed with the courts in China by the investors with respect to the RMB Shares traded on the STAR Market.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ordinary shares, ADSs and/or RMB Shares 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, ADSs and/or RMB Shares 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, ADSs and/or RMB Shares will likely depend entirely upon any future price appreciation of the ordinary shares, ADSs and/or RMB Shares. There is no guarantee that the ordinary shares, ADSs and/or RMB Shares will appreciate in value or even maintain the price at which you purchased the ordinary shares, ADSs and/or RMB Shares. You may not realize a return on your investment in the ordinary shares, ADSs and/or RMB Shares and you may even lose your entire investment in the ordinary shares, ADSs and/or RMB Shares.

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, ADSs and/or RMB Shares and trading volume could decline.

The trading market for the ordinary shares, ADSs and RMB Shares 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, ADSs and/or RMB Shares or publishes inaccurate or unfavorable research about our business, the market price for the ordinary shares, ADSs and/or RMB Shares would likely decline. Historically, we are aware of instances in which analysts have published inaccurate research about our business. 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, ADSs and/or RMB Shares to decline significantly.

Because we are a Cayman Islands company, our shareholders may have fewer shareholder rights than they would have under Hong Kong law, Chinese 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 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, mainland China and the U.S. In particular, the Cayman Islands has a less developed body of securities law than Hong Kong, mainland China or the U.S. and less judicially interpreted body of corporate law than in Delaware.

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. Our directors have 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, mainland China 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 U.S. federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in Hong Kong, mainland China or U.S. federal courts.

Some of our directors and executive officers reside outside of Hong Kong and the U.S. and a substantial portion of their assets are located outside of Hong Kong and the U.S. 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 U.S. in the event that shareholders believe that their rights have been infringed under the securities laws of Hong Kong, the U.S. or otherwise. In addition, some of our directors and executive officers reside outside of China. 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 U.S., 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.

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, a Chinese 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 the 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 their 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 our ADS holders may not receive the voting materials in time to ensure that they can vote or instruct their agent to vote their 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.

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.

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.

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). Our amended and restated memorandum and articles of association further state that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. 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") and provide that any person or entity purchasing or otherwise acquiring any interest in any of our securities 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 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.

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 parties who bring actions or proceedings against us may 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 incur in connection with such claim, to the extent the claimant is unsuccessful in obtaining a judgment on the merits in which the claiming party prevails.

The case law and potential legislative action on such fee-shifting articles are evolving and there exists considerable uncertainty regarding the validity of, and potential judicial and legislative responses to, such articles. 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, 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 depositary. However, the depositary may close its books at any time it deems expedient in connection with the performance of its duties. The depositary may refuse to deliver, transfer or register transfers of ADSs when our books or the books of the depositary are closed, or at any time if we or the depositary think it is advisable to do so because of any requirement of law, under any provision of the deposit agreement 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 depositary has closed its books or we have closed our 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.

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

The depositary 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 depositary 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 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 U.S. 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.

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 distribute 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 distributions if it is unlawful or impractical. 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 registered or distributed pursuant to an exemption from registration. The depositary is not responsible for making a distribution available to 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. 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, ADSs, and/or RMB Shares and deprive shareholders of an opportunity to receive a premium for their ordinary shares, ADSs, and/or RMB Shares.

Our directors, executive officers and principal shareholders beneficially owned approximately 49% of our outstanding ordinary shares as of February 14, 2025. 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, ADSs, and/or RMB Shares. 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.

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 composition of our income and assets, we believe that we were not a PFIC for the taxable year ended December 31, 2024. 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.

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 U.S. 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 U.S. 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.

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.

Risks Related to Our Continuation to Switzerland

Your rights as a shareholder will change as a result of the Continuation.

As announced in August 2024, we are proposing to change our jurisdiction of incorporation from the Cayman Islands to Switzerland through a transaction known as a continuation under Section 206 of the Companies Act (as amended) of the Cayman Islands and Article 161 of the Swiss Federal Code on Private International Law (such transaction, the "Continuation"). Because of differences in Swiss law and Cayman law and certain changes that will be made to our governing documents in connection with the Continuation, your rights as a shareholder will change if the Continuation is completed. For a description of these differences, see "Proposal No. 1: Approval of the Continuation — Comparison of Shareholder Rights" in the Registration Statement on Form S-4, as amended, filed with the SEC on January 21, 2025.

As a result of increased shareholder voting requirements upon completion of the Continuation, we will have less flexibility with respect to certain aspects of capital management than previously.

Under Cayman law, our directors may issue, without shareholder approval, any ordinary shares authorized in our amended and restated articles of association that are not issued or reserved. In addition, our board of directors has the right, subject to statutory limitations, to declare and pay dividends on our ordinary shares without a shareholder vote. Swiss law allows our shareholders to authorize our board of directors to issue new registered shares from the redomiciled Swiss public company for general corporate purposes based on a capital band included in the proposed Swiss articles, and for convertible instruments and for long term incentive plan purposes based on a conditional capital included in the proposed Swiss articles, in each case without additional shareholder approval. However, the shareholder authorization for general corporate purposes must be renewed by the shareholders at least every five years, and both the authorizations under the capital band and the conditional capital are limited to 50% of a company's stated capital. Swiss law also reserves for approval by shareholders many corporate actions over which our board of directors currently has authority. For example, dividends must be approved by shareholders. While we do not believe that the differences between Cayman law and Swiss law relating to our capital management will have an adverse effect on our company, we cannot assure you that situations will not arise where such flexibility would have provided substantial benefits to our shareholders.

The Continuation will result in additional direct and indirect costs whether or not completed.

The Continuation will result in additional direct costs. Following the Continuation, we may hold a large portion of meetings of our board of directors and management strategy meetings as well as our annual general meetings, beginning in 2025, in Basel. We also plan to continue expanding our physical presence in Switzerland. With that, we will further strengthen our presence in Switzerland. We will incur additional costs and expenses, primarily Swiss tax and professional fees, to comply with Swiss corporate and tax laws. In addition, we will incur attorneys' fees, accountants' fees, filing fees, mailing expenses and financial printing expenses in connection with the Continuation, whether or not it is approved. The Continuation may also result in certain indirect costs by diverting attention of our management and employees from our business with resulting increased administrative costs and expenses.

If you fail to make a required tax filing, the Continuation could result in adverse tax consequences for you.

Depending on your circumstances, you may be required to make a filing with the U.S. Internal Revenue Service or your respective tax authority, as a result of the change of our place of incorporation. Failure to make this filing on a timely basis could result in your owing taxes because of the change, even though you will not have realized any income or liquidity as a result of the change. For a more detailed description of the tax consequences associated with this transaction, please read "Proposal No. 1: Approval of the Continuation — Material Tax Considerations — United States Tax Considerations" in the Registration Statement on Form S-4, as amended, filed with the SEC on January 21, 2025.

You may be subject to Swiss withholding taxes on the payment of dividends.

Under current Swiss law, distributions made out of capital contribution reserves recognized by the Swiss Federal Tax Administration or made in the form of a par value reduction are not subject to Swiss withholding tax. We currently expect to have qualifying capital contribution reserves in the amount of approximately US$10.6 billion available for distribution not subject to Swiss withholding tax as of the effective date of the Continuation. However, there can be no assurances that the Swiss withholding rules will not be changed in the future or that shareholders will approve a distribution out of qualifying capital contribution reserves recognized by the Swiss Federal Tax Administration. Further, over the long term, the amount of qualifying contribution reserves available may be limited. If we are unable to make a distribution out of qualifying capital contribution reserves, then any dividends paid will generally be subject to a Swiss withholding tax at a rate of 35%. The withholding tax must be withheld from the gross distribution and paid to the Swiss Federal Tax Administration. Currently, dividends, if any, paid on our shares are not subject to withholding tax in the Cayman Islands. A U.S. holder that qualifies for benefits under the Convention between the United States of America and the Swiss Confederation for the Avoidance of Double Taxation with Respect to Taxes on Income, (the "U.S.-Swiss Treaty"), may apply for a refund of the tax withheld in excess of the 15% treaty rate (or for a full refund in case of qualified pension funds). A China Holder that qualifies for benefits under the Agreement between the Government of the People's Republic of China and the Swiss Federal Council for the Avoidance of Double Taxation with Respect to Taxes on Income and on Capital ("PRC-Swiss Treaty") may apply for a refund of the tax withheld in excess of the 10% or 5% treaty rate (as applicable). A Hong Kong shareholder that qualifies for benefits under the Agreement between the Government of the Hong Kong Special Administrative Region of the People's Republic of China and the Swiss Federal Council for the Avoidance of Double Taxation with respect to Taxes on Income ("Hong Kong-Swiss Treaty") may apply for a refund of the tax withheld in excess of the 10% treaty rate (or a full refund in case of specific qualified persons, including, a pension fund, or a corporate shareholder that directly holds at least 10% our capital). Subject to applicable laws and regulations, this may also apply to other shareholders that are entitled to a dividend withholding tax rate lower than the Swiss withholding tax rate under the tax treaties between the shareholders' own tax residency jurisdictions and Switzerland. Switzerland currently has concluded more than 100 tax treaties with the same treatment regarding the refund of Swiss withholding taxes.

Under current Swiss law, repurchases of shares for the purposes of capital reduction are treated as a partial liquidation subject to 35% Swiss withholding tax, irrespective of the tax residency of the shareholder. The repurchase of shares for purposes other than capital reduction, such as to retain as treasury shares for use in connection with equity incentive plans, convertible debt, similar instruments or acquisitions, will not be subject to the 35% Swiss withholding tax, irrespective of the tax residency of the shareholder. Any portion of the repurchase price attributable to par value or qualifying capital contribution reserves recognized by the Swiss Federal Tax Administration will not be subject to the 35% Swiss withholding tax. See "Proposal No. 1: Approval of the Continuation — Material Tax Considerations — Taxation of Shareholders Subsequent to the Continuation — Swiss Taxation" in the Registration Statement on Form S-4, as amended, filed with the SEC on January 21, 2025.

We will be subject to various Swiss taxation as a result of the Continuation.

We will be subject to corporate income tax at federal, cantonal and communal levels on our worldwide income. However, qualifying net dividend income and net capital gains on the sale of qualifying investments in subsidiaries are effectively exempt from federal, cantonal and communal corporate income tax under the Swiss participation relief rules. Consequently, we expect dividends from our subsidiaries and capital gains from sales of investments in our subsidiaries to be exempt from Swiss corporate income tax. In addition, we will be subject to an annual cantonal capital tax on our year-end taxable equity. We will also be subject to a Swiss issuance stamp tax levied on any future issuance of shares or any other increase in our equity unless the equity is increased in the context of a merger or other qualifying restructuring transaction. In addition, we will be subject to some other Swiss taxes (e.g., VAT and Swiss securities transfer stamp tax). We are currently not subject to income, capital, stamp or issuance taxes in the Cayman Islands.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

We recognize the importance of safeguarding the security of our computer systems, software, networks, and other technology assets. Our cybersecurity efforts are aimed at preserving the confidentiality, integrity, and continued availability of information under our ownership or care with the aim to continually improve security features in order to keep pace with the evolving cyber threat landscape.

Overview of Cybersecurity Risk Management and Strategy

Our cybersecurity risk identification, assessment and management process is a critical part of our overall enterprise risk management ("ERM") system. Within our ERM system, we adhere to our Information Security Management Policy ("ISM Policy") which is aimed at providing guidelines to monitor, review and continually improve our Information Security Management System ("ISMS"). Our ISMS is informed by ISO/IEC 27001:2022 standards and is operated based on an action model that identifies information security missions and objectives, including improvement measures to achieve continuous optimization. Our Cybersecurity Incident Response Plan ("CIRP") is a critical component of our cybersecurity incident identification and management process, which, along with our incident response team, is designed to guide our response to potential cybersecurity incidents effectively and efficiently. Our ISM Policy, ISMS and CIRP are all internal processes we use to assess, identify and manage material risks from cybersecurity threats.

We also utilize external partnerships to help protect the Company from cybersecurity threats. This combination of people, processes and technology assist us to proactively manage and mitigate threats to our information technology environment. We have controls in place to defend against risks associated with cyber-attacks impacting our operations, compliance and financial reporting objectives. We are externally audited and certified under the ISO 27001 and assessed yearly according to National Institute of Standards and Technology ("NIST") guidelines. Our external partners also evaluate our cybersecurity maturity and coverage as part of their services and keep us informed of emerging global threats.

We conduct a Testing, Training & Exercise program to test, sustain and refine our ability to respond to cybersecurity incidents in accordance with the best practices. We also maintain an information security training program for our employees.

Our Third-Party Security Management Standard provides a framework for managing third-party information security risks and defines controls to minimize risks to the Company. It applies to third parties who have access to or process Company information. This framework includes processes for conducting, as appropriate, due diligence, risk assessment and planning, contract management, access control, ongoing monitoring, and possible service termination of, or changes to the third-party as part of the selection and management process.

We have implemented a Threat Intelligence function that informs of external cyber threats which allows us to proactively protect the Company and to allow us to improve the speed of our vulnerability management capabilities.

Cybersecurity threats have to date not materially affected us, our business strategy, results of operations or financial condition. Similar to other companies, we and our third-party vendors have and will continue to experience threats to our systems and data.

Board Oversight of Risks from Cybersecurity Threats

The Board of Directors ("Board") oversees risk management related to the operation of the business and corporate functions as well as the implementation of business strategy. Our Board has delegated to the Audit Committee oversight of risk management, which includes risks from cybersecurity threats. We routinely review critical elements of our cybersecurity policies and program with the Audit Committee.

The management team – including our Chief Information Security Officer ("CISO") – provides periodic reports to the Audit Committee which cover cybersecurity and other information technology risks affecting the Company. Such reports are typically provided at an Audit Committee meeting and enable Audit Committee members to ask questions of management and engage in additional discussions in an open forum. The Audit Committee also periodically evaluates our overall cybersecurity strategy.

Management's Role in Assessing and Managing Material Risks from Cybersecurity Threats

Our Information Security Steering Committee ("ISSC") is responsible for oversight of matters related to information security and currently consists of professionals in legal operations and risk management, information governance, human resources operations, internal audit, computerized systems, global security and technical operations, and research technology, all whose input bring significant value when assessing and managing cybersecurity risk. Our ISSC meets periodically and is presented with an update on cybersecurity matters from our CISO. Our CISO is responsible for facilitating the implementation of the plans and decisions made by the ISSC and directly provides updates to the Audit Committee as detailed above.

Our Vice President of Global Technology Solutions head our Global Technology Solutions Team along with our CISO are responsible for leading the individuals tasked with maintaining our enterprise-wide cyber resilience strategy, policy, standards, architecture, and processes. Our CISO has over eighteen years of information technology and cybersecurity experience in multiple industries, including building and leading governance, risk, and compliance functions that cover ISO 27001 certified compliance, NIST Cybersecurity Framework assessments, Sarbanes-Oxley ("SOX") information technology compliance, regional compliances, policy management, information technology risk management, vendor risk management, and security awareness. Our Vice President of Global Technology Solutions has over twenty years of experience leading technology organization and managing information security across multiple industries, including SOX 404 compliance, GxP audit and compliance, NIST Cybersecurity Framework assessments, managing incident response and communication with executives and board of directors.

Item 2. Properties

We lease all of our facilities, other than the following facilities that we own: our offices and laboratories in Changping, Beijing, our manufacturing facility in Guangzhou, China, and our manufacturing facility and clinical R&D center at the Princeton Innovation Park in Hopewell, New Jersey. We lease an aggregate of approximately 134,000 square meters of office space at approximately 46 other locations across the U.S., Europe, China, MENA, and South America, in cities such as Cambridge, Massachusetts; Ridgefield Park, New Jersey; and Emeryville, San Mateo and San Carlos, California in the U.S.; Beijing, Shanghai, Suzhou, and Guangzhou in China; and Basel, Switzerland, primarily for our offices and for our manufacturing facility in Suzhou, China, pursuant to leases with various expiration dates, with the latest expiring in 2031. We believe that our facilities are currently suitable and sufficient to meet our needs. We intend to add new facilities or expand existing facilities as we add employees and enter new locations, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Please refer to "Note 7: Leases" in the notes to our consolidated financial statements in this Annual Report for further information on our real property leases.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims of a nature considered ordinary course in our business, including the intellectual property litigation described herein. Most of the issues raised by such claims are highly complex and subject to substantial uncertainties. For a description of risks relating to these legal proceedings, see "Part I—Item 1A—Risk Factors" of this Annual Report, including the discussion under the headings entitled "Risks Related to Our Intellectual Property." The outcome of any such proceedings, regardless of the merits, is inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Pharmacyclics Litigation

On June 13, 2023, Pharmacyclics LLC ("Pharmacyclics") filed a complaint in the U.S. District Court for the District of Delaware (the "Court") against the Company and its subsidiary, BeiGene USA, Inc., alleging that BRUKINSA infringes Pharmacyclics' U.S Patent No. 11,672,803 issued on June 13, 2023 (the "'803 patent"). Pharmacyclics seeks a declaration of infringement, unspecified monetary damages and other relief. The Company intends to vigorously defend against the claims.

On October 12, 2023, the Court entered a joint stipulation filed by the parties to stay the infringement suit pending resolution of a petition for post-grant review ("PGR") of the '803 Patent with the U.S. Patent and Trademark Office ("USPTO") that was later filed by BeiGene on November 1, 2023. On May 1, 2024, the USPTO granted BeiGene's PGR petition and is expected to issue a final decision on the validity of the '803 patent within 12 months.

ANDA Litigation

On March 8, 2024, the Company's two wholly-owned subsidiaries, BeiGene USA, Inc. and BeiGene Switzerland GmbH filed patent infringement suits under Hatch-Waxman Act against Sandoz Inc. ("Sandoz") and separately against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Ltd. (collectively "MSN") in the U.S. District Court for the District of New Jersey. The patent infringement suits are in response to Sandoz's and MSN's notices to the Company concerning the filings of Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA"), seeking FDA approval to market a generic version of BRUKINSA along with "Paragraph IV certifications" challenging certain BRUKINSA Orange Book patents for invalidity, unenforceability and/or non-infringement. According to the notices, neither Sandoz nor MSN have challenged BRUKINSA's composition of matter patent, which remains intact in protecting BRUKINSA from generic competition until its expiration in 2034. On August 15, 2024, the court entered a joint stipulation and order dismissing the suit against Sandoz. On November 14, 2024, BeiGene entered into a settlement agreement with MSN wherein BeiGene granted MSN the right to sell a generic version of BRUKINSA in the U.S. no earlier than June 15, 2037, subject to potential acceleration or extension under circumstances customary for settlement of this type. On November 19, 2024, the court entered a joint stipulation and order dismissing the suit against MSN.

AbbVie Litigation

On September 6, 2024, AbbVie Inc. filed a complaint in the U.S. District Court for the Northern District of Illinois against the Company, one of its wholly-owned subsidiaries and an individual scientist, alleging misappropriation of trade secrets concerning the Company's Bruton's tyrosine kinase ("BTK") degrader program, including the lead compound, BGB-16673. The complaint seeks an unspecified amount of monetary damages, declaratory judgment, restitution and other equitable remedies. The Company is vigorously defending against the claims and filed a motion to dismiss the complaint in its entirety on December 19, 2024.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our American Depositary Shares ("ADSs") have been publicly traded on the Nasdaq Global Select Market under the symbol "BGNE" from February 3, 2016 to January 1, 2025, and under the symbol "ONC" since January 2, 2025. Our ordinary shares have been publicly traded on the Stock Exchange of Hong Kong Limited under the stock code "06160" since August 8, 2018. Our ordinary shares traded in Renminbi (the "RMB Shares") have been publicly traded on the Science and Technology Innovation Board of the Shanghai Stock Exchange in China under the stock code "688235" since December 15, 2021.

Shareholders

As of January 31, 2025, we had approximately 29,773 holders of record of our ordinary shares, 29,620 of which are holders of record of our RMB Shares, and 8 holders of record of our ADSs. These numbers do not include beneficial owners whose ordinary shares or ADSs are held by nominees in street name. Because many ordinary shares and ADSs are held by broker nominees, we are unable to estimate the total number of beneficial holders represented by these record holders.

Dividend Policy

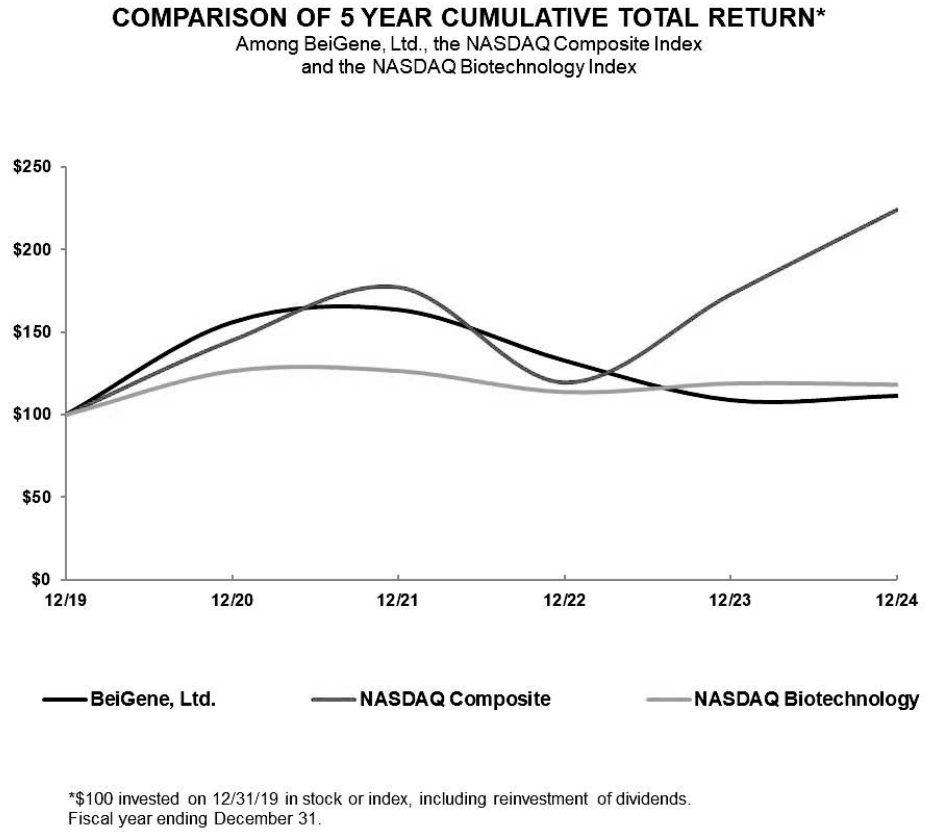
We have never declared or paid any dividends on our ordinary shares or any other securities. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. If 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 PRC subsidiaries' formation and organizational documents and the accounting standards and regulations in the PRC. Subject to applicable law and our amended and restated articles of association, any future determination to pay dividends will be made at the discretion of our board of directors 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 our board of directors may deem relevant.

Performance Comparison Graph

This graph is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph shows the total shareholder return of an investment of $100 in cash at market close on December 31, 2019 through December 31, 2024 for our ADSs, the Nasdaq Composite Index (U.S.), and the Nasdaq Biotechnology Index.

Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of any dividends, although no dividends have been declared or paid to date. The shareholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future shareholder returns.



	12/31/19	12/31/20	12/31/21	12/31/22	12/31/23	12/31/24
BeiGene, Ltd.	**100.00**	**155.88**	**163.45**	**132.69**	**108.81**	**111.43**
Nasdaq Composite	**100.00**	**144.92**	**177.06**	**119.45**	**172.77**	**223.87**
Nasdaq Biotechnology	**100.00**	**126.42**	**126.45**	**113.65**	**118.87**	**118.20**

Equity Compensation Plan Information

Our equity compensation plan information required by this item is incorporated by reference to the information in "Part III—Item 12—Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" of this Annual Report.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Taxation

Cayman Islands Taxation

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation, and there is no taxation in the nature of inheritance tax or estate duty or withholding tax applicable to us or to any holder of the ADSs, ordinary shares and RMB Shares. There are no other taxes likely to be material to us levied by the Government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within, the jurisdiction of the Cayman Islands. No stamp duty is payable in the Cayman Islands on the issue of shares by, or any transfers of shares of, Cayman Islands companies (except those which hold interests in land in the Cayman Islands). The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of the ADSs, ordinary shares and RMB Shares will not be subject to taxation in the Cayman Islands and no withholding will be required on the payment of a dividend or capital to any holder of the ADSs, ordinary shares or RMB Shares, as the case may be, nor will gains derived from the disposal of the ADSs, ordinary shares or RMB Shares be subject to Cayman Islands income or corporation tax.

PRC Taxation

Under the Enterprise Income Tax Law ("EIT Law"), an enterprise established outside the PRC with a "de facto management body" within the PRC is considered a "resident enterprise," which means that it is treated in a manner similar to a Chinese enterprise for PRC enterprise income tax purposes. The implementation rules of the EIT Law define "de facto management body" as a managing body that exercises substantial and overall management and control over the production and operations, personnel, accounting and properties of an enterprise. In addition, the Notice Regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprise as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies ("Circular 82)", issued by the State Taxation Administration, which provides guidance on the determination of the tax residence status of a Chinese-controlled offshore incorporated enterprise, defines Chinese-controlled offshore incorporated enterprise as an enterprise that is incorporated under the laws of a foreign country or territory and that has a PRC enterprise or enterprise group as its primary controlling shareholder. Although BeiGene, Ltd. does not have a PRC enterprise or enterprise group as our primary controlling shareholder and is therefore not a Chinese-controlled offshore incorporated enterprise within the meaning of Circular 82, in the absence of guidance specifically applicable to us, we have applied the guidance set forth in Circular 82 to evaluate the tax residence status of BeiGene, Ltd. and its subsidiaries organized outside the PRC.

According to Circular 82, a Chinese-controlled offshore incorporated enterprise will be regarded as a PRC tax resident by virtue of having a "de facto management body" in China and will be subject to PRC enterprise income tax on its worldwide income only if all of the following criteria are met:

- the primary location of the enterprise's senior executives of the day-to-day operational management and senior management departments performing their duties is in the PRC;
- decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in the PRC;
- the enterprise's primary assets, accounting books and records, company seals, and board and shareholder meeting minutes are located or maintained in the PRC; and
- 50% or more of voting board members or senior executives habitually reside in the PRC.

Currently, some of the members of our management team are located in China. However, we do not believe that we meet all of the conditions outlined in the immediately preceding paragraph. BeiGene, Ltd. and its offshore subsidiaries are incorporated outside the PRC. As a holding company, our key assets and records, including the resolutions and meeting minutes of our board of directors and the resolutions and meeting minutes of our shareholders, are located and maintained outside the PRC. We are not aware of any offshore holding companies with a corporate structure similar to ours that has been deemed a PRC "resident enterprise" by the PRC tax authorities. Accordingly, we believe that BeiGene, Ltd. and its offshore subsidiaries should not be treated as a "resident enterprise" for PRC tax purposes if the criteria for "de facto management body" as set forth in Circular 82 were deemed applicable to us. However, as the tax residency 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" as applicable to our offshore entities, we will continue to monitor our tax status.

The implementation rules of the EIT Law provide that, (1) if the enterprise that distributes dividends is domiciled in the PRC or (2) if gains are realized from transferring equity interests of enterprises domiciled in the PRC, then such dividends or capital gains are treated as China-sourced income. It is not clear how "domicile" may be interpreted under the EIT Law, and it may be interpreted as the jurisdiction where the enterprise is a tax resident. Therefore, if we are considered as a PRC tax resident enterprise for PRC tax purposes, any dividends we pay to our overseas shareholders or ADS holders as well as gains realized by such shareholders or ADS holders from the transfer of our shares or ADSs may be regarded as China-sourced income. 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 up to 10% (or 20% in the case of non-PRC individual ADS holders or shareholders) and gains realized by non-PRC resident enterprise 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). It is also unclear whether, if we are considered a PRC resident enterprise, holders of our shares or ADSs would be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or areas.

Item 6. Reserved

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under "Part I—Item 1A—Risk Factors" and under "Forward-Looking Statements and Market Data" in this Annual Report.

Non-GAAP Financial Measures

We provide certain financial measures that are not defined under accounting principals generally accepted in the United States of America ("GAAP"), commonly referred to as non-GAAP financial measures, including Adjusted Operating Expenses and Adjusted Income (Loss) from Operations and certain other non-GAAP measures, each of which include adjustments to GAAP figures. These non-GAAP measures are intended to provide additional information on our operating performance. Adjustments to our GAAP figures exclude, as applicable, non-cash items such as share-based compensation, depreciation and amortization. Certain other special items or substantive events may also be included in the non-GAAP adjustments periodically when their magnitude is significant within the periods incurred. We maintain an established non-GAAP policy that guides the determination of what items may be excluded in non-GAAP financial measures. We believe that these non-GAAP measures, when considered together with the GAAP figures, can enhance an overall understanding of our operating performance. The non-GAAP financial measures are included with the intent of providing investors with a more complete understanding of our historical and expected financial results and trends and to facilitate comparisons between periods and with respect to projected information. In addition, these non-GAAP financial measures are among the indicators BeiGene's management uses for planning and forecasting purposes and measuring our performance. These non-GAAP financial measures should be considered in addition to, and not as a substitute for, or superior to, GAAP financial measures. The non-GAAP financial measures used by BeiGene may be calculated differently from, and therefore may not be comparable to, non-GAAP financial measures used by other companies.

Overview

Our fourth quarter and full year results demonstrate our tremendous growth as a global oncology powerhouse, reinforced by the continued success of BRUKINSA and the development of one of the most prolific solid tumor pipelines in oncology with multiple data readouts expected in 2025. BRUKINSA is now the unequivocal leader in new CLL patient starts in the U.S., holds the broadest label of any BTK inhibitor and serves as the cornerstone of our hematology franchise, showing immense promise as a backbone alongside our late stage BCL2 inhibitor, sonrotoclax, and our potential first-in-class BTK CDAC. We are also building future solid tumor franchises in breast, lung, and gastrointestinal cancers by leveraging our platforms in multi-specific antibodies, protein degraders and antibody-drug conjugates. 2025 marks an inflection point as we anticipate achieving positive GAAP operating income and operating cash flow alongside our intention to change our name to BeOne with our new NASDAQ ticker, ONC.

Key highlights for the full year 2024 are as follows:

- Total global revenues of $1.1 billion and $3.8 billion, respectively, in the fourth quarter and full year, increases of 77.8% and 55.0%, respectively, compared to the prior year periods;
- Narrowed GAAP operating loss and achieved full-year positive non-GAAP operating income
- Global BRUKINSA revenues of $828.0 million and $2.6 billion for the fourth quarter and full year 2024, increases of 100.5% and 104.9%, respectively, compared to the prior year periods;
- Progressed pivotal-stage programs for BCL2 inhibitor sonrotoclax and BTK CDAC BGB-16673;
- Advanced six and thirteen NMEs into the clinic in the fourth quarter and full year, respectively; and
- Anticipate multiple data readouts for innovative solid tumor programs in 1H 2025.

Recent Business Developments

On January 13, 2025 we participated in the 43rd Annual J.P. Morgan Healthcare Conference and announced that we expect to achieve positive operating income for full year 2025 pursuant to generally accepted accounting principles.

On December 27, 2024, we announced that the U.S. Food and Drug Administration ("FDA") approved TEVIMBRA® (tislelizumab-jsgr), in combination with platinum and fluoropyrimidine-based chemotherapy, for the first-line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma in adults whose tumors express PD-L1 (≥1).

On December 23, 2024, we announced that our American Depository Shares will begin trading on the Nasdaq Global Select Market under our new ticker symbols "ONC" as of January 2, 2025.

On December 12, 2024, we announced entering into a global licensing agreement with CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd. for SYH2039, a novel methionine adenosyltransferase 2A (MAT2A)-inhibitor being explored for solid tumors.

On November 27, 2024, we announced that the European Commission approved TEVIMBRA® in combination with chemotherapy for the first-line treatment of esophageal squamous cell carcinoma and gastric or gastroesophageal junction adenocarcinoma.

On November 19, 2024, we announced entering into a settlement agreement with MSN Pharmaceuticals, Inc. and MSN Laboratories Private Ltd. resolving patent litigation related to MSN's Abbreviated New Drug Application seeking approval to market a generic version of BRUKINSA® (zanubrutinib) in the U.S.

On November 14, 2024, we announced our intention to change the Company's name to "BeOne Medicines Ltd." confirming our commitment to develop innovative medicines to eliminate cancer by partnering with the global community to serve as many patients as possible. Implementation of our new name is subject to shareholder approval to be sought at a future shareholder meeting.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		Change	
	2024	2023	$	%
	(dollars in thousands)			
Revenues				
Product revenue, net	$ 3,779,546	$ 2,189,852	$ 1,589,694	72.6 %
Collaboration revenue	30,695	268,927	(238,232)	(88.6)%
Total revenues	3,810,241	2,458,779	1,351,462	55.0 %
Cost of sales - product	594,089	379,920	214,169	56.4 %
Gross profit	3,216,152	2,078,859	1,137,293	54.7 %
Operating expenses				
Research and development	1,953,295	1,778,594	174,701	9.8 %
Selling, general and administrative	1,831,056	1,508,001	323,055	21.4 %
Total operating expenses	3,784,351	3,286,595	497,756	15.1 %
Loss from operations	(568,199)	(1,207,736)	639,537	(53.0)%
Interest income, net	47,836	74,009	(26,173)	(35.4)%
Other (expense) income, net	(12,638)	307,891	(320,529)	(104.1)%
Loss before income tax expense	(533,001)	(825,836)	292,835	(35.5)%
Income tax expense	111,785	55,872	55,913	100.1 %
Net loss	$ (644,786)	$ (881,708)	$ 236,922	(26.9)%

Revenue

Total revenue increased by $1.4 billion to $3.8 billion for the year ended December 31, 2024, from $2.5 billion for the year ended December 31, 2023, primarily due to increased sales of BRUKINSA, as well as increased sales of in-licensed products from Amgen and tislelizumab. Collaboration revenue decreased year over year due to the recognition of the remaining deferred revenue associated with the Novartis collaborations upon termination of the agreements in 2023.

Total revenue by geographic area is presented as follows (amounts in thousands of U.S. dollars)[1]:

	Year Ended December 31,			
	2024	%	2023	%
United States total revenue	**$ 1,957,498**	**51.4 %**	**$ 1,128,219**	**45.9 %**
Product revenue	1,950,530	51.2 %	945,551	38.5 %
Collaboration revenue	6,968	0.2 %	182,668	7.4 %
China total revenue	**1,411,307**	**37.0 %**	**1,101,951**	**44.8 %**
Product revenue	1,390,699	36.5 %	1,093,091	44.5 %
Collaboration revenue	20,608	0.5 %	8,860	0.3 %
Europe total revenue	**362,626**	**9.5 %**	**202,014**	**8.2 %**
Product revenue	359,507	9.4 %	122,228	5.0 %
Collaboration revenue	3,119	0.1 %	79,786	3.2 %
ROW total revenue	**78,810**	**2.1 %**	**26,595**	**1.1 %**
Product revenue	78,810	2.1 %	28,982	1.2 %
Collaboration revenue	—	— %	(2,387)	(0.1) %
Total Revenue	**3,810,241**	**100.0 %**	**2,458,779**	**100.0 %**

[1]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.

Net product revenue consisted of the following:

	Year Ended December 31,		Changes	
	2024	2023	$	%
	(dollars in thousands)			
BRUKINSA®	$ 2,644,226	$ 1,290,396	$ 1,353,830	104.9 %
Tislelizumab	620,836	536,620	84,216	15.7 %
XGEVA®	224,403	92,828	131,575	141.7 %
BLINCYTO®	74,331	54,342	19,989	36.8 %
KYPROLIS®	66,171	39,799	26,372	66.3 %
POBEVCY®	53,509	56,547	(3,038)	(5.4)%
REVLIMID®	36,028	76,018	(39,990)	(52.6)%
Other	60,042	43,302	16,740	38.7 %
Total product revenue	$ 3,779,546	$ 2,189,852	$ 1,589,694	72.6 %

Net product revenue was $3.8 billion for the year ended December 31, 2024, compared to $2.2 billion in the prior year, primarily due to increased sales of BRUKINSA globally, driven by significant growth in the U.S. and Europe. In addition, product revenues in 2024 were positively impacted by growth from in-licensed products from Amgen and tislelizumab.

Global sales of BRUKINSA totaled $2.6 billion for the year ended December 31, 2024, representing a 104.9% increase compared to the prior year. U.S. sales of BRUKINSA totaled $2.0 billion for the year ended December 31, 2024 compared to $945.6 million in the prior year, representing growth of 106.3%. U.S. volume growth continued to accelerate in the period due primarily to demand growth coming from expanded use in CLL as BRUKINSA continued to gain share in new patient starts in CLL and all other approved indications. In addition, U.S. sales were also positively impacted in the fourth quarter of 2024 by seasonality and the timing of customer order patterns of approximately $30.0 million. BRUKINSA sales in the EU totaled $358.8 million for the year ended December 31, 2024, representing growth of 193.6% compared to the prior-year period, driven by continued gains in market share across all major markets. BRUKINSA sales in China totaled $258.1 million for the year ended December 31, 2024, representing growth of 33.2% compared to the prior year.

Sales of tislelizumab totaled $620.8 million for the year ended December 31, 2024, representing a 15.7% increase compared to the prior year. Certain additional tislelizumab indications have been included in the 2025 NRDL. There were no price reductions resulting from inclusion.

Collaboration revenue totaled $30.7 million for the year ended December 31, 2024, primarily related to revenue generated under the Novartis broad markets marketing and promotion agreement and royalty revenue under the Amgen collaboration. Collaboration revenue totaled $268.9 million for the year ended December 31, 2023, primarily related to the recognition of the remaining deferred revenue associated with the former Novartis tislelizumab and ociperlimab collaborations which were terminated in the prior year.

Gross Margin

Gross margin on global product sales increased to $3.2 billion, or 84.3% as a percentage of sales, for the year ended December 31, 2024, compared to $1.8 billion, or 82.7% as a percentage of sales, for the year ended December 31, 2023, primarily due to proportionately higher sales mix of BRUKINSA compared to other products in our portfolio, partially offset by the impact of accelerated depreciation expense of $32.7 million resulting from the move to more efficient, larger scale production lines for tislelizumab. On an adjusted basis, which does not include the accelerated depreciation, gross margin as a percentage of product sales increased to 85.5% for the year ended December 31, 2024, from 83.2% in the comparable period of the prior year.

Research and Development Expense

Research and development expense increased by $174.7 million, or 9.8%, to $2.0 billion for the year ended December 31, 2024, from $1.8 billion for the year ended December 31, 2023. The following table summarizes the external cost of development programs, upfront license and development milestone fees, and internal research and development expense for the years ended December 31, 2024 and 2023:

	Year Ended December 31,		Changes	
	2024	2023	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 539,446	$ 551,417	$ (11,971)	(2.2)%
Upfront license and development milestone fees	114,049	46,800	67,249	143.7 %
Amgen co-development expenses[1]	75,165	53,315	21,850	41.0 %
Total external research and development expenses	728,660	651,532	77,128	11.8 %
Internal research and development expenses	1,224,635	1,127,062	97,573	8.7 %
Total research and development expenses	$ 1,953,295	$ 1,778,594	$ 174,701	9.8 %
Adjusted research and development expense[2]	$ 1,668,368	$ 1,558,960	$ 109,408	7.0 %

1. Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the year ended December 31, 2024 totaled $148.4 million, of which $75.2 million was recorded as R&D expense. The remaining $73.2 million was recorded as a reduction for the R&D cost share liability.

2. Adjusted research and development expense is intended to provide investors and others with information about our performance without the effect of items that, by their nature, tend to obscure core operating results due to potential variability across periods based on the timing, frequency and magnitude of such items. Refer to Non-GAAP Financial Measures and Non-GAAP Reconciliation in this MD&A for more information about, and a detailed reconciliation of, these items.

The increase in external research and development expenses for the year ended December 31, 2024 was primarily attributable to higher upfront license and development milestone fees and increases in Amgen co-development expense, partially offset by lower external clinical trial costs.

Internal research and development expense increased $97.6 million, or 8.7%, to $1.2 billion for the year ended December 31, 2024 from $1.1 billion in the prior year, and was primarily attributable to the expansion of our global development organization and our clinical and preclinical drug candidates, as well as our continued efforts to internalize research and clinical trial activities. Included within internal research and development expenses for the year ended December 31, 2024 is $27.1 million of accelerated depreciation expense related to the move of clinical production to larger, more efficient production lines.

Selling, General and Administrative Expense

	Year Ended December 31,		Changes	
	2024	2023	$	%
	(dollars in thousands)			
Selling, general and administrative expense	$ 1,831,056	$ 1,508,001	$ 323,055	21.4 %
Adjusted selling, general and administrative expense[1]	$ 1,549,864	$ 1,284,689	$ 265,175	20.6 %

[1.] Adjusted selling, general and administrative expense is intended to provide investors and others with information about our performance without the effect of items that, by their nature, tend to obscure core operating results due to potential variability across periods based on the timing, frequency and magnitude of such items. Refer to Non-GAAP Financial Measures and Non-GAAP Reconciliation in this MD&A for more information about, and a detailed reconciliation of, these items.

Selling, general and administrative expense increased by $323.1 million, or 21.4%, to $1.8 billion for the year ended December 31, 2024, from $1.5 billion for the year ended December 31, 2023. The increase was due to continued investment in the global commercial launch of BRUKINSA primarily in the U.S. and Europe. Selling, general and administrative expenses as a percentage of product sales were 48.4% for the year ended December 31, 2024 compared to 68.9% in the prior-year period. We expect continued investment growth in selling and marketing expenses as our product sales increase.

Interest Income, Net

Interest income, net decreased by $26.2 million, or 35.4%, to $47.8 million for the year ended December 31, 2024, compared to $74.0 million for the year ended December 31, 2023. The decrease in interest income was primarily attributable to lower interest rates earned on our cash and cash equivalents and lower cash balances in interest-bearing investments. Interest expense increased resulting from a higher debt balance, partially offset by an increase in interest capitalization related to Hopewell construction.

Other (Expense) Income, Net

Other expense, net for the year ended December 31, 2024 was $12.6 million, due to foreign exchange losses, primarily from holding net monetary assets denominated in the RMB at certain U.S. dollar functional entities, including BeiGene, Ltd. (the “Parent Company”), and unrealized losses on equity investments, partially offset by government subsidy income.

Other income, net for the year ended December 31, 2023 was $307.9 million, primarily due to the noncash gain of $362.9 million recorded for the receipt of our ordinary shares as consideration for our settlement with BMS and government subsidy income, partially offset by foreign exchange losses resulting from the strengthening of the U.S. dollar compared to the RMB and the revaluation impact of RMB-denominated deposits held in U.S. dollar functional currency subsidiaries and unrealized losses on equity investments.

Income Tax Expense

Income tax expense was $111.8 million for the year ended December 31, 2024 compared with $55.9 million for the year ended December 31, 2023. The income tax expense for the year ended December 31, 2024 was primarily attributable to higher pre-tax income resulting in current U.S. tax expense determined after other special tax deductions and research and development tax credits, including tax expense of $12.1 million due to the impact of tax reserves on uncertain tax positions related to research and development tax credits, lower taxable income in China, higher tax expense in certain EU and ROW jurisdictions and the deferred impact of the Company’s unremitted earnings in the U.S. The Company’s tax expense for 2024 reflects the historic allocation of pre-tax earnings and losses among our significant jurisdictions. This allocation and resulting tax expense depends on various factors including the level of income and unremitted earnings generated in the U.S., and amount of research and development costs incurred in China and therefore may vary from the historic allocation.

In December 2021, the Organization for Economic Cooperation and Development (“OECD”) enacted model rules for a new global minimum tax framework (“BEPS Pillar Two”), and various governments around the world have enacted, or are in the process of enacting legislation on this. While we do not anticipate that this will have a material impact on our tax provision or effective tax rate, we will continue to monitor and assess pending legislation, guidance, and implementation by individual countries and evaluate the potential impact on our business in future periods.

This section of this Form 10-K generally discusses 2024 and 2023 items and year-to-year comparisons between 2024 and 2023. Discussions of 2022 items and year-to-year comparisons between 2023 and 2022 can be found in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Part II, Item 7 of the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

Non-GAAP Reconciliation

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Reconciliation of GAAP to adjusted cost of sales - products:		
GAAP cost of sales - products	$ 594,089	$ 379,920
Less: Depreciation	42,707	8,578
Less: Amortization of intangibles	4,729	3,739
Adjusted cost of sales - products	$ 546,653	$ 367,603
Reconciliation of GAAP to adjusted research and development:		
GAAP research and development	$ 1,953,295	$ 1,778,594
Less: Share-based compensation expenses	186,113	163,550
Less: Depreciation	98,814	56,084
Adjusted research and development	$ 1,668,368	$ 1,558,960
Reconciliation of GAAP to adjusted selling, general and administrative:		
GAAP selling, general and administrative	$ 1,831,056	$ 1,508,001
Less: Share-based compensation expenses	255,680	204,038
Less: Depreciation	25,417	15,774
Less: Amortization of intangibles	95	3,500
Adjusted selling, general and administrative	$ 1,549,864	$ 1,284,689
Reconciliation of GAAP to adjusted operating expenses		
GAAP operating expenses	$ 3,784,351	$ 3,286,595
Less: Share-based compensation expenses	441,793	367,588
Less: Depreciation	124,231	71,858
Less: Amortization of intangibles	95	3,500
Adjusted operating expenses	$ 3,218,232	$ 2,843,649
Reconciliation of GAAP to adjusted loss from operations:		
GAAP loss from operations	$ (568,199)	$ (1,207,736)
Plus: Share-based compensation expenses	441,793	367,588
Plus: Depreciation	166,938	80,436
Plus: Amortization of intangibles	4,824	7,239
Adjusted income (loss) from operations	$ 45,356	$ (752,473)

Liquidity and Capital Resources

The following table represents our cash and debt balances as of December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Cash, cash equivalents and restricted cash	$ 2,638,747	$ 3,185,984
Total debt	$ 1,018,013	$ 885,984

We have incurred annual net losses and negative cash flows from operations since inception, resulting from the cost of funding our research and development programs and selling, general and administrative expenses associated with our operations, as well as supporting the commercialization of our products globally. We incurred net losses of $0.6 billion and $0.9 billion for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $8.6 billion.

To date, we have financed our existing operations and investments in long-term assets principally through proceeds from public and private offerings of our securities, proceeds from debt and our collaborations, and since the third quarter of 2024 cash flow from operations. Based on our current operating plan, we expect that our existing cash and cash equivalents as of December 31, 2024 will enable us to fund our operating expenses and planned long-term investments for at least the next 12 months after the date that the financial statements included in this report are issued. We have also financed our operations and investments with proceeds from debt incurred primarily from various banks both through our subsidiaries and the Parent Company of $1.0 billion at December 31, 2024. The majority of those debt obligations, or approximately $762.1 million, owed by BeiGene, Ltd., have due dates within the next 12 months. As of December 31, 2024, BeiGene, Ltd. will require loans or distributions from subsidiaries in fiscal year 2025 to fund its operations (see Note 10 in the Notes to the Financial Statements for further discussion of deferred taxes on the U.S. unremitted earnings expected to be distributed to the Parent Company). We believe we will have sufficient cash and cash equivalents and other sources of capital to be able to repay and/or refinance those debt obligations on a consolidated basis.

On December 15, 2021, we completed our initial public offering on the STAR Market of the Shanghai Stock Exchange (the "STAR Offering"). As required by the PRC securities laws, the net proceeds from the STAR Offering must be used in compliance with the planned uses as disclosed in the PRC prospectus as well as our proceeds management policy for the STAR Offering approved by our board of directors. As of December 31, 2024, the Company had cash remaining related to the STAR Offering proceeds of $0.6 billion.

The following table provides information regarding our cash flows for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	(in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	$ 3,185,984	$ 3,875,037
Net cash used in operating activities	(140,631)	(1,157,453)
Net cash (used in) provided by investing activities	(548,350)	60,004
Net cash provided by financing activities	193,449	416,478
Net effect of foreign exchange rate changes	(51,705)	(8,082)
Net decrease in cash, cash equivalents and restricted cash	(547,237)	(689,053)
Cash, cash equivalents and restricted cash at end of period	$ 2,638,747	$ 3,185,984

Operating Activities

Cash used in operating activities improved versus the prior year due to our significantly improved revenue and $1.1 billion increase in gross margin in the current year and a decrease in cash used to fund working capital, offset by continued funding of our development pipeline, and commercial operations to support our global expansion.

Investing Activities

Investing activities used $548.4 million of cash for the year ended December 31, 2024, compared to $60.0 million of cash provided in the prior year due primarily to a decrease in proceeds from sales and maturities of investment securities, partially offset by a decrease in capital expenditures.

Financing Activities

Financing activities provided $193.4 million of cash for the year ended December 31, 2024, compared to $416.5 million of cash provided in the prior year period due primarily to a net reduction in short-term debt borrowings.

Our borrowing and repayment cycle is dictated by the short-term maturities of our debt and the ability to increase our borrowings is dependent on interest rates, credit spreads, bank lending capacity and other factors. We expect to repay approximately $851.5 million of loans in 2025 and expect to be able to re-finance those on a consistent basis with our historical experience, with the cost of those borrowings depending on prevailing interest rates and credit spreads.

Effects of Exchange Rates on Cash

As noted above, we hold RMB denominated cash in our Parent Company (largely arising from the STAR Offering) and incur foreign currency gains or losses when remeasuring such cash to the U.S. dollar. In the year ended December 31, 2024, we incurred realized losses on cash of $16.5 million that is included in the reconciling items between net loss and net cash used in operating activities on the consolidated statements of cash flows primarily related to the remeasurement of RMB denominated cash to USD. The RMB denominated cash in our Parent Company, however, is required to be used to fund RMB denominated expenditures and thus foreign currency gains or losses on such cash does not affect our ability to fund those expenditures.

We also have substantial operations in China, where the functional currency is the RMB and as such the net cash flows are translated to the U.S. dollar for financial reporting. This process generates translation gains and losses on RMB-denominated cash held in China that are included in the effects of foreign exchange rate changes on the consolidated statements of cash flows, as such translation gains and losses are excluded from cash flows from operating, investing and financing activities.

Future Liquidity and Material Cash Requirements

Our material cash requirements in the short- and long-term consist of the following operational, capital, and manufacturing expenditures, a portion of which contain contractual or other obligations. We plan to fund our material cash requirements with cash on hand.

Contractual and Other Obligations

The following table summarizes our significant contractual obligations as of December 31, 2024:

		Payments Due by Period	
	Total	Short-term	Long-term
		(in thousands)	
Contractual obligations:			
Operating lease commitments	$ 68,534	$ 19,824	$ 48,710
Purchase commitments	131,944	110,423	21,521
Debt obligations	1,018,013	851,529	166,484
Interest on debt	55,230	39,856	15,374
Co-development funding commitment	335,261	225,251	110,010
Funding commitment	7,404	1,838	5,566
Pension plan	16,405	3,922	12,483
Capital commitments	48,347	48,347	—
Total	$ 1,681,138	$ 1,300,990	$ 380,148

Operating Lease Commitments

We lease office facilities in California, Massachusetts, Maryland, and New Jersey in the U.S.; Basel, Switzerland; and office or manufacturing facilities in Beijing, Shanghai, Suzhou and Guangzhou in China; 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, 2024, purchase commitments amounted to $131.9 million, of which $32.5 million related to minimum purchase requirements for supply purchased from CMOs and $99.4 million related to binding purchase order obligations of inventory from Amgen. We do not have any minimum purchase requirements for inventory from Amgen.

Debt Obligations and Interest

Total debt obligations coming due in the next twelve months are $851.5 million. Total long-term debt obligations are $166.5 million. We have numerous financial and non-financial covenants on our debt obligations with various banks and other lenders. Some of these covenants include default and/or cross-default provisions that could require acceleration of repayment of our loans in the event of default. However, our debt is primarily short-term in nature. Any acceleration would be a matter of months but may impact our ability to refinance our debt obligations if an event of default occurs. As of December 31, 2024, we are in compliance with all covenants of our material debt agreements. See above regarding Liquidity and Capital Resources and Note 12 in the Notes to the Financial Statements for further detail of our debt obligations.

Interest on bank loans 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 clinical development costs for the licensed oncology pipeline assets, up to a total cap of $1.25 billion. We are funding our portion of the co-development costs by contributing cash and/or development services. As of December 31, 2024, our remaining co-development funding commitment was $335.3 million.

Funding Commitment

Funding commitment represents our committed capital related to two of our equity method investments. As of December 31, 2024, our remaining capital commitment was $7.4 million and is expected to be paid from time to time over the investment period.

Pension Plan

We maintain a defined benefit pension plan in Switzerland that is collectively financed by employer and employee contributions. As of December 31, 2024, the plan was unfunded $16.4 million, with $3.9 million of employer contributions expected in 2025. The timing and amount of future long-term funding requirements will vary as a result of future changes in staffing and compensation levels, various actuarial assumptions and actual investment returns on plan assets. In the event of an underfunding, Switzerland pension foundations can levy additional contributions on the employer.

Capital Commitments

We had capital commitments amounting to $48.3 million for the acquisition of property, plant and equipment as of December 31, 2024, related to various facilities across the globe.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. 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.

Certain of these estimates are considered critical as they involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our consolidated financial statements. Our critical accounting estimates are summarized below. See Note 2 to our consolidated financial statements included in this Annual Report for a description of our significant accounting policies.

Revenue Recognition

We recognize revenue when we transfer control of goods or services to our customers. Revenue is measured as the amount of consideration we expect to receive in exchange for goods and services. We generate revenue from product sales and revenue transactions with our collaboration partners.

Product Revenue

To determine the appropriate transaction price for our product sales at the time we recognize a sale to a direct customer, we estimate any rebates, chargebacks or discounts that ultimately will be due to the direct customer and other customers in the distribution chain under the terms of our contracts. Significant judgments are required in making these estimates. 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.

Estimates for variable consideration for which reserves are established at the time of sale include government and commercial rebates, provisions for acceptance of NRDL pricing, chargebacks, trade discounts and allowances, sales returns allowances and other incentives that are offered within contracts between the Company and our 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, channel inventory levels, 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. To date, sales returns have not been significant.

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.

Collaboration Revenue

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. As part of the accounting for these arrangements, we must develop assumptions that require significant judgments to determine the standalone selling price for each performance obligation identified in the contract.

Standalone selling prices for licenses of intellectual property and the right to access and use intellectual property during an option period performance obligations are determined based on the probability-weighted present value of forecasted cash flows associated with the intellectual property. Stand-alone selling prices for research and development services performance obligations are based on the present value of estimated clinical trial costs plus a reasonable margin.

The estimates of standalone selling prices involve management's key assumptions such as revenue growth rate, estimated clinical trial costs, mark-up rate, probability of technical and regulatory success, and discount rates. These significant assumptions are forward looking and could be affected by future economic, regulatory and market conditions.

At December 31, 2024, our existing deferred revenue balance was less than $1.0 million, and collaboration revenue is not expected to be a significant driver of our financial results until if and when additional agreements are entered into.

Measurement of Accrued Research and Development Expenses

Clinical trial costs are a significant component of our research and development expenses and are recognized as the related services are incurred and measured at the cost expected to be paid for those services. As such, certain of our research and development expenses in any one period are an estimate by us as to the amount incurred for that period but not yet invoiced to us by the service provider. 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 not yet invoiced 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 probable.

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 differ from amounts ultimately paid in any one period. To date, we have not made any material adjustments to our prior estimates of research and development expenses.

Measurement of Deferred Tax Assets

Deferred tax assets represent amounts available to reduce income taxes payable on taxable income in future years. Such assets arise because of temporary differences between the financial reporting and tax basis of assets and liabilities, as well as from net operating losses and tax credit carryforwards. We evaluate the recoverability of these future tax deductions and credits by assessing the adequacy of future expected taxable income from all sources, including reversal of temporary differences, forecasted operating earnings and available tax planning strategies. These sources of income rely heavily on estimates that are based on a number of factors, including historical experience and short-range and long-range business forecasts. 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. Currently, we are in a three-year cumulative book loss position and as required by ASC 740, we provided a valuation allowance on all of our deferred tax assets.

Subsequent Measurement of Long-Lived Assets

We test long-lived assets, which include property, plant and equipment and intangible assets with finite useful lives, for impairment at least annually and whenever events or circumstances change that indicate impairment may have occurred. A significant amount of judgment is involved in determining if an indicator of impairment has occurred. Such indicators may include, among others and without limitation: a significant decline in our expected future cash flows; a sustained, significant decline in the trading prices of our ADSs, our ordinary shares, and/or our RMB Shares and market capitalization; a significant adverse change in legal factors or in the business climate; unanticipated competition; and slower growth rates. For the years ended December 31, 2024, 2023 and 2022, we determined there was no impairment of the value of our long-lived assets.

Recent Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Risk

We are exposed to risk related to changes in interest rates on our outstanding borrowings. We had $720.1 million of outstanding floating rate debt as of December 31, 2024. A 100-basis point increase in interest rates as of December 31, 2024 would increase our annual pre-tax interest expense by approximately $7.2 million.

Foreign Currency Exchange Rate Risk

China Exchange Rate Regime

RMB is not freely convertible into foreign currencies for capital account transactions. The State Administration of Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into foreign currencies. 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 depreciated approximately 2.8% for both the years ended December 31, 2024 and 2023, and depreciated approximately 8.2% for the year ended December 31, 2022, 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.

Transactional Risk

We are exposed to foreign exchange risk arising from various currency exposures when we enter into transactions denominated in foreign currencies. Our reporting currency is the U.S. dollar, and our most significant functional currencies are the U.S. dollar and the RMB. A portion of our operating transactions and monetary assets and liabilities are in currencies other than the U.S. dollar and RMB, primarily the U.S. dollar against the RMB, Euro, and Australian dollar. During the years ended December 31, 2024, 2023 and 2022, we recognized foreign exchange losses of $16.0 million, $64.8 million and $233.8 million, respectively, resulting from the strengthening of the U.S. dollar compared to the RMB and the revaluation impact of RMB-denominated deposits held in U.S. dollar functional currency entities, including the Parent Company. As of December 31, 2024, the Parent Company held RMB-denominated deposits of $220.4 million. A hypothetical 10% appreciation in the U.S. dollar exchange rate compared with the RMB as of December 31, 2024 would have resulted in an increase in foreign exchange loss of approximately $20.0 million.

Translational Risk

We also face foreign currency exposure that arises from translating the results of our global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period, primarily the RMB against the U.S. dollar. 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 reduce the effect of fluctuating currency exchange rates.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the year ended December 31, 2024.

Item 8. Financial Statements and Supplementary Data

BEIGENE, LTD.

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of BeiGene, Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BeiGene, Ltd. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 27, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Product Revenue, Net

Description of the Matter	At December 31, 2024, the Company recorded $286.3 million of accrued sales chargebacks, rebates, returns and other deductions. As discussed in Note 2 to the consolidated financial statements under the caption "Revenue Recognition", the Company recognizes revenue when the transfer of control of goods or services to the customer is completed. To determine the appropriate transaction price at the time revenue is recognized, the Company estimates variable consideration related to rebates, chargebacks, trade discounts and allowances, and other incentives that will ultimately be due to the customer and others in the distribution channel under the terms of their contracts. Where appropriate, these estimates take into consideration, among other items, the Company's historical experience, current contractual and statutory requirements, channel inventory levels, and forecasted customer buying and payment patterns. The Company recognizes revenue related to variable consideration to the extent it is probable that a significant revenue reversal will not occur and estimates variable consideration from rebates, chargebacks, trade discounts and allowances, and other incentives using the expected value method. Auditing the Company's accrued revenue rebates in the United States is challenging due to the extent of effort required to audit the significant number of United States-based rebate programs, as the terms vary by program and by customer. Additionally, due to the volume of rebates and third-party processes and the timing of invoicing received from vendors, the actual amounts incurred for all programs are not known at the time the financial statements are filed.
How We Addressed the Matter in Our Audit	We evaluated and tested the design and operating effectiveness of internal controls over the Company's process used in determining the measurement and completeness of accrued revenue rebates in the United States. This included testing controls over management's review of contractual rebates and other inputs used in the estimation of accrued revenue rebates in the United States, including but not limited to the Company's historical results, current contractual and statutory requirements, channel inventory levels, and forecasted customer buying and payment patterns. We tested controls over management's review of contractual terms, and total invoicing to date, as well as controls to ensure that the data used to evaluate and support the significant assumptions were complete, accurate, and, where applicable, verified to external data sources. To test the accrued revenue rebates in the United States, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in determining the accrued revenue rebates and evaluating the assumptions and inputs used by management. To evaluate the measurement and completeness of the accrual, we performed analytical procedures in combination with confirmations of a sample of the inventory remaining in the distribution channel at period end. We assessed the historical accuracy of management's accrued revenue rebates estimates by comparing prior period accrued revenue rebates to the amount of actual payments made in subsequent periods. We examined terms and conditions for a sample of contracts with the Company's customers and others in the distribution channel, tested a sample of credits issued and payments made throughout the year, and agreed rates to underlying contract terms. We performed independent calculations of the revenue rebate accruals using actual rebate invoicing and executed third-party contracts and assessed forecasted customer buying and payment patterns based on historical trends. Finally, we assessed subsequent events and subsequent period invoicing to determine whether there was any new information that would require adjustment to the accruals.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2022.

Boston, Massachusetts

February 27, 2025

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of BeiGene, Ltd.

Opinion on Internal Control Over Financial Reporting

We have audited BeiGene, Ltd.'s internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, BeiGene, Ltd. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated February 27, 2025 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's 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 generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts

February 27, 2025

BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS

(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)

		Year Ended December 31,		
	Note	2024	2023	2022
		$	$	$
Revenues				
Product revenue, net	13	3,779,546	2,189,852	1,254,612
Collaboration revenue	3	30,695	268,927	161,309
Total revenues		3,810,241	2,458,779	1,415,921
Cost of sales - product		594,089	379,920	286,475
Gross profit		3,216,152	2,078,859	1,129,446
Operating expenses				
Research and development		1,953,295	1,778,594	1,640,508
Selling, general and administrative		1,831,056	1,508,001	1,278,603
Total operating expenses		3,784,351	3,286,595	2,919,111
Loss from operations		(568,199)	(1,207,736)	(1,789,665)
Interest income, net		47,836	74,009	52,480
Other (expense) income, net	5	(12,638)	307,891	(223,852)
Loss before income taxes		(533,001)	(825,836)	(1,961,037)
Income tax expense	10	111,785	55,872	42,778
Net loss		(644,786)	(881,708)	(2,003,815)
Net loss per share	14	(0.47)	(0.65)	(1.49)
Weighted-average shares outstanding—basic and diluted	14	1,368,746,793	1,357,034,547	1,340,729,572
Net loss per American Depositary Share ("ADS")		(6.12)	(8.45)	(19.43)
Weighted-average ADSs outstanding—basic and diluted		105,288,215	104,387,273	103,133,044

The accompanying notes are an integral part of these consolidated financial statements.

BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)

		Year Ended December 31,		
	Note	2024	2023	2022
		$	$	$
Net loss		(644,786)	(881,708)	(2,003,815)
Other comprehensive (loss) income, net of tax of nil:				
Foreign currency translation adjustments	16	(47,565)	(25,464)	(90,421)
Pension liability adjustments, net	19	(1,942)	(5,611)	365
Unrealized holding (loss) gain, net	16	(35)	9,046	(5,311)
Comprehensive loss		(694,328)	(903,737)	(2,099,182)

The accompanying notes are an integral part of these consolidated financial statements.

BEIGENE, LTD.

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)

	Note	As of December 31, 2024	As of December 31, 2023
		$	$
Assets			
Current assets:			
Cash and cash equivalents		2,627,410	3,171,800
Accounts receivable, net		676,278	358,027
Inventories, net	6	494,986	416,122
Prepaid expenses and other current assets	11	192,919	257,465
Total current assets		3,991,593	4,203,414
Property, plant and equipment, net	8	1,578,423	1,324,154
Operating lease right-of-use assets	7	139,309	95,207
Intangible assets, net	9	51,095	57,138
Other non-current assets	11	160,490	125,362
Total non-current assets		1,929,317	1,601,861
Total assets		5,920,910	5,805,275
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		404,997	315,111
Accrued expenses and other payables	11	803,713	693,731
Tax payable	10	25,930	22,951
Operating lease liabilities, current portion	7	17,576	21,950
Research and development cost share liability, current portion	3	111,154	68,004
Short-term debt	12	851,529	688,366
Total current liabilities		2,214,899	1,810,113
Non-current liabilities:			
Long-term debt	12	166,484	197,618
Operating lease liabilities, non-current portion	7	44,277	22,251
Deferred tax liabilities	10	42,007	16,494
Research and development cost share liability, non-current portion	3	54,286	170,662
Other long-term liabilities	11	66,735	50,810
Total non-current liabilities		373,789	457,835
Total liabilities		2,588,688	2,267,948
Commitments and contingencies	20		
Shareholders' equity:			
Ordinary shares, 0.0001 par value per share; 9,500,000,000 shares authorized; 1,387,367,704 and 1,359,513,224 shares issued and outstanding as of December 31, 2024 and 2023, respectively		138	135
Additional paid-in capital		12,087,908	11,598,688
Accumulated other comprehensive loss	16	(148,988)	(99,446)
Accumulated deficit		(8,606,836)	(7,962,050)
Total shareholders' equity		3,332,222	3,537,327
Total liabilities and shareholders' equity		5,920,910	5,805,275

The accompanying notes are an integral part of these consolidated financial statements.

BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)

		Year Ended December 31,		
	Note	2024	2023	2022
		$	$	$
Cash flows from operating activities:				
Net loss		(644,786)	(881,708)	(2,003,815)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization expense		171,762	87,675	66,278
Share-based compensation expense	15	441,618	367,618	303,162
Acquired in-process research and development	3	60,000	46,800	68,665
Amortization of research and development cost share liability	3	(73,226)	(55,294)	(96,402)
Unrealized losses on long-term investments	5	24,022	16,221	21,996
Deferred income tax expense		25,983	689	2,059
Gain on BMS termination settlement		—	(362,917)	—
Other items, net		11,163	(5,998)	9,047
Changes in operating assets and liabilities:				
Accounts receivable		(329,443)	(188,306)	304,112
Inventories		(91,496)	(140,948)	(56,689)
Other assets		45,126	12,120	(3,282)
Accounts payable		121,497	21,484	(4,352)
Accrued expenses and other payables		111,354	180,111	45,627
Deferred revenue		633	(255,587)	(151,816)
Other liabilities		(14,838)	587	(1,209)
Net cash used in operating activities		(140,631)	(1,157,453)	(1,496,619)
Cash flows from investing activities:				
Purchases of property and equipment		(492,663)	(561,896)	(325,434)
Proceeds from sale or maturity of short-term investments		2,655	673,240	1,563,618
Purchase of in-process research and development		(31,800)	(15,000)	(143,665)
Purchase of intangible assets	9	(4,674)	(19,365)	—
Purchase of long-term investments	5	(19,006)	(14,900)	(15,911)
Other investing activities		(2,862)	(2,075)	(1,485)
Net cash (used in) provided by investing activities		(548,350)	60,004	1,077,123
Cash flows from financing activities:				
Proceeds from long-term loan	12	9,053	22,502	37,372
Repayment of long-term loan	12	(28,031)	(13,690)	—
Proceeds from short-term loans	12	868,270	661,530	313,774
Repayment of short-term loans	12	(704,216)	(309,576)	(417,081)
Proceeds from option exercises and employee share purchase plan		45,373	55,712	46,964
Other financing activities		3,000	—	—
Net cash provided by (used in) financing activities		193,449	416,478	(18,971)
Effect of foreign exchange rate changes, net		(51,705)	(8,082)	(69,383)
Net decrease in cash, cash equivalents, and restricted cash		(547,237)	(689,053)	(507,850)
Cash, cash equivalents, and restricted cash, beginning of year		3,185,984	3,875,037	4,382,887
Cash, cash equivalents, and restricted cash, end of year		2,638,747	3,185,984	3,875,037
Supplemental cash flow disclosures:				
Cash and cash equivalents		2,627,410	3,171,800	3,869,564
Short-term restricted cash		9,312	11,473	196
Long-term restricted cash		2,025	2,711	5,277
Income taxes paid		69,430	56,003	29,500
Interest paid		51,175	19,753	25,169
Supplemental non-cash activities:				
Accruals for capital expenditures		70,314	91,804	95,346
Purchase of in-process research and development included in accounts payable		60,000	31,800	—

The accompanying notes are an integral part of these consolidated financial statements.

BEIGENE, LTD.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(Amounts in thousands of U.S. Dollars ("$"), except for number of shares and per share data)

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Income/(Loss)	Accumulated Deficit	Total
	Shares	Amount				
		$	$	$	$	$
Balance at December 31, 2021	1,334,804,281	133	11,191,007	17,950	(5,076,527)	6,132,563
Cost from issuance of ordinary shares	—	—	(152)	—	—	(152)
Issuance of shares reserved for share option exercises	1,375,621	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	19,960,278	2	46,962	—	—	46,964
Share-based compensation	—	—	303,162	—	—	303,162
Other comprehensive loss	—	—	—	(95,367)	—	(95,367)
Net loss	—	—	—	—	(2,003,815)	(2,003,815)
Balance at December 31, 2022	1,356,140,180	135	11,540,979	(77,417)	(7,080,342)	4,383,355
Issuance of shares reserved for share option exercises	84,227	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	26,561,925	2	53,006	—	—	53,008
Cancellation of ordinary shares	(23,273,108)	(2)	(362,915)	—	—	(362,917)
Share-based compensation	—	—	367,618	—	—	367,618
Other comprehensive loss	—	—	—	(22,029)	—	(22,029)
Net loss	—	—	—	—	(881,708)	(881,708)
Balance at December 31, 2023	1,359,513,224	135	11,598,688	(99,446)	(7,962,050)	3,537,327
Use of shares reserved for share option exercises	(2,258,161)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	30,112,641	3	45,550	—	—	45,553
Deconsolidation of a subsidiary	—	—	2,052	—	—	2,052
Share-based compensation	—	—	441,618	—	—	441,618
Other comprehensive loss	—	—	—	(49,542)	—	(49,542)
Net loss	—	—	—	—	(644,786)	(644,786)
Balance at December 31, 2024	1,387,367,704	138	12,087,908	(148,988)	(8,606,836)	3,332,222

The accompanying notes are an integral part of these consolidated financial statements.

1. Description of Business

BeiGene, Ltd. (the "Company", "BeiGene", "it", "its") is a leading global oncology company discovering and developing innovative treatments that are more accessible and affordable to cancer patients worldwide. In 2024, the Company generated total global revenue of approximately $3.8 billion, increasing revenue by approximately $1.4 billion from the prior year, while reducing its operating loss from the prior year by approximately $0.6 billion.

Since its inception in 2010, the Company has become a fully integrated global organization with more than 11,000 employees worldwide.

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 ("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.

Use of Estimates

The preparation of the consolidated financial statements in conformity with 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, assessing the impairment of long-lived assets, valuation and recognition of share-based compensation expenses, 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.

Functional Currency and Foreign Currency Translation

Functional currency and foreign currency gains and losses

The Company uses the U.S. dollar ("$" or U.S. dollar) as its reporting currency. Transactions in subsidiaries are recorded in the functional currency of the respective subsidiary and such transactions denominated in currencies other than the functional currency give rise to foreign exchange remeasurement (monetary assets and liabilities) and related gains and losses that are classified in other (expense) income, net in the consolidated statement of operations. The determination of functional currency is based on the criteria of Accounting Standard Codification ("ASC") 830, *Foreign Currency Matters*. For those periods presented, the Company has not entered into any foreign currency derivative instruments to hedge its foreign currency positions.

Foreign currency translation

For subsidiaries whose functional currencies are not the U.S. dollar, the Company uses the average exchange rate for the period and the exchange rate at the balance sheet date to translate the operating results and financial position to the U.S. dollar, which is the Company's reporting currency. Translation differences are recorded in accumulated other comprehensive loss, a component of shareholders' equity.

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.

In addition to the restricted cash balances above, the Company is required by the PRC securities law to use the proceeds from the STAR offering in strict compliance with the planned uses as disclosed in the PRC offering prospectus as well as those disclosed in the Company's proceeds management policy approved by its board of directors.

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 costs 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 weighted average cost. 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 of future prices 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, convertible note instruments, 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.

- 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.

- Convertible note instruments are recorded using the fair value option method of accounting. Accordingly, convertible note instruments are remeasured at fair value on a recurring basis, with any changes in the fair value option recorded in other (expense) income, net.

- Public equity securities with readily determinable fair values are recorded at fair value. Subsequent changes in fair value are recorded in other (expense) 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 (expense) 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 (expense) 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 (expense) 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 allowance for credit losses were recorded for any periods presented. The Company recognized an impairment loss of $7,635 and $7,529 related to its investments in equity during the years ended December 31, 2024 and 2023, respectively. No impairment losses on equity investments were recorded for the year ended December 31, 2022.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation and amortization. Property, plant and equipment, other than land and construction in progress, are depreciated 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

The Company periodically evaluates whether events and circumstances have occurred that indicate the estimated useful lives of its long-lived assets may require reassessment.

Leases

The Company applies ASC, Topic 842, *Leases* ("ASC 842") to account for its leases. 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, 2024. 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.

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. As of December 31, 2024, the Company held land use rights in the following regions:

	Terms
Guangzhou	50 years
Beijing	36 years
Suzhou	30 years
Shanghai	47 years

Intangible Assets

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. Intangible assets associated with milestone payments made to third parties subsequent to regulatory approval are recorded at cost. Identifiable intangible assets consist of post-approval milestone payments under license and commercialization agreements, that are amortized over the remainder of the product patent or the term of the commercialization agreements; and trading licenses that are amortized over the initial license term.

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, 2024, 2023 and 2022, the Company determined that there were no indicators of impairment of its other intangible assets.

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, 2024, 2023 and 2022, 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.

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, 2024 and 2023:

As of December 31, 2024	Quoted Price in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	$	$	$
Cash equivalents:			
Money market funds	950,704	—	—
Prepaid expenses and other current assets:			
Convertible debt instrument	—	—	618
Other non-current assets:			
Equity securities with readily determinable fair values	2,113	168	—
Convertible debt instrument	—	—	4,616
Total	952,817	168	5,234

As of December 31, 2023	Quoted Price in Active Market for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
	$	$	$
Cash equivalents			
Money market funds	1,052,149	—	—
Prepaid expenses and other current assets:			
U.S. Treasury securities	2,600	—	—
Convertible debt instrument	—	—	4,668
Other non-current assets:			
Equity securities with readily determinable fair values	3,046	542	—
Convertible debt instrument	—	—	4,215
Total	1,057,795	542	8,883

The Company's cash equivalents are highly liquid investments with original maturities of 3 months or less. The Company's investments in U.S. Treasury securities are classified as 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"), a publicly-traded biotechnology company. The common stock investment is measured and carried at fair value and classified as a Level 1 investment. The warrants to purchase additional shares of common stock are measured using the Black-Scholes option-pricing valuation model and classified as a Level 2 investment. Refer to Note 5, *Investments* for details of the determination of the carrying amount of private equity investments without readily determinable fair values and equity method investments.

The Company holds convertible notes issued by private biotech companies. The Company has elected the fair value option method of accounting for the convertible notes. Accordingly, the convertible notes are remeasured at fair value on a recurring basis using Level 3 inputs, with any changes in the fair value option recorded in other (expense) income, net. The Company recorded losses on fair value adjustments of $4,842 and $1,492 for the years ended December 31, 2024 and 2023, respectively. There was no fair value adjustment during the year ended December 31, 2022.

There were no transfers of instruments between levels of valuation categories during the years ended December 31, 2024 and 2023.

As of December 31, 2024 and 2023, the Company held time deposits of nil and $42,852, respectively, that were classified as cash equivalents. As of December 31, 2024 and 2023, 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 debt approximates its 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

The Company applies ASC, Topic 606, *Revenue from Contracts with Customers* ("ASC 606") to account for its revenue transactions.

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, 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

In the U.S. and EU, the Company generates product revenues from the sale of BRUKINSA® and TEVIMBRA®. In China, the Company generates product revenues from the sale of its internally developed drugs TEVIMBRA, BRUKINSA and PARTRUVIX®, and the sale of in-licensed products through its agreements with Amgen, BMS, Bio-Thera, EUSA Pharma and Luye Pharmaceutical. 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 U.S., the Company distributes its products through specialty pharmacies and specialty distributors. The specialty pharmacies and specialty distributors subsequently resell the product to health care providers and patients. In the EU, the Company distributes its products through distributors or directly to hospitals. In China, the Company sells its internally developed products to multiple distributors, who in turn sell 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.

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 30-90 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.

Estimates for variable consideration for which reserves are established at the time of sale include government and commercial rebates, provisions for acceptance of National Reimbursement Drug List ("NRDL") pricing in the PRC, chargebacks, trade discounts and allowances, sales returns allowances and other incentives that are offered within contracts between the Company and its 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 the Company's historical experience, current contractual and statutory requirements, channel inventory levels, 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. 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.

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.

Options to License Intellectual Property: Upfront non-refundable payments for options to license the Company's intellectual property are evaluated to determine if the option represents a material right and is distinct from the other performance obligations identified in the arrangement. For options determined to be a material right and distinct, the Company defers the non-refundable up-front fees allocated to the option and recognizes revenues at a point in time, at the earlier of when the option is exercised or the option period expires.

Right to Access Intellectual Property during the Option Period: The portion of a transaction price allocated to the other parties right to access the Company's intellectual property to generate their own data during an option period is deferred and recognized as collaboration revenue over the option period on a straight-line basis as the right to use the intellectual property is provided and the data generated.

Research and Development Services: The portion of a 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.

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.

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

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 (prior to government approval), 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 income upon receipt. During the years ended December 31, 2024, 2023 and 2022, the Company recognized other income of $22,326, $23,989, and $32,540, respectively, for government grants received after the related expenses have been incurred.

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. The Company received government assistance in the form of cash primarily to support the Guangzhou manufacturing facility build-out and research and development programs.

Government assistance received to support the Guangzhou manufacturing facility build-out is recognized as other long-term liabilities and amortized over the same useful lives of the related assets as depreciation expense. As of December 31, 2024 and 2023, other long-term liabilities related to the Guangzhou manufacturing facility build-out totaled $30,235 and $34,084, respectively. For the years ended December 31, 2024, 2023 and 2022, depreciation expense is presented net of amortization of government assistance of $3,053, $2,938 and $3,169, respectively.

Government assistance received to support research and development programs is recorded as other long-term liabilities upon receipt and recognized as other income when the associated research and development programs are completed. As of December 31, 2024 and 2023, other long-term liabilities related to research and development programs totaled $89 and $120, respectively. For the years ended December 31, 2022, the Company recognized other income of $1,664 upon the completion of a designated research and development program. No income was recognized during the years ended December 31, 2024 and 2023 related to grants received for research and development programs.

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.

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.

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

Basic 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.

Diluted loss per share, when required, 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, if any, using the if-converted method, and ordinary shares issuable upon the conversion of the share options, and unvested restricted shares units and performance-based restricted shares units ("PSUs"), using the treasury stock method. The dilutive effects of PSUs are included in the weighted average common share calculation based on the cumulative achievement against the performance targets only when the performance targets have been achieved as of the end of the reporting period.

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 cash and credit risk

Financial instruments that are potentially subject to credit risk consist of cash and cash equivalents and accounts receivable.

As of December 31, 2024 and 2023, $2,627,410 and $3,171,800 were deposited with various major reputable financial institutions located in the U.S., PRC and other international financial institutions. 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, 2024 and 2023, the Company had accounts receivable, net of $676,278 and $358,027, respectively. Accounts receivable, net represent amounts arising from product sales. The Company monitors economic conditions to identify facts or circumstances that may indicate receivables are at risk of collection.

Customer concentration risk

For the year ended December 31, 2024, sales to the Company's three largest product distributors, ASD Specialty Healthcare, McKesson and Shanghai Pharmaceutical represented approximately 18.0%, 16.9% and 11.1% of product revenue, respectively, and collectively, represented approximately 51.0% of trade accounts receivable as of December 31, 2024.

For the year ended December 31, 2023, sales to the Company's four largest product distributors, Sinopharm, Shanghai Pharmaceutical, ASD Specialty Healthcare and China Resources represented approximately 16.0%, 14.2%, 12.4% and 11.4% of product revenue, respectively, and collectively, represented approximately 53.2% of trade accounts receivable as of December 31, 2023. For the year ended December 31, 2023, the Company's collaboration revenue consisted entirely of revenue recognized under its out-licensing collaboration agreements with Novartis.

Recent Accounting Pronouncements

New accounting standards which have been adopted

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting* (Topic 280): Improvements to Reportable Segment Disclosures. This update requires disclosure of incremental segment information on an annual and interim basis. This update is effective for annual periods beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024. Early adoption is permitted. This guidance should be applied retrospectively to all prior periods presented in the financial statements. The Company operates in one segment. 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 adopted ASU 2023-07 effective December 31, 2024. Refer to Footnote 21 for segment related disclosures.

New accounting standards which have not yet been adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): Disaggregation of Income Statement Expenses. This update requires that at each interim and annual reporting period public entities disclose (1) the amounts of purchases of inventory, employee compensation, depreciation, amortization, and depletion) in commonly presented expense captions; (2) certain amounts that are already required to be disclosed under current GAAP in the same disclosure as the other disaggregation requirements; (3) a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively; and (4) the total amount of selling expenses and, in annual reporting periods, the definition of selling expenses. In January 2025, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures* (Subtopic 220-40): Clarifying the Effective Date. This update clarifies that ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes* (Topic 740): Improvements to Income Tax Disclosures. This update requires that public entities on an annual basis, (1) in the rate reconciliation, disclose specific categories and provide additional information for reconciling items that meet a quantitative threshold; (2) about income taxes paid, disclose the amount of income taxes paid (net of refunds received) disaggregated by federal, state, and foreign taxes and by individual jurisdiction in which income taxes paid (net of refunds received) is equal to or greater than 5 percent of total income taxes paid (net of refunds received); and (3) disclose income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign and income tax expense (or benefit) disaggregated by federal, state, and foreign. This update is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. This guidance should be applied on a prospective basis. Retrospective application is permitted. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

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 and options to out-license 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

During the three years ended December 31, 2024, the Company's collaboration revenue related to its out-licensing collaborative agreements has consisted of research and development services revenue and right to access intellectual property revenue from its former collaboration agreements with Novartis for tislelizumab and ociperlimab. Other collaboration revenue consists primarily of revenue under the Novartis broad markets agreement and, beginning in 2024, royalty revenue under the Amgen collaboration agreement.

The following table summarizes total collaboration revenue recognized for the years ended December 31, 2024, 2023 and 2022:

	Year Ended December 31,		
	2024	2023	2022
Revenue from Collaborators	$	$	$
Research and development service revenue	—	79,431	46,822
Right to access intellectual property revenue	—	104,477	104,994
Material rights revenue	—	71,980	—
Other	30,695	13,039	9,493
Total	30,695	268,927	161,309

Novartis

Tislelizumab Collaboration and License

In January 2021, the Company entered into a collaboration and license agreement with Novartis, granting Novartis rights to develop, manufacture and commercialize tislelizumab in North America, Europe, and Japan (the "Novartis Territory"). The Company and Novartis 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 had the ability to 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 received an upfront cash payment of $650,000 from Novartis. A portion of the transaction price was allocated to the R&D services to be performed under the agreement and deferred and was being recognized as collaboration revenue as the R&D services were performed using a percentage-of-completion method.

In September 2023, the Company and Novartis agreed to mutually terminate the collaboration and license agreement, effective immediately. Pursuant to the termination agreement, the Company regained full, global rights to develop, manufacture and commercialize tislelizumab with no royalty payments due to Novartis. Novartis may continue its ongoing clinical trials and has the ability to conduct future combination trials with tislelizumab subject to BeiGene's approval. BeiGene agreed to provide Novartis with ongoing clinical supply of tislelizumab to support its clinical trials. Pursuant to the termination agreement, Novartis agreed to provide transition services to the Company to enable key aspects of the tislelizumab development and commercialization plan to proceed without disruption, including manufacturing, regulatory, safety and clinical support. Upon termination of the agreement in September 2023, there were no further performance obligations, and the remaining deferred revenue balance associated with the tislelizumab R&D services was recognized in full.

The following table summarizes collaboration revenue recognized in connection with the tislelizumab collaboration and license agreement for the years ended December 31, 2024, 2023 and 2022:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Research and development service revenue	—	72,278	39,655
Other [1]	2,113	5,067	9,493
Total	2,113	77,345	49,148

[1] Represents revenue recognized on sale of tislelizumab clinical supply to Novartis in conjunction with the collaboration.

Ociperlimab Option, Collaboration and License Agreement and China Broad Market Development Agreement

In December 2021, the Company expanded its collaboration with Novartis by entering into an option, collaboration and license agreement with Novartis to develop, manufacture and commercialize the Company's investigational TIGIT inhibitor ociperlimab in the Novartis Territory. In addition, the Company and Novartis entered into an agreement granting the Company rights to market, promote and detail five approved Novartis oncology products, TAFINLAR® (dabrafenib), MEKINIST® (trametinib), VOTRIENT® (pazopanib), AFINITOR® (everolimus), and ZYKADIA® (ceritinib), across designated regions of China referred to as "broad markets." In the first quarter of 2022, the Company initiated marketing and promotion of these five products.

Under the terms of the option, collaboration and license agreement, the Company received an upfront cash payment of $300,000. At inception, a portion of the upfront cash payment was deferred related to performance obligations to be satisfied at a later point in time or over time.

In July 2023, the Company and Novartis mutually agreed to terminate the ociperlimab option, collaboration and license agreement, effective immediately. Pursuant to the termination agreement, the Company regained full, global rights to develop, manufacture and commercialize ociperlimab. Upon termination the Company had no further performance obligations under the collaboration, and all remaining deferred revenue balances were recognized in full. The China broad markets agreement remains in place.

The following table summarizes collaboration revenue recognized in connection with the ociperlimab option, collaboration and license agreement for the years ended December 31, 2024, 2023 and 2022:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Research and development service revenue	—	7,153	7,167
Right to access intellectual property revenue	—	104,477	104,994
Material rights revenue	—	71,980	—
Other [2]	18,259	8,859	—
Total	18,259	192,469	112,161

[2] Represents revenue generated under the broad markets marketing and promotion agreement in conjunction with the collaboration.

In-Licensing Arrangements - Commercial

Amgen

In October 2019, the Company entered into a global strategic oncology collaboration with Amgen ("Amgen Collaboration Agreement") for the commercialization and development in China, excluding Hong Kong, Taiwan and Macau, 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. The agreement became effective on January 2, 2020, following approval by the Company's shareholders and satisfaction of other closing conditions.

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 the products globally and supplying the products to the Company at an agreed upon price. The Company and Amgen 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.

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 $1,250,000. 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 LUMAKRAS (sotorasib) ("AMG 510"), Amgen's 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 AMG 510).

On April 20, 2022, the parties entered into the First Amendment to Amgen Collaboration Agreement, which amends certain terms and conditions relating to the financial responsibilities of the parties in connections with the development and commercialization of certain Amgen proprietary products for the treatment of oncology-related diseases and conditions. In connection with the Company's ongoing assessment of the Amgen Collaboration Agreement cost-share contributions, the Company determined that further investment in the development of LUMAKRAS was no longer commercially viable for BeiGene. As a result, in February 2023, the Company and Amgen entered into the Second Amendment to the Amgen Collaboration Agreement to (i) stop sharing costs with Amgen for the further development of LUMAKRAS during the period starting January 1, 2023 and ending August 31, 2023; and (ii) cooperate in good faith to prepare a transition plan with the termination of LUMAKRAS from the Amgen Collaboration Agreement.

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 $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 Anthony Hooper joined the Company's board of directors as the Amgen designee in January 2020. Amgen relinquished its right to appoint a designated director to the Company's board of directors in January 2023.

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 $132.74 per ADS, or $2,109,902 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 $601,857 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 $2,779,241 were allocated based on the relative fair value method, with $2,162,407 recorded to equity and $616,834 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 Company's portion of the co-development funding on the pipeline assets for the years ended December 31, 2024, 2023 and 2022 were as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
BeiGene's portion of the development funding	148,391	108,608	195,357
Less: Amortization of research and development cost share liability	73,226	55,294	96,402
Research and development expense	75,165	53,314	98,955

	As of December 31, 2024
Remaining portion of development funding cap	335,261

As of December 31, 2024 and 2023, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of December 31,	
	2024	2023
	$	$
Research and development cost share liability, current portion	111,154	68,004
Research and development cost share liability, non-current portion	54,286	170,662
Total research and development cost share liability	165,440	238,666

The net reimbursement paid under the commercial profit-sharing agreement for in-line product sales is classified in the consolidated statements of operations for the three years ended December 31, 2024 as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Cost of sales - product	37,150	8,358	5,898
Selling, general and administrative	(83,674)	(60,917)	(54,865)
Research and development	(2,438)	1,688	(1,216)
Total	(48,962)	(50,871)	(50,183)

The Company purchases commercial inventory from Amgen to distribute in China. Total inventory purchases amounted to $247,655, $108,691 and $71,720, respectively, during the year ended December 31, 2024, 2023 and 2022. Net amounts payable to Amgen as of December 31, 2024 and 2023 were $116,563 and $55,474, respectively.

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.

Upfront and milestone payments made under these arrangements for the years ended December 31, 2024, 2023 and 2022 are set forth below. All upfront and development milestones were expensed to research and development expense. All regulatory and commercial milestones were capitalized as intangible assets and are being amortized over the remainder of the respective product patent or the term of the commercialization agreements.

		Year Ended December 31,		
		2024	2023	2022
Payments due to collaboration partners	Classification	$	$	$
Upfront payments	Research and development expense	60,027	46,800	68,665
Development milestone payments	Research and development expense	54,000	—	5,500
Regulatory and commercial milestone payments	Intangible asset	—	24,365	—
Total		114,027	71,165	74,165

The Company has entered into a number of in-licensing collaborative arrangements during the years ended December 31, 2024, 2023 and 2022. A summary of amounts incurred under these arrangements is included above. 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.

4. Restricted Cash

The Company's restricted cash 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. Restricted cash as of December 31, 2024 and 2023 was as follows:

	As of December 31,	
	2024	2023
	$	$
Short-term restricted cash	9,312	11,473
Long-term restricted cash	2,025	2,711
Total	11,337	14,184

In addition to the restricted cash balances above, the Company is required by the PRC securities law to use the proceeds from the STAR Offering in strict compliance with the planned uses as disclosed in the PRC offering prospectus as well as those disclosed in the Company's proceeds management policy approved by the board of directors. As of December 31, 2024, the Company had cash remaining related to the STAR Offering proceeds of $588,235.

5. Investments

The following table summarizes the Company's investments in equity securities:

	As of December 31,	
	2024	2023
	$	$
Equity securities with readily determinable fair values [1]		
Fair value of Leap common stock	2,113	3,046
Fair value of Leap warrants	168	542
Equity securities without readily determinable fair values		
Pi Health, Inc. [2]	40,798	—
Other	48,157	55,860
Equity-method investments	33,081	25,981
Total	124,317	85,429

[1] Represents common stock and warrants to purchase additional shares of common stock of Leap. The Company measures the investment in the common stock and warrants at fair value, with changes in fair value recorded to other (expense) income, net.

[2] In the first quarter of 2024, the Company divested the net assets comprising substantially all of its Pi Health business with a carrying value of $38,063. The consideration received for the divestiture consisted of preferred stock in a newly formed entity, Pi Health, Inc., with a fair value of $40,798 and cash consideration of $1,000. The transaction resulted in a pre-tax gain of $3,735 recorded within other (expense) income, net during year ended December 31, 2024. The Company will account for its investment prospectively as a private equity security without a readily determinable fair value and the divestiture is not treated as a discontinued operation in the Statement of Operations and therefore the historical results of operations of the Pi Health business will remain in the Company's continuing operations.

The following table summarizes unrealized (losses) gains related to investments in equity securities recorded in other (expense) income, net:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Equity securities with readily determinable fair values	(1,307)	(425)	(30,102)
Equity securities without readily determinable fair values	(7,596)	(6,448)	5,065
Equity-method investments	(10,275)	(7,856)	(3,682)

6. Inventories, Net

The Company's inventories, net consisted of the following:

	As of December 31,	
	2024	2023
	$	$
Raw materials	170,584	148,772
Work in process	60,118	39,098
Finished goods	264,284	228,252
Total inventories, net	494,986	416,122

7. Leases

The Company has operating leases for office and manufacturing facilities in the U.S., Switzerland, and China. The leases have remaining lease terms of up to six 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, the land acquired for the Company's research, development and office facility in Changping, Beijing, the land acquired for the Company's research, development and manufacturing facility in Suzhou, and the land acquired for the Company's research and development facility in Shanghai. The Company also has certain leases with terms of 12 months or less for certain equipment, office and lab space, which are expensed and not recorded on the balance sheet.

The components of lease expense were as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Operating lease cost	26,575	25,978	25,938
Variable lease cost	4,580	6,101	6,834
Short-term lease cost	2,897	1,683	1,299
Total lease cost	34,052	33,762	34,071

Supplemental balance sheet information related to leases was as follows:

	As of December 31,	
	2024	2023
	$	$
Operating lease right-of-use assets	60,639	43,490
Land use rights, net	78,670	51,717
Total operating lease right-of-use assets	139,309	95,207
Current portion of operating lease liabilities	17,576	21,950
Operating lease liabilities, non-current portion	44,277	22,251
Total lease liabilities	61,853	44,201

Maturities of operating lease liabilities are as follows:

	Amounts
	$
Year ending December 31, 2025	19,824
Year ending December 31, 2026	13,279
Year ending December 31, 2027	12,583
Year ending December 31, 2028	11,738
Year ending December 31, 2029	7,188
Thereafter	3,922
Total lease payments	68,534
Less imputed interest	(6,681)
Present value of lease liabilities	61,853

Other supplemental information related to leases is summarized below:

	Year ended December 31,		
	2024	2023	2022
	$	$	$
Operating cash flows used in operating leases	56,005	27,985	28,064
ROU assets obtained in exchange for new operating lease liabilities	47,066	11,854	22,278

	As of December 31,	
	2024	2023
Weighted-average remaining lease term (years)	4	3
Weighted-average discount rate	5.23 %	7.22 %

8. Property, Plant and Equipment, Net

Property, plant and equipment, net are recorded at cost less accumulated depreciation and consisted of the following:

	As of December 31,	
	2024	2023
	$	$
Land	65,485	65,485
Building	607,857	231,656
Manufacturing equipment	244,255	186,856
Laboratory equipment	240,885	205,349
Software, electronics and office equipment	100,348	83,281
Leasehold improvements	64,680	60,124
Property and equipment, at cost	1,323,510	832,751
Less: Accumulated depreciation	(399,105)	(249,212)
Construction in progress	654,018	740,615
Property, plant and equipment, net	1,578,423	1,324,154

The Company has made a significant investment in its newly opened manufacturing and R&D center in Hopewell, New Jersey. In the year ended December 31, 2024, $272,670 of assets were placed into service. As of December 31, 2024, the Company had construction in progress of $500,900 related to the Hopewell facility, the majority of which will be put into service in 2025.

In March 2024, the Company acquired a land use right and the facility currently being constructed on the land for $73,054. The Company plans to complete the construction of the facility and build a research and development center on the land. Based on the relative fair values of the land use right and construction in progress, $29,431 of the total purchase price was allocated to the land use right and $43,623 was allocated to the construction in progress. In May 2024, the Company acquired additional construction in progress in connection with the properties for $22,538.

Construction in progress ("CIP") as of December 31, 2024 and 2023 primarily related to the Hopewell facility, the new research and development facility acquired in 2024, a new building for Beijing Innerway Bio-tech Co., Ltd., and additional capacity at the Guangzhou and Suzhou manufacturing facilities. CIP by fixed asset class are summarized as follows:

	As of December 31,	
	2024	2023
	$	$
Building	528,629	579,649
Manufacturing equipment	89,897	119,380
Laboratory equipment	9,805	16,135
Other	25,687	25,451
Total	654,018	740,615

Depreciation expense for the years ended December 31, 2024, 2023 and 2022 were $166,938, $80,436 and $62,302, respectively. Included within depreciation expense for the year ended December 31, 2024 is $59,792 of accelerated depreciation expense resulting from the move of production to more efficient, larger scale equipment for tislelizumab.

9. Intangible Assets

Intangible assets as of December 31, 2024 and 2023 are summarized as follows:

	December 31, 2024			December 31, 2023		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
	$	$	$	$	$	$
Finite-lived intangible assets:						
Developed products	62,889	(12,370)	50,519	64,274	(7,807)	56,467
Other	8,987	(8,411)	576	8,987	(8,316)	671
Total finite-lived intangible assets	71,876	(20,781)	51,095	73,261	(16,123)	57,138

Developed products represent post-approval milestone payments under license and commercialization agreements. The Company is amortizing the developed products over the remainder of the respective product patent or the term of the commercialization agreements.

Amortization expense for developed products is included in cost of sales-product in the accompanying consolidated statements of operations. Amortization expense for other intangible assets is included in selling, general and administrative expense in the accompanying consolidated statements of operations. The weighted-average life for each finite-lived intangible assets is approximately 11 years. Amortization expense is as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Amortization expense - Cost of sales - product	4,729	3,739	3,225
Amortization expense - Selling, general and administrative	95	3,500	751
Total	4,824	7,239	3,976

Estimated amortization expense for each of the five succeeding years and thereafter, as of December 31, 2024 is as follows:

Year Ending December 31,	Cost of Sales - Product	Selling, General and Administrative Expense	Total
	$		
2025	4,682	67	4,749
2026	4,682	67	4,749
2027	4,682	67	4,749
2028	4,682	67	4,749
2029	4,682	67	4,749
2030 and thereafter	27,109	241	27,350
Total	50,519	576	51,095

10. Income Taxes

The components of income (loss) before income taxes are as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
U.S.	201,516	117,446	67,744
PRC	(263,159)	(315,852)	(583,610)
Other	(471,358)	(627,430)	(1,445,171)
Total	(533,001)	(825,836)	(1,961,037)

The current and deferred components of the income tax expense (benefit) from continuing operations are as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Current tax expense (benefit)			
U.S.	57,222	25,170	4,844
PRC	12,331	24,956	27,905
Other	16,225	5,059	6,547
Total	85,778	55,185	39,296
Deferred tax expense (benefit)			
U.S.	23,556	—	—
PRC	180	687	3,480
Other	2,271	—	2
Total	26,007	687	3,482
Income tax expense (benefit)	111,785	55,872	42,778

The reconciliation of the statutory tax rate to our effective income tax rate is as follow:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Loss before tax	(533,001)	(825,836)	(1,961,037)
U.S. statutory tax rate	21 %	21 %	21 %
Expected taxation at U.S. statutory tax rate	(111,930)	(173,426)	(411,818)
Foreign and preferential tax rate differential	93,741	144,310	209,384
Non-deductible expenses	1,130	19,134	29,223
Stock compensation expenses	53,446	32,581	33,872
State tax expense (benefit)	(7,988)	(5,872)	1,683
Change in valuation allowance	157,286	845,811	229,550
Tax relief credits	—	(704,928)	—
Research tax credits and incentives	(43,602)	(64,343)	(42,844)
Deductible research expenses	(13,644)	—	—
Tax on unremitted earnings	23,743	—	—
Foreign-derived intangible income	(40,397)	(37,395)	(6,272)
Taxation for the year	111,785	55,872	42,778
Effective tax rate	(21.0)%	(6.8)%	(2.2)%

Significant components of deferred tax assets (liabilities) are as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Accruals and reserves	121,549	106,708	97,896
Net operating losses carryforward	1,137,890	996,588	862,214
Stock-based compensation	38,397	26,687	19,700
Research tax credits	34,561	68,117	86,000
Tax relief credits	704,928	704,928	—
Intangible asset amortization	1,081,442	699,974	813,043
Lease liability obligation	11,882	7,893	10,348
R&D and other capitalized costs	277,061	164,190	63,156
Total gross deferred tax assets	3,407,710	2,775,085	1,952,357
Less valuation allowance	(3,403,505)	(2,771,470)	(1,943,775)
Net deferred tax assets	4,205	3,615	8,582
Property, plant and equipment, net	(10,795)	(12,374)	(14,480)
Tax on unremitted earnings	(23,735)	—	—
Right of use asset	(11,682)	(7,735)	(10,098)
Total gross deferred tax liabilities	(46,212)	(20,109)	(24,578)
Net deferred tax assets/(liabilities)	(42,007)	(16,494)	(15,996)

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, 2024, it is more likely than not that net deferred tax assets will not be realized. Adjustments may 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.

The valuation allowances for the years ended December 31, 2024, 2023 and 2022 were as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Beginning balance, as of January 1	2,771,470	1,943,775	1,758,409
Additions/(subtractions) charged to income tax provision	157,286	845,811	229,550
Additions/(subtractions) charged to equity	497,823	—	—
Currency translation and other	(23,074)	(18,116)	(44,184)
Ending balance, as of December 31	3,403,505	2,771,470	1,943,775

As of December 31, 2024 and 2023, the Company had net operating losses of approximately $6,720,659 and $5,945,753, respectively. As of December 31, 2024, net operating losses were primarily comprised of: $2,185,546 from entities in the PRC which expire in years 2025 through 2034; and $4,526,020 derived from Switzerland which expires in years 2025 through 2031. The Company has approximately $43,677 of U.S. research tax credits which will expire between 2036 and 2044 and approximately $704,928 of Switzerland tax relief credits which will expire in 2028, if not utilized.

The gross unrecognized tax benefits for the years ended December 31, 2024, 2023 and 2022 were as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Beginning balance, as of January 1	14,264	11,555	9,925
Additions based on tax positions related to prior tax years	—	—	—
Reductions based on tax positions related to prior tax years	—	—	—
Additions based on tax positions related to the current tax year	2,975	2,709	1,630
Reductions based on lapse of statute of limitations	—	—	—
Ending balance, as of December 31	17,239	14,264	11,555

Current and prior year additions include assessment of U.S. federal and state tax credits and incentives. As of December 31, 2024, the Company had $17,239 of unrecognized tax benefits substantially all of which, if recognized, would reduce the effective tax rate. 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, 2024, 2023 and 2022, the Company's accrued interest and penalties, where applicable, related to uncertain tax positions were not material.

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, 2024, Australia tax matters are open to examination for the years 2013 through 2024, China tax matters are open to examination for the years 2014 through 2024, Switzerland tax matters are open to examination for the years 2021 through 2024, and U.S. federal tax matters are open to examination for years 2015 through 2024. Various U.S. states and other non-US tax jurisdictions in which the Company files tax returns remain open to examination for 2014 through 2024.

The Company qualifies for the Technology Advanced Service Enterprises and High and New Technology Enterprise status for certain subsidiaries in China, which begin to expire at the end of 2025. The income tax benefits attributable to this status for the year ended December 31, 2024 is approximately $4,631, or less than $0.01 per share outstanding.

During 2024, the Company concluded that a portion of earnings from certain subsidiaries, primarily in the U.S. and Canada, are no longer indefinitely reinvested. As a result, the Company recognized a deferred tax liability of $23,735. The Company continues to assert that earnings in other jurisdictions remain permanently reinvested.

11. Supplemental Balance Sheet Information

Prepaid expenses and other current assets consist of the following:

	As of December 31,	
	2024	2023
	$	$
Prepaid research and development costs	64,277	60,476
Prepaid taxes	23,792	37,320
Other receivables	32,828	37,859
Prepaid general and administrative expenses	21,253	14,619
Prepaid manufacturing cost	19,333	42,066
Short-term restricted cash	9,312	11,473
Prepaid insurance	6,242	8,872
Other current assets	15,882	44,780
Total	192,919	257,465

Other non-current assets consist of the following:

	As of December 31,	
	2024	2023
	$	$
Long-term investments	128,933	89,644
Prepaid supply cost	12,249	18,122
Rental deposits and other	8,481	8,195
Prepayment of property and equipment	5,927	4,144
Prepaid VAT	2,875	2,546
Long-term restricted cash	2,025	2,711
Total	160,490	125,362

Accrued expenses and other payables consisted of the following:

	As of December 31,	
	2024	2023
	$	$
Compensation related	248,348	217,803
Sales rebates and returns related	235,600	139,936
External research and development activities related	154,269	162,969
Commercial activities	77,530	87,572
Accrued general and administrative expenses	31,106	36,203
Individual income tax and other taxes	34,904	30,083
Other	21,956	19,165
Total	803,713	693,731

Other long-term liabilities consist of the following:

	As of December 31,	
	2024	2023
	$	$
Deferred government grant income	30,324	34,204
Pension liability	16,405	14,995
Asset retirement obligation	3,794	1,127
Other	16,212	484
Total	66,735	50,810

12. Debt

The following table summarizes the Company's short-term and long-term debt obligations as of December 31, 2024 and 2023:

Lender	Borrower	Line of Credit	Term	Maturity Date	Interest Rate	As of December 31,			
						2024		2023	
						$	RMB	$	RMB
China Construction Bank	BeiGene Guangzhou Biologics Manufacturing Co., Ltd.	RMB580,000	9-year	June 11, 2027	1	16,440	120,000	14,089	100,000
China Merchants Bank	BeiGene Guangzhou Biologics Manufacturing Co., Ltd.	RMB350,000	9-year	January 20, 2029	2	8,611	62,857	8,856	62,857
China Merchants Bank	BeiGene Guangzhou Biologics Manufacturing Co., Ltd.	RMB378,000	9-year	November 8, 2029	3	8,148	59,475	5,636	40,000
China CITIC Bank	BeiGene (Suzhou) Co., Ltd.	RMB480,000	10-year	July 28, 2032	4	1,384	10,100	—	—
China Merchants Bank	BeiGene, Ltd.	$380,000	1-year	5		380,000	2,773,723	300,000	2,129,321
China Minsheng Bank	BeiGene, Ltd.	$150,000	1-year	December 16, 2025	6.8%	150,000	1,094,891	150,000	1,064,660
China Industrial Bank	BeiGene, Ltd.	RMB675,000	364-days	March 27, 2025	6	92,475	675,000	—	—
China Merchants Bank	BeiGene Guangzhou Biologics Manufacturing Co., Ltd.	RMB400,000	1-year	June 5, 2025	3.0%	54,800	400,000	56,356	400,000
HSBC Bank	BeiGene, Ltd.	RMB340,000	1-year	May 5, 2025	7	46,580	340,000	47,903	340,000
China Industrial Bank	BeiGene (Suzhou) Co., Ltd.	RMB200,000	1-year	May 29, 2024	2.8%	—	—	28,177	200,000
Shanghai Pudong Development Bank	BeiGene, Ltd.	RMB700,000	1-year	November 24, 2025	2.9%	93,091	679,492	49,312	350,000
China Merchants Bank	BeiGene (Suzhou) Co., Ltd.	RMB200,000	1-year	May 24, 2024	3.2%	—	—	28,037	199,000
Total short-term debt						851,529	6,215,538	688,366	4,885,838
China Construction Bank	BeiGene Guangzhou Biologics Manufacturing Co., Ltd.	RMB580,000	9-year	June 11, 2027	1	41,100	300,000	59,174	420,000
China Merchants Bank	BeiGene Guangzhou Biologics Manufacturing Co., Ltd.	RMB350,000	9-year	January 20, 2029	2	27,987	204,286	37,638	267,143
China Merchants Bank	BeiGene Guangzhou Biologics Manufacturing Co., Ltd.	RMB378,000	9-year	November 8, 2029	3	33,020	241,025	42,337	300,500
China CITIC Bank	BeiGene (Suzhou) Co., Ltd.	RMB480,000	10-year	July 28, 2032	4	64,377	469,900	58,469	415,000
Total long-term debt						166,484	1,215,211	197,618	1,402,643

1. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 4.2% as of December 31, 2024. The Company repaid $13,739 (or RMB100,000) during the year ended December 31, 2024. The loan is secured by BeiGene Guangzhou Biologics Manufacturing Co., Ltd.'s property ownership certificate and fixed assets.

2. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.7% as of December 31, 2024. The Company repaid $8,730 (RMB62,857) during the year ended December 31, 2024. The loan is secured by Guangzhou Factory's second land use right and certain fixed assets.

3. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.8% as of December 31, 2024. The Company repaid $5,562 (RMB40,000) during the year ended December 31, 2024. 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.

4. The outstanding borrowings bear a floating interest rate benchmarked against prevailing interest rates of certain PRC financial institutions. The loan interest rate was 3.7% as of December 31, 2024. The Company drew down $9,053 (RMB65,000) during the year ended December 31, 2024. The loan is secured by BeiGene (Suzhou) Co., Ltd.'s property ownership certificate of the small molecule manufacturing campus in Suzhou, China.

5. The outstanding borrowings bear floating interest rates benchmarking the secured overnight financing rate. The loan interest rate was 6.2% as of December 31, 2024. $80,000 of the borrowing matures on January 27, 2025, and $300,000 matures on December 17, 2025.

6. The outstanding borrowings bear floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 2.6% as of December 31, 2024.

7. The outstanding borrowings bear floating interest rates benchmarking Hong Kong interbank market rate for RMB. The loan interest rate was 4.4% as of December 31, 2024.

The Company has numerous financial and non-financial covenants on its debt obligations with various banks and other lenders. Some of these covenants include default and/or cross-default provisions that could require acceleration of repayment of loans in the event of default. However, the Company's debt is primarily short-term in nature. Any acceleration would be a matter of months but may impact the Company's ability to refinance debt obligations if an event of default occurs. As of December 31, 2024, the Company is in compliance with all covenants of our material debt agreements.

Contractual Maturities of Debt Obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2024 are as follows:

Maturity dates	Amounts
	$
Year ending December 31, 2025	851,529
Year ending December 31, 2026	46,207
Year ending December 31, 2027	46,207
Year ending December 31, 2028	25,657
Year ending December 31, 2029	19,657
Thereafter	28,756
Total	1,018,013

Interest Expense

Interest on bank loans is paid quarterly until the respective loans are fully settled. Interest expense recognized for the years ended December 31, 2024, 2023 and 2022 amounted to $46,894, $20,800 and $21,699, respectively, among which, $32,158, $16,571 and $2,594 was capitalized, respectively. Interest paid for the years ended December 31, 2024, 2023 and 2022, net of amounts capitalized, amounted to $19,723, $3,484 and $22,489, respectively.

13. Product Revenue

The Company's product revenue is primarily derived from the sale of its internally developed products BRUKINSA and TEVIMBRA in the U.S., China, and other regions; XGEVA, BLINCYTO and KYPROLIS in China under a license from Amgen; REVLIMID® and VIDAZA® in China under a license from BMS; and POBEVCY® in China under a license from Bio-Thera.

The table below presents the Company's net product sales for the years ended December 31, 2024, 2023 and 2022.

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Product revenue - gross	4,786,744	2,718,969	1,438,440
Less: Rebates and sales returns	(1,007,198)	(529,117)	(183,828)
Product revenue - net	3,779,546	2,189,852	1,254,612

The following table disaggregates net product revenue by product for the years ended December 31, 2024, 2023 and 2022.

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
BRUKINSA®	2,644,226	1,290,396	564,651
Tislelizumab	620,836	536,620	422,885
XGEVA®	224,403	92,828	63,398
BLINCYTO®	74,331	54,342	36,107
KYPROLIS®	66,171	39,799	13,696
POBEVCY®	53,509	56,547	38,124
REVLIMID®	36,028	76,018	79,049
Other	60,042	43,302	36,702
Total product revenue - net	3,779,546	2,189,852	1,254,612

The following table presents the roll-forward of accrued sales chargebacks, rebates, returns and other deductions for the years ended December 31, 2024 and 2023.

	Rebates, Returns and Other Deductions	Contra AR Accruals	Total
	$	$	
Balance at December 31, 2022	41,817	8,580	50,397
Amounts charged against product revenue	275,031	254,086	529,117
Payments and credits	(176,912)	(232,231)	(409,143)
Balance at December 31, 2023	139,936	30,435	170,371
Amounts charged against product revenue	491,756	515,442	1,007,198
Payments and credits	(396,092)	(495,178)	(891,270)
Balance at December 31, 2024	235,600	50,699	286,299

14. Loss Per Share

Loss per share was calculated as follows:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Numerator:			
Net loss	(644,786)	(881,708)	(2,003,815)
Denominator:			
Weighted average shares outstanding for computing basic and diluted loss per share	1,368,746,793	1,357,034,547	1,340,729,572
Loss per share	(0.47)	(0.65)	(1.49)

For the years ended December 31, 2024, 2023 and 2022, 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, 2024, 2023 and 2022.

15. Share-Based Compensation

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, 2024, ordinary shares cancelled or forfeited under the 2011 Plan that were carried over to the 2016 Plan totaled 5,166,900. 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 the Hong Kong Stock Exchange ("HKEx") rules. In December 2018, the shareholders of the Company 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, 2024, share-based awards to acquire 83,064,175 ordinary shares were available for future grant under the 2016 Plan.

In order to continue to provide incentive opportunities under the 2016 Plan, the Board of Directors and shareholders of the Company approved an amendment to the 2016 Plan (the "Amendment No. 2"), which became effective as of June 22, 2022, to increase the number of authorized shares available for issuance under the 2016 Plan by 66,300,000 ordinary shares, or 5%, of the Company's outstanding shares as of March 31, 2022. In June 2024, the shareholders approved a third amended and restated 2016 Plan to increase the number of shares authorized for issuance by 92,820,000.

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 HKEx, the board of directors of the Company approved an amended and restated 2018 Plan to implement changes required by the HKEx rules.

Upon the effectiveness of Amendment No. 2 to the 2016 Plan, on June 22, 2022, the 2018 Plan was terminated to the effect that no new equity awards shall be granted under the plan but the outstanding equity awards under the plan shall continue to vest and/or be exercisable in accordance with their terms.

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 HKEx rules. In December 2018, the shareholders of the Company 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. In June 2024, the shareholders of the Company approved a fourth amended and restated ESPP to increase the number of shares authorized for issuance by 5,070,000 ordinary shares to 12,425,315 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.

The following tables summarizes the shares issued under the ESPP:

		Market Price[1]		Purchase Price[2]		
Issuance Date	Number of Ordinary Shares Issued	ADS	Ordinary	ADS	Ordinary	Proceeds
August 31, 2024	1,035,996	$ 165.20	$ 12.69	$ 140.27	$ 10.78	$ 11,178
February 29, 2024	1,021,397	$ 165.65	$ 12.74	$ 140.80	$ 10.83	$ 11,063
August 31, 2023	794,144	$ 207.55	$ 15.97	$ 176.42	$ 13.57	$ 10,777
February 28, 2023	930,582	$ 171.10	$ 13.16	$ 145.44	$ 11.19	$ 10,414
August 31, 2022	861,315	$ 171.66	$ 13.20	$ 145.91	$ 11.22	$ 9,667
February 28, 2022	667,160	$ 210.52	$ 16.19	$ 178.94	$ 13.76	$ 9,183

[1] The market price is the lower of the closing price on Nasdaq 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, 2024, 4,953,682 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.

The following table summarizes the Company's share option activities under the 2011, 2016 and 2018 Plans:

	Number of Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
		$	$	Years	$
Outstanding at December 31, 2021	72,204,888	7.08			
Granted	12,516,816	12.34	6.40		
Exercised	(5,898,217)	4.63			52,258
Forfeited	(2,296,634)	16.46			
Outstanding at December 31, 2022	76,526,853	7.85			
Granted	9,817,925	16.37	8.14		
Exercised	(6,974,331)	4.54			92,051
Forfeited	(1,225,334)	17.60			
Outstanding at December 31, 2023	78,145,113	9.06			
Granted	9,180,301	12.53	6.62		
Exercised	(6,812,624)	3.87			69,946
Forfeited	(2,530,134)	15.87			
Outstanding at December 31, 2024	77,982,656	9.70		4.83	429,581
Exercisable as of December 31, 2024	60,173,280	8.42		3.7	406,868
Vested and expected to vest at December 31, 2024	75,311,250	9.55		4.7	426,174

As of December 31, 2024, the unrecognized compensation cost related to 15,137,970 unvested share options expected to vest was $82,424. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.4 years.

The total fair value of employee share option awards vested during the years ended December 31, 2024, 2023 and 2022 was $68,420, $61,121 and $62,548, respectively.

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 is used in conjunction with 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,		
	2024	2023	2022
Fair value of ordinary share	$5.72 ~ $9.19	$7.26 ~ $10.72	$5.51 ~ $9.04
Risk-free interest rate	3.8% ~ 4.6%	3.4% ~ 4.6%	1.8% ~ 3.9%
Expected exercise multiple	2.8	2.8	2.8
Expected volatility	57% ~ 58%	58% ~ 60%	51% ~ 60%
Expected dividend yield	0%	0%	0%
Contractual life	10 years	10 years	10 years

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
		$
Outstanding at December 31, 2021	36,082,982	18.33
Granted	38,707,669	12.46
Vested	(12,533,586)	16.37
Forfeited	(6,859,892)	16.72
Outstanding at December 31, 2022	55,397,173	14.87
Granted	34,573,994	15.57
Vested	(17,862,598)	14.71
Forfeited	(5,707,546)	15.47
Outstanding at December 31, 2023	66,401,023	15.22
Granted	49,693,592	12.53
Vested	(21,251,477)	15.53
Forfeited	(9,012,471)	14.46
Outstanding at December 31, 2024	85,830,667	13.67
Expected to vest at December 31, 2024	72,956,067	13.67

As of December 31, 2024, the unrecognized compensation cost related to unvested restricted share units expected to vest was $801,403. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.7 years.

Share-based compensation expense

The following table summarizes total share-based compensation cost recognized for the years ended December 31, 2024, 2023 and 2022:

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Research and development	186,113	163,550	139,348
Selling, general and administrative	255,680	204,038	163,814
Total	441,793	367,588	303,162

16. Accumulated Other Comprehensive (Loss) Income

The movement of accumulated other comprehensive (loss) income was as follows:

	Foreign Currency Translation Adjustments	Unrealized Gains/Losses on Available-for-Sale Securities	Pension Liability Adjustments	Total
	$	$	$	$
December 31, 2022	(62,523)	(9,011)	(5,883)	(77,417)
Other comprehensive income (loss) before reclassifications	(25,464)	9,046	(6,422)	(22,840)
Amounts reclassified from accumulated other comprehensive loss [1]	—	—	811	811
Net-current period other comprehensive (loss) income	(25,464)	9,046	(5,611)	(22,029)
December 31, 2023	(87,987)	35	(11,494)	(99,446)
Other comprehensive loss before reclassifications	(47,565)	(35)	(2,753)	(50,353)
Amounts reclassified from accumulated other comprehensive loss [1]	—	—	811	811
Net-current period other comprehensive loss	(47,565)	(35)	(1,942)	(49,542)
December 31, 2024	(135,552)	—	(13,436)	(148,988)

[1] The amounts reclassified from accumulated other comprehensive (loss) income were included in other (expense) income, net in the consolidated statements of operations.

17. Shareholders' Equity

During the years ended December 31, 2024, 2023 and 2022, the Company completed the following equity transactions:

BMS Settlement

On August 1, 2023, the Company entered into a Settlement and Termination Agreement (the "Settlement Agreement") with BMS-Celgene and certain of its affiliates relating to the termination of the parties' ongoing contractual relationships, the previously-disclosed ongoing arbitration proceeding concerning ABRAXANE® (the "Arbitration"), the License and Supply Agreement ("LSA"), the Amended and Restated Quality Agreement (the "QA"), and the Share Subscription Agreement (the "SSA"), entered into by the parties in 2017 and 2018. Pursuant to the Settlement Agreement, the parties agreed to mutually dismiss the Arbitration and BMS-Celgene and its affiliates agreed to transfer 23,273,108 ordinary shares of the Company originally purchased in 2017, in each case subject to and in accordance with the terms and conditions of the Settlement Agreement. In consideration for the shares being returned, the Company agreed to drop its claims pursuant to the Settlement Agreement. Furthermore, the parties agreed to terminate the LSA and QA on December 31, 2023, subject to the Company's right to continue selling all inventory of REVLIMID and VIDAZA until sold out or February 2025, whichever is earlier. The Settlement Agreement provides for a settlement and release by each party of claims arising from or relating to the Arbitration, the LSA, the QA and the SSA, as well as other disputes and potential disputes between the parties, in each case subject to and in accordance with the terms and conditions of the Agreement. The receipt of the shares occurred on August 15, 2023. The Company recorded a noncash gain upon receipt of $362,917, which represents the fair value on the day the shares were received. The gain was recorded within other (expense) income, net in the consolidated statements of operations. The shares were constructively retired during the year ended December 31, 2023. The Company recorded the amount of the cancelled shares in excess of par to additional paid-in capital.

18. 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, 2024, 2023 and 2022, no appropriation to statutory reserves was made, because the PRC subsidiaries had an accumulated deficit as of the end of 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, 2024 and 2023, amounts restricted were the net assets of the Company's PRC subsidiaries, which, after intercompany eliminations, amounted to $1,709,961 and $2,114,277, respectively.

19. 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 $101,779, $94,358 and $83,860 for the years ended December 31, 2024, 2023 and 2022, 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 or Roth basis. In addition, the Company has a matching contribution to the 401(k) Plan, which, in the 2024 plan year, matched dollar for dollar of eligible contributions up to 6%. Company contributions to the 401(k) Plan totaled $20,839, $15,316 and $10,298 in the years ended December 31, 2024, 2023 and 2022, 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 $3,825, $2,710, and $3,887 in the years ended December 31, 2024, 2023 and 2022, respectively.

Company contributions into defined contribution plans for the remaining subsidiaries were immaterial.

Defined Benefit Plan

The Company 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, 2024 and 2023, the projected benefit obligations under the Swiss Plan were approximately $80,199 and $70,600, respectively, and plan assets were approximately $63,794 and $55,605, respectively. The funded status of the Swiss Plan is included in other long-term liabilities in the accompanying consolidated balance sheets.

The Company's annual contribution to the Swiss Plan is estimated to be approximately $3,922 in 2025 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 in the following 10 years and have been estimated based on the same assumptions used to measure the Company's benefit obligations as of December 31, 2024:

	Amounts
	$
Year ending December 31, 2025	692
Year ending December 31, 2026	604
Year ending December 31, 2027	994
Year ending December 31, 2028	593
Year ending December 31, 2029	1,922
Thereafter	8,657
Total	13,462

20. Commitments and Contingencies

Purchase Commitments

As of December 31, 2024, the Company had purchase commitments amounting to $131,944, of which $32,538 related to minimum purchase requirements for supply purchased from contract manufacturing organizations and $99,406 related to binding purchase order obligations of inventory from Amgen. The Company does not have any minimum purchase requirements for inventory from Amgen.

Capital Commitments

The Company had capital commitments amounting to $48,347 for the acquisition of property, plant and equipment as of December 31, 2024 related to various facilities across the globe.

Co-Development Funding Commitment

Under the Amgen Collaboration Agreement, the Company is responsible for co-funding global clinical development costs for the Amgen oncology pipeline assets up to a total cap of $1,250,000. The Company is funding its portion of the co-development costs by contributing cash and/or development services. As of December 31, 2024, the Company's remaining co-development funding commitment was $335,261.

Funding Commitment

The Company had committed capital related to two equity method investments in the amount of $15,053. As of December 31, 2024, the remaining capital commitment was $7,404 and is expected to be paid from time to time over the investment period.

Other Business Agreements

The Company enters into agreements in the ordinary course of business with contract research organizations ("CROs") to provide research and development services. These contracts are generally cancellable 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.

21. Segment and Geographic Information

Operating segments are defined as components of an enterprise for which separate financial information is available and evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. 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 primary measure of segment profitability for the Company's operating segment is considered to be consolidated net loss. Significant segment expenses reviewed by the CODM on a regular basis included within net loss include cost of product sales, research and development expenses and selling, general and administrative expenses which are separately presented on the Company's Consolidated Statements of Operations. Other segment items within net loss include interest income, net, other (expense) income, net and income tax expense.

The Company's long-lived assets are primarily located in the U.S. and China.

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,		
	2024	2023	2022
	$	$	$
U.S. - total revenue	**1,957,498**	**1,128,219**	**502,626**
Product revenue	1,950,530	945,551	389,710
Collaboration revenue	6,968	182,668	112,916
China- total revenue	**1,411,307**	**1,101,951**	**840,032**
Product revenue	1,390,699	1,093,091	840,032
Collaboration revenue	20,608	8,860	—
Europe- total revenue	**362,626**	**202,014**	**63,257**
Product revenue	359,507	122,228	14,864
Collaboration revenue	3,119	79,786	48,393
Rest of world- total revenue	**78,810**	**26,595**	**10,006**
Product revenue	78,810	28,982	10,006
Collaboration revenue	—	(2,387)	—
Total Revenue	**3,810,241**	**2,458,779**	**1,415,921**

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Based on their evaluation, required by paragraph (b) of Rules 13a-15 or 15d-15, promulgated under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act are effective, at a reasonable assurance level, as of December 31, 2024, to ensure that information required to be disclosed in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in U.S. Securities and Exchange Commission rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and management necessarily was required to apply its judgment in designing and evaluating the controls and procedures.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). 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. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness 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. Based on our assessment and those criteria, management concluded that we maintained effective internal control over financial reporting as of December 31, 2024.

The effectiveness of our internal control over financial reporting as of December 31, 2024, has been tested by Ernst & Young LLP, our independent registered public accounting firm, as stated in their report which is included in "Item 8—Financial Statements and Other Supplementary Data" in this Annual Report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the three months ended December 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

(a)

Not applicable.

(b)

There were no trading arrangements for the purchase or sale of our securities entered into, modified or terminated by our directors or officers during the fourth quarter of 2024.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

On March 30, 2022, the SEC added us to its conclusive list of issuers identified under the HFCAA following the filing of our annual report on Form 10-K with the SEC on February 28, 2022, which annual report was audited by Ernst & Young Hua Ming LLP, a registered public accounting firm in mainland China that the PCAOB previously was unable to inspect or investigate completely, because of a position taken by an authority in the foreign jurisdiction. However, as our global business has expanded, we have evaluated, designed and implemented business processes and control changes and built substantial organizational capabilities outside of China. Therefore, on March 23, 2022, following a review process carried out by our audit committee, Ernst & Young Hua Ming LLP resigned as our independent registered public accounting firm for the audit of our financial statements and internal control over financial reporting to be filed with the SEC. On the same day, our audit committee approved the engagement of Ernst & Young LLP, located in Boston, Massachusetts, U.S., as the Company's independent registered public accounting firm for the audit of our financial statements and internal control over financial reporting commencing for the fiscal year ending December 31, 2022. Given that Ernst & Young LLP (U.S.) now serves as the principal accountant to audit our consolidated financial statements, we are able to comply with the HFCAA and certify that we have retained a registered public accounting firm that the PCAOB has determined it is able to inspect or investigate which would preclude a further finding by the SEC that we are a Commission-Identified Issuer.

In December 2022, the PCAOB announced that it has secured complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong and confirmed that until such time as the PCAOB issues any new determination, there are no Commission-Identified Issuers at risk of having their securities subject to a trading prohibition under the HFCAA.

To the extent known by the Company, the Company is not aware of and has no reason to believe that any governmental entity in the foreign jurisdiction in which the Company is incorporated or otherwise organized owns shares of any capital stock of record of the Company. Furthermore, to the extent known by the Company, the Company is not aware of and has no reason to believe that that any government entity in the foreign jurisdiction where its consolidated foreign operating entities are incorporated or otherwise organized owns shares of any capital stock of record of its consolidated foreign operating entities. The Company has determined that no governmental entity in China has a controlling financial interest in the Company or its consolidated foreign operating entities. To the extent known by the Company, the Company is not aware of and has no reason to believe that any official of the Chinese Communist Party is a board member of the Company or its consolidated foreign operating entities. The articles of incorporation of the Company, as amended, and those of its consolidated foreign operating entities, do not contain any wording received from any charter of the Chinese Communist Party.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

Item 11. Executive Compensation

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

Item 14. Principal Accountant Fees and Services

Our independent public accounting firm is Ernst & Young LLP (PCAOB ID: 0042), located in Boston, Massachusetts, U.S.

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, which proxy statement will be filed with the U.S. Securities and Exchange Commission not later than 120 days after the close of our fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The financial statements listed in the Index to Consolidated Financial Statements beginning on page 130 are filed as part of this Annual Report.

We have included Additional Financial Information of Parent Company - Financial Statements Schedule I for the years ended December 31, 2024, 2023 and 2022 on page 181. No other financial statement schedules have been filed as part of this report because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

The exhibits filed as part of this Annual Report are set forth on the Exhibit Index immediately following our consolidated financial statements. The Exhibit Index is incorporated herein by reference.

Schedule I - Condensed Financial Information of Registrant

BeiGene, Ltd.
Financial Information of Parent Company
Condensed Statements of Operations
(Amounts in thousands of U.S. Dollars ("$"))

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Operating expenses			
Research and development	353,903	326,560	637,152
Selling, general and administrative	357,103	304,543	228,801
Total operating expenses	711,006	631,103	865,953
Loss from operations	(711,006)	(631,103)	(865,953)
Interest income, net	3,101	48,982	39,585
Other income (expense), net	63,522	(297,856)	(1,173,306)
Loss before income taxes	(644,383)	(879,977)	(1,999,674)
Income tax expense	403	1,731	4,141
Net loss	(644,786)	(881,708)	(2,003,815)

BeiGene, Ltd.
Financial Information of Parent Company
Condensed Statements of Comprehensive Loss
(Amounts in thousands of U.S. Dollars ("$"))

	Year Ended December 31,		
	2024	2023	2022
	$	$	$
Net loss	(644,786)	(881,708)	(2,003,815)
Other comprehensive (loss) income, net of tax of nil:			
Foreign currency translation adjustments	(47,565)	(25,464)	(90,421)
Pension liability adjustments, net	(1,942)	(5,611)	365
Unrealized holding gain (loss), net	(35)	9,046	(5,311)
Comprehensive loss	(694,328)	(903,737)	(2,099,182)

BeiGene, Ltd.
Financial Information of Parent Company
Condensed Balance Sheets
(Amounts in thousands of U.S. Dollars ("$"))

	As of December 31,	
	2024	2023
	$	$
Assets		
Current assets:		
Cash and cash equivalents	400,135	723,964
Prepaid expenses and other current assets	249,016	785,471
Total current assets	649,151	1,509,435
Loans to subsidiaries	1,731,266	2,030,249
Investment in wholly owned subsidiaries	2,081,335	1,207,352
Other non-current assets	114,728	69,361
Total assets	4,576,480	4,816,397
Liabilities and shareholders' equity		
Current liabilities:		
Accrued expenses and other payables	424,111	197,289
Indebtedness to subsidiaries	—	362,917
Short-term debt	762,146	547,215
Total current liabilities	1,186,257	1,107,421
Other long-term liabilities	58,000	171,649
Total liabilities	1,244,257	1,279,070
Total shareholders' equity	3,332,223	3,537,327
Total liabilities and shareholders' equity	4,576,480	4,816,397

BeiGene, Ltd.
Financial Information of Parent Company
Condensed Statements of Cash Flows
(Amounts in thousands of U.S. Dollars ("$"))

	Year Ended December 31,		
	2024	**2023**	**2022**
	$	**$**	**$**
Cash flows from operating activities:			
Net loss	(644,786)	(881,708)	(2,003,815)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	—	15,000	—
Amortization of research and development cost share liability	(73,226)	(55,294)	(96,402)
Unrealized (gains) losses in subsidiaries	(85,471)	237,351	932,071
Other items, net	31,651	(374,370)	(596,496)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	1,053	30,519	6,671
Accrued expenses and other payables	627,307	(140,126)	875,826
Net cash used in operating activities	(143,472)	(1,168,628)	(882,145)
Cash flows from investing activities:			
Purchases of short-term investments	—	(2,075)	(1,485)
Proceeds from sale or maturity of short-term investments	2,628	552,000	1,487,028
Purchase of in-process research and development	—	(15,000)	(75,000)
Investment in subsidiaries	(406,624)	(883,328)	(2,675,908)
Other investing activities	(37,120)	188,656	79,004
Net cash used in investing activities	(441,116)	(159,747)	(1,186,361)
Cash flows from financing activities:			
Proceeds from short-term loans	813,058	547,842	296,188
Repayment of short-term loans	(593,898)	(293,002)	(247,460)
Proceeds from option exercises and employee share purchase plan	45,371	55,712	46,965
Net cash provided by financing activities	264,531	310,552	95,693
Effect of foreign exchange rate changes, net	(4,356)	—	—
Net decrease in cash, cash equivalents, and restricted cash	(324,413)	(1,017,823)	(1,972,813)
Cash, cash equivalents, and restricted cash, beginning of year	724,548	1,742,371	3,715,184
Cash, cash equivalents, and restricted cash, end of year	400,135	724,548	1,742,371

Notes

1. Schedule I has been provided pursuant to the requirements of Rules 12-04(a) and 5-04(c) of Regulation S-X (the "Rules"), which require condensed financial information as to the financial position, changes in financial position and results of operations of a parent company as of the same dates and for the same periods for which audited consolidated financial statements have been presented when the restricted net assets of consolidated subsidiaries exceed 25 percent of consolidated net assets as of the end of the most recently completed fiscal year.

2. The condensed financial information has been prepared using the same accounting policies as set out in the consolidated financial statements. For purposes of this condensed financial information, BeiGene, Ltd. (the "Parent Company")'s investments in its wholly owned and majority owned subsidiaries are recorded under the equity method of accounting in accordance with ASC 323.

3. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted as allowed under the Rules. These footnote disclosures provide certain supplemental information relating to the operations of the Company and, as such, these statements should be read in conjunction with the notes to the consolidated financial statements.

4. As of December 31, 2024, the Parent Company had a remaining capital commitment of $7,350 on an equity investment which is expected to be paid from time to time over the investment period. The Parent Company has unconditionally guaranteed the payment and performance of the obligations of BeiGene Switzerland GmbH in accordance with the terms of the global strategic oncology collaboration with Amgen Inc. No amounts have been recognized related to this guarantee. The Parent Company has no other material contingencies, long-term obligations or guarantees not already disclosed in its consolidated financial statements.

Item 16. Form 10-K Summary

Not applicable.

Exhibit Index

Exhibit No.		Exhibit Description	Filed/ Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
3.1		Seventh Amended and Restated Memorandum and Articles of Association of the Registrant, as currently in effect		8-K (Exhibit 3.1)	6/15/2023	001-37686
4.1	.1	Deposit Agreement dated February 5, 2016 by and among the Company, the Depositary and holders of the American Depositary Receipts		8-K (Exhibit 4.1)	2/11/2016	001-37686
	.2	Amendment No. 1 to Deposit Agreement, dated April 11, 2016, by and among the Registrant, Citibank, N.A. and holders of the American Depositary Receipts		8-K (Exhibit 4.1)	4/11/2016	001-37686
	.3	Letter Agreement, dated as of July 11, 2016, between the Registrant and Citibank, N.A.		10-Q (Exhibit 4.7)	8/10/2016	001-37686
	.4	Form of Letter Agreement between the Registrant and Citibank, N.A.		10-Q (Exhibit 4.9)	5/10/2017	001-37686
4.2		Form of American Depositary Receipt (included in Exhibit 4.1.1)				
4.3		Specimen Certificate for Ordinary Shares		S-1 (Exhibit 4.3)	12/9/2015	333-207459
4.4	.1	Registration Rights Agreement, dated as of November 16, 2016, by and among the Registrant and the investors named therein		8-K (Exhibit 4.1)	11/17/2016	001-37686
	.2	Amendment No. 1 to Registration Rights Agreement, dated December 1, 2020, between the Company and the Investors		8-K (Exhibit 10.1)	12/2/2020	001-37686
	.3	Amendment No. 2 to Registration Rights Agreement, dated May 3, 2023, between the Company and the Investors		10-Q (Exhibit 10.3)	5/4/2023	001-37686
4.5		Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	X			
Collaboration, License and Commercial Agreements						
10.1		Share Subscription Agreement, dated July 5, 2017, by and between Celgene Switzerland LLC and the Registrant		8-K (Exhibit 10.1)	7/6/2017	001-37686
10.2##		Letter Agreement, dated June 14, 2019, by and among the Registrant, BeiGene Switzerland GmbH, Celgene Corporation and Celgene Switzerland LLC, to terminate the Amended and Restated Exclusive License and Collaboration Agreement, dated August 31, 2017		10-Q (Exhibit 10.1)	8/8/2019	001-37686
10.3	.1##	Share Purchase Agreement, dated October 31, 2019, by and between the Registrant and Amgen Inc.		10-K (Exhibit 10.9)	3/2/2020	001-37686
	.2	Amendment No. 1 to Share Purchase Agreement, dated December 6, 2019, by and between the Registrant and Amgen Inc.		10-K (Exhibit 10.10)	3/2/2020	001-37686
	.3	Restated Amendment No. 2 to Share Purchase Agreement, dated September 24, 2020, by and between the Registrant and Amgen Inc.		8-K (Exhibit 10.1)	9/24/2020	001-37686

Exhibit No.		Exhibit Description	Filed/ Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
	.4	Amendment No. 3 to Share Purchase Agreement, dated January 30, 2023, by and between the Registrant and Amgen Inc.		10-K (Exhibit 10.4.4)	2/27/2023	001-37686
10.4	.1##	Collaboration Agreement, dated October 31, 2019, by and among the Registrant, BeiGene Switzerland GmbH and Amgen Inc.		10-K (Exhibit 10.11)	3/2/2020	001-37686
	.2##	First Amendment to Collaboration Agreement, dated April 20, 2022, by and among the Registrant, BeiGene Switzerland GmbH and Amgen Inc.		10-Q (Exhibit 10.1)	8/8/2022	001-37686
	.3##	Second Amendment to Collaboration Agreement, dated February 26, 2023, by and among the Registrant, BeiGene Switzerland GmbH and Amgen Inc.		10-Q (Exhibit 10.1)	5/4/2023	001-37686
10.5		Guarantee, dated October 31, 2019, by and between the Registrant and Amgen Inc.		10-K (Exhibit 10.12)	3/2/2020	001-37686
Equity and Other Compensation Plans						
10.6†		2011 Option Plan, as amended and form of option agreements thereunder		S-1 (Exhibit 10.1)	10/16/2015	333-207459
10.7†	.1†	Third Amended and Restated 2016 Share Option and Incentive Plan		8-K (Exhibit 10.1)	6/5/2024	001-37686
	.2†	Form of Global Performance Share Unit Award Agreement for Employees under the Third Amended and Restated 2016 Share Option and Incentive Plan		10-Q (Exhibit 10.5)	8/7/2024	001-37686
	.3†	Form of Global Restricted Share Unit Award Agreement for Non-Employee Directors under the Third Amended and Restated 2016 Share Option and Incentive Plan		10-Q (Exhibit 10.5)	8/2/2023	001-37686
	.4†	Form of Global Restricted Share Unit Award Agreement for Employees under the Third Amended and Restated 2016 Share Option and Incentive Plan		10-Q (Exhibit 10.6)	8/7/2024	001-37686
	.5†	Form of Global Restricted Share Unit Award Agreement for Consultants under the Third Amended and Restated 2016 Share Option and Incentive Plan		10-Q (Exhibit 10.7)	8/7/2024	001-37686
	.6†	Form of Global Non-Qualified Share Option Agreement for Employees under the Third Amended and Restated 2016 Share Option and Incentive Plan		10-Q (Exhibit 10.8)	8/7/2024	001-37686
	.7†	Form of Global Non-Qualified Share Option Agreement for Non-Employee Directors under the Third Amended and Restated 2016 Share Option and Incentive Plan		10-Q (Exhibit 10.9)	8/2/2023	001-37686
	.8†	Form of Global Non-Qualified Share Option Agreement for Non-Employee Consultants under the Third Amended and Restated 2016 Share Option and Incentive Plan		10-Q (Exhibit 10.9)	8/7/2024	001-37686
10.8†		Fourth Amended and Restated 2018 Employee Share Purchase Plan		8-K (Exhibit 10.2)	6/5/2024	001-37686
10.9†		Senior Executive Cash Incentive Bonus Plan		S-1 (Exhibit 10.19)	1/19/2016	333-207459
10.10†		Independent Director Compensation Policy, as amended		8-K (Exhibit 10.1)	3/20/2024	001-37686

Exhibit No.		Exhibit Description	Filed/ Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
Agreements with Executive Officers and Directors						
10.11†		Form of Indemnification Agreement, entered into between the Registrant and its directors and officers		S-1 (Exhibit 10.3)	1/19/2016	333-207459
10.12†		Employment Agreement, dated April 25, 2017, by and between the Registrant and John V. Oyler		8-K (Exhibit 10.1)	4/26/2017	001-37686
10.13	.1†	Executive Employment Agreement, dated April 28, 2018, by and between BeiGene (Beijing) Co., Ltd. and Xiaobin Wu		10-Q (Exhibit 10.1)	8/9/2018	001-37686
	.2†	Amended and Restated Employment Apportionment Agreement, dated June 16, 2023, by and between BeiGene (Beijing) Co., Limited, BeiGene Guangzhou Biologics Manufacturing Co., Ltd., BeiGene Pharmaceutical (Shanghai) Co., Ltd. and Xiaobin Wu		10-Q (Exhibit 10.4)	8/2/2023	001-37686
10.14†		Separation and Transition Agreement, dated July 17, 2024, by and between the Registrant and Julia Wang		10-Q (Exhibit 10.4)	8/7/2024	001-37686
10.15†		Consulting Agreement, dated December 7, 2023, by and between the Registrant and Xiaodong Wang		10-K (Exhibit 10.16)	2/26/2024	001-37686
10.16†		Employment Agreement, dated December 30, 2021, by and between BeiGene (Shanghai) Co., Ltd. and Lai Wang		10-K (Exhibit 10.20)	2/28/2022	001-37686
10.17†		Offer Letter, dated June 10, 2022, by and between the Registrant and Chan Lee		10-Q (Exhibit 10.3)	8/2/2023	001-37686
10.18†		Consulting Agreement, dated January 23, 2024, by and between the Registrant and Thomas Malley		10-Q (Exhibit 10.2)	5/8/2024	001-37686
10.19†		Offer Letter, effective July 22, 2024, by and between the Registrant and Aaron Rosenberg		10-Q (Exhibit 10.3)	8/7/2024	001-37686

Exhibit No.	Exhibit Description	Filed/ Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
Other Agreements					
10.20	Facility Agreement, dated as of December 9, 2024, by and between the Registrant and China Merchants Bank Co., Ltd.		8-K (Exhibit 10.1)	12/10/2024	001-37686
10.21##	Settlement and Termination Agreement, dated as of August 1, 2023, by and between the Registrant, BeiGene Switzerland GmbH, Bristol-Myers Squibb Company, Celgene Corporation, Celgene Switzerland LLC, Celgene Kappa Holdings LLC, Celgene Holdings East Corporation and Celgene Logistics Sàrl		10-Q (Exhibit 10.1)	11/9/2023	001-37686
10.22##	First Amendment to the Settlement and Termination Agreement, dated as of January 10, 2024, by and between the Registrant, BeiGene Switzerland GmbH, Bristol-Myers Squibb Company, Celgene Corporation, Celgene Switzerland LLC, Celgene Kappa Holdings LLC, Celgene Holdings East Corporation and Celgene Logistics Sàrl		10-K (Exhibit 10.21)	2/26/2024	001-37686
10.23	Second Amendment to the Settlement and Termination Agreement, dated as of December 4, 2024, by and between the Registrant, BeiGene Switzerland GmbH, Bristol-Myers Squibb Company, Celgene Corporation, Celgene Switzerland LLC, Celgene Kappa Holdings LLC, Celgene Holdings East Corporation and Celgene Logistics Sàrl	X			
19.1	Insider Trading Policy		10-K (Exhibit 19.1)	2/26/2024	001-37686
19.2	Special Trading Procedures for Insiders	X			
21	List of Subsidiaries of the Registrant	X			
23.1	Consent of Ernst & Young LLP	X			
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1*	Certification of Principal Executive Officer and Principle Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
97	Compensation Recovery Policy		10-K (Exhibit 97)	2/26/2024	001-37686
99.1	Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	X			
101.INS	Inline XBRL Instance Document - the instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document				

Exhibit No.	Exhibit Description	Filed/ Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X			
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)	X			

† Indicates a management contract or any compensatory plan, contract or arrangement.

Certain portions of the exhibit have been omitted by means of redacting a portion of the text and replacing it with "[*]", because they are both (i) not material and (ii) the type of information that the Registrant treats as private or confidential.

* Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

BEIGENE, LTD.

Date: February 27, 2025

By: /s/ JOHN V. OYLER

John V. Oyler
Chief Executive Officer and Chairman
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints John V. Oyler, Aaron Rosenberg, and Chan Lee, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities indicated below and on the dates indicated:

Signature	Title	Date
/s/ JOHN V. OYLER John V. Oyler	Chief Executive Officer and Chairman *(Principal Executive Officer)*	February 27, 2025
/s/ AARON ROSENBERG Aaron Rosenberg	Chief Financial Officer *(Principal Financial Officer)*	February 27, 2025
/s/ TITUS BALL Titus Ball	Chief Accounting Officer *(Principal Accounting Officer)*	February 27, 2025
/s/ OLIVIER BRANDICOURT Olivier Brandicourt	Director	February 27, 2025
/s/ MARGARET DUGAN Margaret Dugan	Director	February 27, 2025
/s/ MICHAEL GOLLER Michael Goller	Director	February 27, 2025
/s/ ANTHONY C. HOOPER Anthony C. Hooper	Director	February 27, 2025
/s/ RANJEEV KRISHANA Ranjeev Krishana	Director	February 27, 2025
/s/ ALESSANDRO RIVA Alessandro Riva	Director	February 27, 2025
/s/ CORAZON (CORSEE) D. SANDERS Corazon (Corsee) D. Sanders	Director	February 27, 2025
/s/ SHALINI SHARP Shalini Sharp	Director	February 27, 2025
/s/ XIAODONG WANG Xiaodong Wang	Director	February 27, 2025
/s/ QINGQING YI Qingqing Yi	Director	February 27, 2025

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CORPORATE OFFICERS

John V. Oyler
Co-Founder, Chairman and Chief Executive Officer

Xiaobin Wu
President, Chief Operating Officer and General Manager, China

Aaron Rosenberg
Chief Financial Officer

Lai Wang
Global Head of R&D

Chan Lee
Senior Vice President, General Counsel

BOARD OF DIRECTORS

John V. Oyler
Co-Founder, Chairman and Chief Executive Officer

Olivier Brandicourt
Blackstone Life Sciences

Margaret Dugan
Schrodinger, Inc.

Michael Goller
Baker Bros. Advisors LP

Anthony C. Hooper
Formerly of Amgen Inc.

Ranjeev Krishana
Baker Bros. Advisors LP

Alessandro Riva
Transgene S.A.

Corazon (Corsee) D. Sanders
Formerly of Bristol Myers Squibb Corporation

Shalini Sharp
Formerly of Ultragenyx Pharmaceutical Inc.

Xiaodong Wang
Co-Founder and Chairman of Scientific Advisory Board

Qingqing Yi
Hillhouse Capital

SHAREHOLDER MEETING

May 21, 2025
8:30 a.m. local time
Mourant Governance Services (Cayman) Limited
94 Solaris Avenue
Camana Bay
Grand Cayman KY1-1108
Cayman Islands

EMPLOYEES

over 11,000 (as of December 31, 2024)

STOCK CODES

Nasdaq: ONC
HKEX: 06160
SSE: 688235

INVESTOR RELATIONS

Liza Heapes
+1 857-302-5663

Gabrielle Zhou
+86 10-5895-8058

ir@beigene.com

BeiGene