
2025 Annual Report
BeOne
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, 2025
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

BEONE MEDICINES LTD.
(Exact Name of Registrant as Specified in its Charter)

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

c/o BeOne Medicines I GmbH
94 Aeschengraben 27
Basel 4051
Switzerland
(Address of principal executive offices, including zip code)

+41 61 685 19 00
(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 30, 2025, 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 $14.7 billion, based upon the closing price of the registrant's ADSs on the Nasdaq Global Select Market on June 30, 2025.

As of February 13, 2026, 1,442,259,810 ordinary shares, par value $0.0001 per share, were outstanding, of which 714,971,127 ordinary shares were held in the form of 54,997,779 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, 2025. Portions of such definitive proxy statement are incorporated by refere into Part III of this Annual Report on Form 10-K.

BeOne Medicines 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;
- the timing, progress and results of our research and development ("R&D") programs, preclinical studies and clinical trials of our drug candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work and the period during which the results of the trials will become available;
- 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;
- 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 ("U.S."), China, the United Kingdom ("UK"), Switzerland, the European Union ("EU") 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;
- our ability to comply with the covenants and other requirements under our facilities agreements and to borrow available amounts under such agreements;
- 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; and
- the effects of our redomiciliation to Switzerland, including its tax treatment, and our name change in 2025.

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 "BeOne," the "Company," "we," "us," and "our" refer to BeOne Medicines 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 to cancer patients worldwide. In 2025, we generated total global revenue of approximately $5.3 billion, increasing revenue by approximately 40.2% from the prior year, while achieving net income of $286.9 million, net cash provided by operating activities of $1.1 billion and positive free cash flow of $941.7 million.

We are serial innovators in hematology and have built a differentiated, wholly-owned, and foundational franchise. We are the only company with potentially best-in-class assets across three foundational chronic lymphocytic leukemia ("CLL") mechanisms of action ("MoAs"). This includes BRUKINSA®, a proven best-in-class Bruton's tyrosine kinase ("BTK") inhibitor, sonrotoclax, a next-generation and potentially best-in-class B-cell lymphoma 2 ("BCL2") inhibitor that received its first global regulatory approval in December 2025, and our potentially first-in-class and best-in-class BTK chimeric degradation activation compound ("BTK-CDAC").

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") CLL population against ibrutinib. BRUKINSA is the only BTK inhibitor to prove superior efficacy to ibrutinib, especially over the long term. 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"). Despite being the third entrant to the market, BRUKINSA became the global market leader across B-cell malignancies in 2025. BRUKINSA generated $3.9 billion in sales in 2025, is approved in over 75 markets and has launched in many key markets, including Europe, Japan, Korea and Brazil. Our Phase 3 MANGROVE trial is evaluating BRUKINSA plus rituximab compared with bendamustine plus rituximab in previously untreated MCL. Pending approval, this would be the first chemo-free regimen available for patients as a first line ("1L") treatment for MCL.

Sonrotoclax is a potentially best-in-class BCL2 inhibitor designed to have greater potency and selectivity, and potential for better tolerability than venetoclax. In late 2025, we received the first approval for sonrotoclax for adult patients with R/R MCL and CLL/small lymphocytic lymphoma ("SLL") patients who have received prior systemic therapy, including a BTK inhibitor. The approval, granted in China, is supported by data demonstrating deep and durable responses and manageable tolerability, underscoring sonrotoclax's emerging role as a foundational medicine across B-cell malignancies. Presented at the American Society of Hematology ("ASH") meeting in 2025, monotherapy data from the Phase 1/2 study of patients with R/R MCL treated with sonrotoclax demonstrated a favorable safety and efficacy profile. Sonrotoclax is under Priority Review by the U.S. Food and Drug Administration ("FDA") for potential accelerated approval in the first half of 2026. Pending approval, sonrotoclax would be the first and only BCL2 inhibitor approved for monotherapy use in R/R MCL.

In the fixed dose BRUKINSA plus sonrotoclax combination, we presented unmatched levels and time to achieve undetectable minimal residual disease ("uMRD"), demonstrating a clear advantage over other fixed duration regimens. The Phase 3 CELESTIAL-TNCLL trial of BRUKINSA plus sonrotoclax in 1L CLL has completed enrollment, and we have initiated a Phase 3 study in the first half of 2026, comparing BRUKINSA plus sonrotoclax against acalabrutinib plus venetoclax in 1L CLL.

Our BTK-CDAC, BGB-16673, 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 best-in-class potential and is the most advanced BTK degrader in development. Data presented at ASH 2025 showed significant efficacy signals and safety data in a heavily pretreated population. We have initiated a Phase 3 head-to-head trial against pirtobrutinib, consistent with our strategy to develop medicines that have potential to meaningfully improve upon the current practice of care. An accelerated approval filing submission based on the Phase 2 trial in R/R CLL could be made to the FDA in 2026 if data supports such submission. With these three differentiated and synergistic assets, we believe we are uniquely positioned to potentially provide the best solution for all CLL patients along their treatment journey and lead a sustainable franchise in the approximately $12 billion global CLL market.

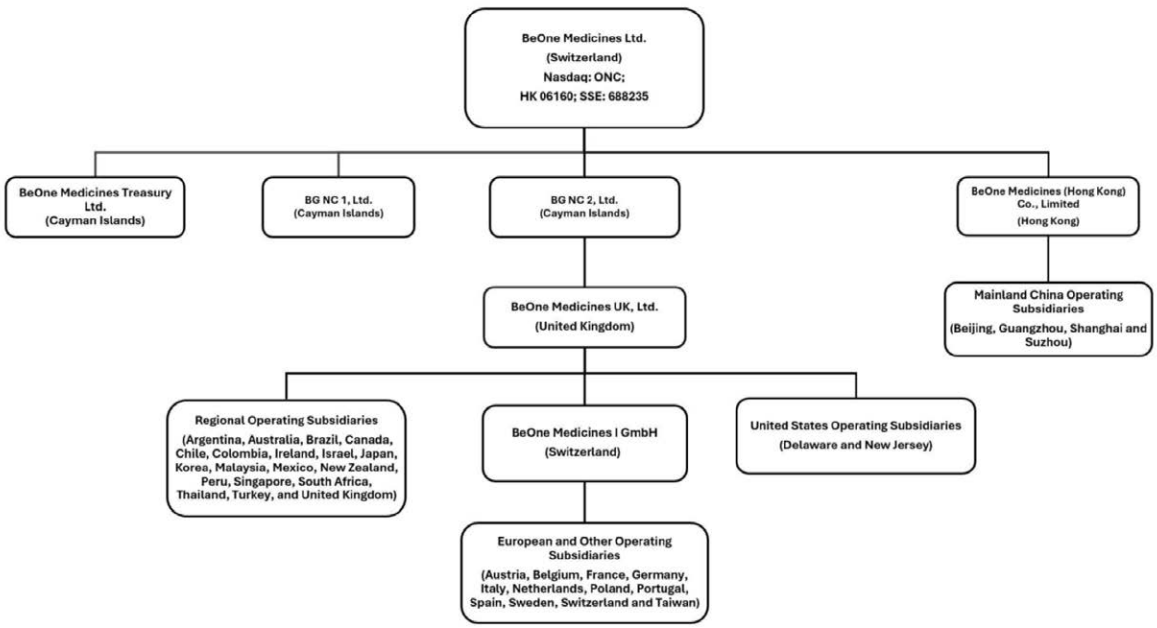
We have a deep and innovative solid tumor pipeline. In 2025, we advanced five differentiated new molecular entities ("NMEs") into the clinic, each of which has the potential to be first-in-class or best-in-class. Our intention is to build depth in the development of potential treatments for the most prevalent cancers, including breast/gynecologic, lung and gastrointestinal. Five solid tumor programs achieved proof of concept in 2025, including our next-generation cyclin-dependent kinase 4 ("CDK4") inhibitor (BGB-43395) and potentially first-in-class B7-H4 antibody-drug conjugate ("ADC") (BG-C9074), our differentiated MoA and first-in-class Glypican-3 ("GPC3")-dependent 4-1BB targeting bispecific T-cell engager (BGB-B2033), our synergistic and potentially best-in-class protein arginine methyltransferase 5 ("PRMT5") (BGB-58067), as well as our carcinoembryonic antigen ("CEA") ADC (BG-C477).

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 nearly 6,000 colleagues across clinical development and manufacturing across the globe allow 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 the highest quality. Our global development "superhighway" is unique to BeOne and critical to generating superior returns on R&D investment. We are innovating with intentionality and building best-in-class combinations to win in the increasingly competitive commercial landscape.

Since our inception in 2010, we have become a fully integrated global organization with nearly 12,000 employees worldwide.

Our Holding Company Structure

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



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. Our global development "superhighway" was uniquely built to address an increasingly challenged industry and improve R&D returns.

We have built a substantial global clinical team of approximately 3,800 people on six continents, allowing us to run clinical trials largely 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 team with 1,200+ 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, 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 small molecules, 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. We have more than 20 CDAC and degrader-antibody conjugate programs progressing through our discovery, investigational new drug ("IND") and clinical development stages. Our research and innovation capabilities are optimized 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.

Expanding our Foundational Hematology Franchise

Our hematology franchise is led by BRUKINSA, which is supported by a broad clinical program with over 7,900 patients enrolled in more than 30 countries and regions across more than 45 trials. We continue to broaden our leadership in hematology, utilizing BRUKINSA as our foundational 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 expand 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 are the only company offering potentially best-in-class, foundational medicines across the three key mechanisms of action in CLL, with BRUKINSA, sonrotoclax and our BTK-CDAC. These assets show promise to offer best-in-disease combinations, and we have comprehensive registrational programs to address patient need in both the treatment naïve and relapsed settings, and with continuous use or fixed duration regimens.

Expanding Access to our PD-1 Inhibitor for Patients Worldwide and Building Global Commercial Capabilities to Support our 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, including submissions based on the HERIZON-GEA-01 trial. We are also developing a hyaluronidase-free, 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., EU and China, and continue our rapid expansion of capabilities into the 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 a strong global financial profile. We believe we are financially well-positioned with cash and cash equivalents of $4.5 billion and debt of $1.0 billion as of December 31, 2025. Our product revenue has grown 39.8% since 2024 from our current portfolio and cornerstone assets, which we expect to grow significantly in 2026 and beyond. We achieved GAAP net income and non-GAAP net income for the first time in fiscal year 2025. We generated net cash provided by operating activities of $1.1 billion and positive free cash flow in 2025. 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 26, 2026:

PRODUCT	MECHANISM OF ACTION	REGULATORY STATUS	BEONE COMMERCIAL RIGHTS	PARTNER
BRUKINSA® (zanubrutinib)	BTK inhibitor	Approved in 77 markets, incl. U.S., EU, China, Japan, and other markets	Global	N/A
TEVIMBRA® (tislelizumab)	Anti-PD-1 antibody	Approved in 51 markets, incl. U.S., EU, China, Japan, and other markets	Global	N/A
PARTRUVIX® (pamiparib)	PARP inhibitor	Approved in China	Global	N/A
Sonrotoclax	BCL2 inhibitor	Approved in China	Global	N/A
IMDELLTRA® (tarlatamab)[1]	Anti-DLL3 x anti-CD3 bispecific T-cell engager (BiTE)	Approved in U.S.	Mainland China	Amgen
XGEVA® (denosumab)	Anti-RANK ligand antibody	Approved in China	Mainland China	Amgen
BLINCYTO® (blinatumomab)	Anti-CD19 x anti-CD3 bispecific T-cell engager (BiTE)	Approved in China	Mainland China	Amgen
KYPROLIS® (carfilzomib)	Proteasome inhibitor	Approved in China	Mainland China	Amgen
ZIIHERA® (zanidatamab)	Anti-HER-2 bispecific antibody	Approved in U.S., EU, China and Canada	Asia (excluding Japan & India), Australia, New Zealand	Jazz Zymeworks
SYLVANT® (siltuximab)	IL-6 antagonist	Approved in China	Greater China	Recordati
QARZIBA® (dinutuximab)	Anti-GD2 antibody	Approved in China	Mainland China	Recordati
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[2]	Novartis
MEKINIST® (trametinib)	MEK inhibitor	Approved in China	China Broad Markets[2]	Novartis
VOTRIENT® (pazopanib)	VEGFR inhibitor	Approved in China	China Broad Markets[2]	Novartis
AFINITOR® (everolimus)	mTOR inhibitor	Approved in China	China Broad Markets[2]	Novartis
ZYKADIA® (ceritinib)	ALK inhibitor	Approved in China	China Broad Markets[2]	Novartis

1. A significant portion of our rights to receive certain tiered mid-single digit royalty payments based on annual net revenue from sales outside of China of IMDELLTRA were sold to Royalty Pharma in the third quarter of 2025.

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

Abbreviations: DLL3 = delta-like ligand 3; CD = cluster of differentiation; 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 2025, global revenues for BTK inhibitors were approximately $12 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 2024 and 2025.

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. A tablet formulation was FDA approved in June 2025, providing patients with more convenience and flexibility.

BRUKINSA has approvals in five indications, including CLL/SLL, WM, R/R MCL, R/R MZL and R/R FL, and is approved in 77 markets and reimbursed in 58 markets.

In the U.S., BRUKINSA received accelerated approval from the 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 BTK inhibitor 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 June 2025, BRUKINSA received approval of its tablet formulation.

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 August 2025, BRUKINSA received approval from the EC of a film-coated tablet formulation for all approved indications.

In China, BRUKINSA has received approvals from the China National Medical Products Administration ("NMPA") for the treatment of adult patients with CLL/SLL and WM, and conditional approvals for adult patients with R/R MCL and 3L FL. Currently, all approved indications for BRUKINSA are included in the 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 over $50 billion in 2025 based on public reports. The 2025 China PD-1/L1 market (net revenue) was approximately $4 billion.

Global revenues are projected to 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.

We have received regulatory approvals for TEVIMBRA marketing applications in multiple geographies, including the EU/European Medicines Agency ("EMA") (comprising 27 countries plus Iceland and Norway) and 23 countries across North America, Europe, Asia Pacific and other markets.

TEVIMBRA was included in the NRDL in 2021 for second-line locally advanced or metastatic UC with high PD-L1 expression, in 2022 for first-line locally advanced unresectable or metastatic non-squamous non-small cell lung cancer ("NSCLC"), first-line locally advanced unresectable or metastatic squamous NSCLC and second-line metastatic hepatocellular carcinoma ("HCC"), in 2023 for second-line locally advanced or metastatic NSCLC with driver gene negative/unknown, second-line metastatic MSI-H solid tumors, second-line locally advanced or metastatic esophageal squamous cell carcinoma ("ESCC"), and first-line recurrent or metastatic nasopharyngeal cancer ("NPC"), in 2024 for first-line locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma ("G/GEJA") with high PD-L1 expression and first-line unresectable locally advanced, recurrent or metastatic ESCC, and in 2025 for first-line metastatic G/GEJA irrespective of PD-L1 expression status, first-line extensive stage small cell lung cancer ("ES-SCLC") and first-line unresectable or metastatic HCC, and in 2026 for peri-operative treatment for resectable stage II and IIIA NSCLC.

Market	Approval
China	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 NSCLC
	in combination with etoposide and platinum chemotherapy as the first-line treatment for patients with extensive-stage small cell lung cancer
	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 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 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 NPC
	for first-line treatment of patients with unresectable or metastatic HCC
	for the treatment of patients with advanced HCC who have received Sorafenib, Lenvatinib or systemic chemotherapy containing Oxaliplatin
	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
	conditional approval for patients with previously treated, locally advanced unresectable or metastatic microsatellite instability-high ("MSI-H") or mismatch repair-deficient ("dMMR") solid tumors

Market	Approval
Europe	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 > 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 >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
	in combination with etoposide and platinum chemotherapy, is indicated for the first-line treatment of adult patients with extensive-stage SCLC
	in combination with gemcitabine and cisplatin, is indicated for the first-line treatment of adult patients with recurrent, not amenable to curative surgery or radiotherapy, or metastatic NPC
	in combination with platinum-containing chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment, is indicated for the treatment of adult patients with resectable NSCLC at high risk of recurrence
	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 > 5%, in combination with platinum and fluoropyrimidine-based chemotherapy
	alternative dosing regimen of 400mg administered once every 6 weeks (Q6W) for all approved indications
Japan	in combination with fluorouracil and cisplatin, is indicated for the first-line treatment of patients with unresectable locally advanced, recurrent or metastatic esophageal carcinoma ("EC")
	is indicated for patients with unresectable locally advanced, recurrent or metastatic EC that have progressed after cancer chemotherapy
U.S.	in combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic ESCC whose tumors express PD-L1 (≥1)
	in adults with unresectable or metastatic ESCC after prior systemic chemotherapy that did not include a PD-L1 inhibitor
	in combination with platinum and fluoropyrimidine based chemotherapy, for the first-line treatment of adults with unresectable or metastatic HER2 negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥ 1)
	alternative dosing regimen of TEVIMBRA (tislelizumab) of 150mg administered once every 2 weeks (Q2W) of 300mg administered once every 4 weeks (Q4W) of 400mg administered once every 6 weeks (Q6W) in 1L /2L ESCC and GC

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 Bristol-Myers Squibb Company ("BMS")

As part of our settlement agreement with BMS, our commercialization of the following cancer medicines licensed from BMS terminated in February 2025: REVLIMID® (lenalidomide), an oral immunomodulatory medicine; and 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, a Recordati company:

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 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 ("BC") 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, 2025, 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 myBeOne Support 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. Oncology Nurse Advocates at myBeOne Support provide education and information about BRUKINSA and TEVIMBRA and their approved indications, and connect patients to advocacy organizations such as cancer 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' lists 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. 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.

Several of our medicines are listed in the NRDL. The latest NRDL list was announced in December 2025. The following medicines and indications have been included in the NRDL, effective January 1, 2026:

- TEVIMBRA in its eligible approved indications:
  - In combination with platinum-based chemotherapy for neoadjuvant treatment, followed by continuation of this product as monotherapy for adjuvant treatment after surgery, for patients with resectable stage II or IIIA NSCLC (approved in October 2024 and included in the NRDL in 2025);
  - As a first-line treatment for patients with unresectable or metastatic HCC (approved in December 2023 and included in the NRDL in 2024);
  - In combination with etoposide and platinum chemotherapy as the first-line treatment for patients with ES-SCLC (approved in June 2024 and included in the NRDL in 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 in 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 not tolerate 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 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);
- 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); and
- 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).

- BRUKINSA successfully renewed its approved indications:
  - In combination with obinutuzumab, for the treatment of adult patients with relapsed or refractory FL who have received at least two prior lines of systemic therapy (approved in May 2024 and included in the NRDL in 2024);
  - For the treatment of patients with CLL or SLL (approved in April 2023 and included in the NRDL at the end of 2023)[2];

[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.

[2] 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.

- For the treatment of patients with WM (approved in April 2023 and included in the NRDL at the end of 2023)[1]; 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 successfully renewed its approved indications:
  - For the treatment of patients with BC in premenopausal and perimenopausal women that can be treated with hormone therapy (approved in September 2023 and included in the NRDL in 2024); and
  - 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).
- PARTRUVIX successfully renewed its eligible approved indications:
  - For the treatment of patients with germline BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube or primary peritoneal cancer who have been treated with two or more lines of chemotherapy (approved in April 2021 and included in the NRDL in 2021).
- SYLVANT successfully renewed its approved indications:
  - For the treatment of adult patients with multicentric Castleman disease ("MCD") who are human immunodeficiency virus ("HIV") negative and human herpesvirus-8 ("HHV-8") negative (approved in December 2021 and included in the NRDL at the end of 2023).

In 2025, NHSA promulgated the first edition of the Commercial Health Insurance Innovative Drug List ("CHIIDL"). It primarily includes innovative drugs with high innovation, significant clinical value, and substantial patient benefits that have not yet been included in the NRDL or for which NRDL coverage remains limited. The CHIIDL is recommended for reference by multi-tiered medical security systems, including commercial health insurance and medical mutual aid. The discount for drugs listed in the CHIIDL are determined through negotiations, with strict price confidentiality mechanisms.

The first edition of the CHIIDL was announced in December 2025. The following medicines and indications have been listed:

- ZIIHERA in its approved indications:
  - For the treatment of patients with unresectable locally advanced or metastatic biliary tract cancer who have previously received systemic therapy and are HER2-high (IHC 3+) (approved in May 2025 and included in the CHIIDL in 2025).
- QARZIBA in its approved indications:
  - For the treatment of patients ≥12 months of age with high-risk neuroblastoma who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplant; also for the treatment of relapsed or refractory neuroblastoma with or without residual disease. Prior to treatment of relapsed neuroblastoma, appropriate measures should be taken to stabilize active progressive disease(approved in August 2021 and included in the CHIIDL in 2025).

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.

[1] 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.

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.

Our Pipeline Products

The following table summarizes our pipeline as of February 26, 2026:

[1] DualityBio collaboration, [2] Ensem collaboration, [3] CSPC collaboration, [4] Amgen collaboration, [5] Zymeworks/Jazz collaboration

The following table summarizes the status of our in-licensed drug candidates as of February 26, 2026:

Partner	Molecule / Asset	Indications	Phase	Commercial Rights
Amgen	Tarlatamab ^	SCLC	Phase 3	Mainland China
	Xaluritamig	Prostate cancer	Phase 1	Mainland China
Zymeworks, Jazz	Zanidatamab † + chemo + Tislelizumab	GEA	Phase 3	Asia*, Australia, New Zealand
	Zanidatamab † (monotherapy)	BTC	Phase 2	Asia*, Australia, New Zealand
DualityBio	BG-C9074/DB1312	BC, EC, OC, CCA, sqNSCLC	Phase 1a	Global
Ensem	CDK2i	BC and other solid tumors	Phase 1	Global
CSPC	MAT2Ai	Solid tumors	Phase 1	Global

^ Half-life extended BiTE®; † ZW25

* Excluding Japan and India

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 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 7,900 patients enrolled in more than 30 countries and regions across more than 45 trials. BRUKINSA is approved in more than 75 markets, and more than 265,000 patients have been treated globally.

Long-term results from the SEQUOIA study demonstrate sustained clinical benefit with BRUKINSA® (zanubrutinib), reinforcing its differentiated profile in frontline CLL, both as monotherapy and in combination with venetoclax. These data were presented at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting.

Additional SEQUOIA results presented at the 2025 American Society of Hematology (ASH) Annual Meeting further confirm the durability of efficacy, showing sustained disease control in treatment-naïve CLL/SLL patients and continued favorable survival outcomes in the non-randomized del(17p) cohort at 6 years of follow-up.

Final analysis of the randomized Phase 2 ROSEWOOD study of zanubrutinib plus obinutuzumab ("ZO") vs obinutuzumab monotherapy in patients with R/R FL confirmed the favorable risk-benefit profile of ZO. The objective response rate ("ORR") and complete response ("CR") rate with ZO improved over time, responses remained durable, and the PFS benefit over O was sustained. ZO had a manageable safety profile with no new safety signals observed; detailed data were presented at the annual ASH 2025 conference.

Results from the ALPINE trial in patients with CLL/SLL showed reduced risk of symptom deterioration associated with earlier disease progression in comparison with ibrutinib; detailed data were presented at the annual ASH 2025 conference.

Based on the clinical data to date, we believe that BRUKINSA has a best-in-class profile and 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 MCL Who Are Ineligible for Stem Cell Transplantation (NCT04002297).

- MAHOGANY: A Study of Zanubrutinib Plus Anti-CD20 Versus Lenalidomide Plus Rituximab in Participants With Relapsed/Refractory Follicular or Marginal Zone Lymphoma (MAHOGANY).

- SEQUOIA: A Global Phase 3 study Comparing Zanubrutinib With Bendamustine Plus Rituximab in Participants With Previously Untreated CLL or SLL, including participants without del(17p) [Cohort 1] and participants with del(17p) [Cohort 2 and Cohort 3]. Participants in Cohort 1 are randomized 1:1 to zanubrutinib (Arm A) or bendamustine plus rituximab (Arm B). Randomization will be stratified by age, Binet stage, immunoglobulin variable region heavy chain (IGHV) mutational status, and geographic region. Participants in Cohort 2 will receive treatment with zanubrutinib. Participants in Cohort 3 will receive treatment with zanubrutinib and venetoclax (NCT03336333).

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.

Sonrotoclax (BGB-11417), a Small Molecule BCL2 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 2,500 patients enrolled through February 2026 in different indications and in different combinations continue to support the pre-clinical best-in-class promise.

This year marked a series of significant milestones for the sonrotoclax program. Sonrotoclax was granted approval in China for adult patients with R/R MCL and CLL/SLL patients who have received at least one systemic therapy, including a BTK inhibitor. The approval is supported by data demonstrating deep and durable responses and manageable tolerability based on parallel submissions of data from two studies. In the Phase 1/2 single-arm study of patients with R/R MCL treated with 320 mg of sonrotoclax (n=103), overall response rate (ORR) as assessed by independent review committee (IRC) was 52.4% (95% CI, 42.4-62.4). In the Phase 2 open-label study of patients with R/R CLL/SLL treated with sonrotoclax (n=100), ORR as assessed by IRC was 77%.

We announced positive topline results for the Phase 2 sonrotoclax study in R/R MCL (NCT05471843) in August 2025. The study met its primary endpoint of ORR, and the study also showed promising results across several secondary efficacy endpoints, including CR rate, duration of response ("DOR") and PFS. The safety profile was generally well-tolerated, and the toxicities were manageable. Based on these results, sonrotoclax was granted Breakthrough Therapy Designation for the treatment of adult patients with R/R MCL by the FDA in October 2025. Our new drug application of sonrotoclax for the treatment of adult patients with R/R MCL, following treatment with a BTK inhibitor, was granted Priority Review by the FDA in November 2025. In R/R CLL, our China-only pivotal Phase 2 trial (NCT05479994) had a positive readout based on 12-month follow-up. The 6-month follow up data formed the basis of our initial submission in China in April 2025, and a rolling submission of our 12-month follow-up data into the China NDA has been completed.

Multiple trials with registration potential have completed enrollment or are nearing complete enrollment. A Phase 2 study of sonrotoclax as monotherapy and in combinations with zanubrutinib in patients with R/R WM (NCT05952037) and a Phase 3 study of sonrotoclax plus zanubrutinib compared with venetoclax plus obinutuzumab in patients with TN CLL/SLL (NCT06073821) have completed enrollment. Our Phase 2 study of sonrotoclax plus zanubrutinib compared with zanubrutinib monotherapy, which is a regulatory requirement of our TN CLL filing package, also completed enrollment.

Initial results from an ongoing Phase 1/1b study (NCT04277637) were presented at ASH 2025. Sonrotoclax plus obinutuzumab was generally well-tolerated in patients with TN CLL/SLL, with no sonrotoclax discontinuations or deaths due to TEAEs. No laboratory or clinical TLS events occurred during sonrotoclax ramp-up. Encouraging antitumor activity was observed with sonrotoclax 320 mg. High rates of blood uMRD4 occurred early and deepened over time. All patients with an available C15 MRD assessment by NGS or FC achieved uMRD4 and remain in remission.

Initial results from an ongoing Phase 1b/2 study with sonrotoclax (NCT04973605) as monotherapy and in various combinations with carfilzomib and dexamethasone in patients with t(11;14)-positive R/R MM were also presented at ASH 2025. The sonrotoclax combination therapy demonstrated a tolerable safety profile and encouraging antimyeloma activity, with an 84% ORR and a 32% CR/sCR rate in heavily pretreated patients with t(11;14)-positive R/R MM.

With these encouraging results, our sonrotoclax program is steadily progressing with its first global approval, its first FDA and EMA new drug applications under review, and ongoing pivotal stage global development.

BGB-16673, a BTK-targeted CDAC

BGB-16673 is an orally available, brain-penetrating BTK targeting 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 1,000 patients treated to date across the global CaDAnCe clinical development program. The FDA granted Fast Track Designation to BGB-16673 in 2024 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 a BTK inhibitor and a BCL2 inhibitor, and adult patients with R/R MCL. In July 2025, we achieved PRIME designation from the EMA for BGB-16673 for the treatment of patients with WM previously treated with a BTK.

Updated efficacy and safety results from the ongoing Phase 1 CaDAnCe-101 study in patients with R/R CLL/SLL were presented at ASH 2025. Data demonstrate that BGB-16673 has a tolerable safety profile and shows robust and deepening responses in heavily pretreated patients.

A Phase 2 expansion cohort of this study is enrolling in R/R CLL after BCL2 inhibitor and BTK inhibitor directed therapy (NCT05006716), and enrollment is ongoing in three Phase 3 studies (NCT06846671, NCT06970743, NCT06973187) designed to support filings in later lines of CLL, including a potential accelerated approval filing in R/R CLL in 2026 if data support such submission. In October 2025, we achieved first subject enrolled in CaDAnCe-304, our head-to-head study versus pirtobrutinib in R/R CLL. We are also enrolling in a platform study (NCT06634589) to generate combination data of strategic importance across multiple B-cell malignancies.

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.

Clinical Development Updates and Regulatory Status

We have completed more than 15 registration-enabling clinical trials in lung, liver, urothelial carcinoma, and nasopharyngeal cancer globally, including 11 Phase 3 randomized trials and four Phase 2 trials supporting regulatory submissions globally. We have four active studies in HER2+ gastroesophageal adenocarcinoma ("GEA"), urothelial carcinoma, gastric cancer, and solid tumors:

- The Phase 3 HERIZON-GEA-01 trial evaluates ZIIHERA® (zanidatamab), a HER2-targeted bispecific antibody, in combination with chemotherapy, with and without TEVIMBRA, as a first-line treatment for HER2-positive locally advanced or metastatic GEA.

- A Phase 3 confirmatory trial in China to investigate tislelizumab plus either cisplatin or carboplatin plus gemcitabine in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977).

- A global Phase 3 trial to investigate tislelizumab administered as subcutaneous injection versus intravenous infusion plus chemotherapy in patients with unresectable or metastatic gastric or gastroesophageal junction ("GEJ") adenocarcinoma (NCT07043400).

- A Phase 2 trial in China to investigate tislelizumab in patients with MSI-H/dMMR solid tumors (NCT03736889).

Notably, the data from the first interim analysis of the HERIZON-GEA-01 trial were announced in January 2026 during the ASCO Gastrointestinal Cancers Symposium ("ASCO GI"). The addition of TEVIMBRA to ZIIHERA and chemotherapy demonstrated statistically significant and clinically meaningful improvements in both PFS and overall survival ("OS") compared to the control arm, regardless of PD-L1 expression level. Results showed a 37% reduction in the risk of disease progression and a greater than 4-month improvement in mPFS as well as a 28% reduction in the risk of death and a greater than 7-month improvement in mOS. There is a high GEA burden in Asia, where we hold ZIIHERA rights, excluding Japan and India, along with TEVIMBRA. We intend to submit supplemental BLAs to the FDA for TEVIMBRA and to the Center for Drug Evaluation ("CDE") of the NMPA for TEVIMBRA and ZIIHERA, based on these data. We also intend to work with regulatory authorities in our licensed territories to expedite regulatory submissions in these markets.

As of December 2025, we had enrolled over 15,800 subjects in clinical trials of tislelizumab monotherapy or in combination in more than 33 countries, including 5,000+ subjects outside of China. These studies include nine 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.

Lung Cancer

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-EGFR x MET x MET trispecific antibody

BG-T187 is an investigational anti-EGFR x MET x MET 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.

BG-C0902, an EGFR x MET x MET trispecific ADC

BG-C0902 is an investigational EGFR x MET x MET trispecific ADC being evaluated in a Phase 1 clinical trial (NCT07181681) as monotherapy or in combination with other therapeutic agents in patients with advanced solid tumors.

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 multiple Phase 1 clinical trials as mono and combo therapy in patients with advanced or metastatic solid tumors. We licensed this asset from CSPC Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd in December 2024.

BGB-C354, an anti-B7-H3 ADC (development discontinued)

BGB-C354 is an investigational ADC targeting B7-H3 that was being evaluated in a Phase 1 clinical trial (NCT06422520) as monotherapy or in combination with tislelizumab in patients with advanced solid tumors. The trial is in closeout.

Gastro-Intestinal Cancer

Zanidatamab, a bispecific HER2-targeted antibody

ZIIHERA® (zanidatamab), a novel investigational bispecific antibody targeting HER2, is approved in the U.S., China, Canada and other markets for adults with previously treated, unresectable or metastatic HER2 positive (IHC 3+) biliary tract cancer ("BTC"). Zanidatamab is currently in late-stage clinical development with Zymeworks Inc./Jazz Pharmaceuticals plc ("Jazz"). We have development and commercial rights to zanidatamab in Asia (excluding Japan and India), 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. In November 2025, Jazz announced positive top-line results from the HERIZON-GEA-01 trial, and full data were disclosed at ASCO GI 2026.

A BLA for the HER2-amplified BTC indication in which zanidatamab is being used as monotherapy was approved by China NMPA in May 2025. In June 2025, Jazz announced that the Marketing Authorization Application for zanidatamab in 2L BTC was granted conditional marketing authorization by the EMA. BeOne intends to submit supplemental BLAs to the FDA for TEVIMBRA and to the CDE of the NMPA for TEVIMBRA and ZIIHERA, based on results from the HERIZON-GEA-01 trial. We also intend to work with regulatory authorities in our licensed territories to expedite regulatory submissions in these markets. We continue to participate with Jazz in a confirmatory study (NCT06282575) as first line treatment for subjects with HER2 + BTC.

In January 2026, the New Drug Submission ("NDS") for ZIIHERA was approved by Health Canada for the treatment of adults with previously treated, unresectable locally advanced or metastatic HER2-positive (IHC 3+) BTC, as monotherapy. The approval was granted under Health Canada's Notice of Compliance with Conditions pathway.

BGB-B2033, an anti-GPC3 x 4-1BB bispecific antibody

BGB-B2033 is an investigational anti-GPC3 x 4-1BB bispecific antibody being evaluated in a Phase 1 clinical trial (NCT06427941) as monotherapy or in combination with tislelizumab and bevacizumab in patients with selected advanced or metastatic solid tumors. In December 2025, the FDA granted Fast Track Designation to BGB-B2033 for the treatment of adult patients with HCC with disease progression on or after prior systemic treatment.

BG-C477, an anti-CEA ADC

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

BG-C137, an anti-FGFR2b ADC

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

BGB-26808, an 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-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-B3227, an anti-MUC1 x CD16A bispecific antibody (development discontinued)

BGB-B3227 is an investigational anti-MUC1 x CD16A bispecific antibody that was being evaluated in a Phase 1 clinical trial (NCT06540066) as monotherapy or in combination with tislelizumab in patients with advanced or metastatic solid tumors. The trial is in closeout.

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-") BC and other advanced solid tumors.

BG-C9074, an anti-B7-H4 ADC

BG-C9074 is an investigational ADC targeting B7-H4 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.

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 in patients with HR+ and HER2- BC and other advanced solid tumors. BG-68501 is licensed from Ensem Therapeutics, Inc.

BG-75098, a CDK2 CDAC

BG-75098 is an investigational CDK2 CDAC being evaluated in a Phase 1 clinical trial (NCT07226349) alone and in combination with BGB-43395 and fulvestrant in participants with advanced solid tumors.

BGB-75202, a KAT6A/B Inhibitor

BG-75202 is an investigational lysine acetyltransferase ("KAT6A/B") inhibitor being evaluated in a Phase 1 clinical trial (NCT07222267) alone and in combination with other therapies in participants with breast cancer and other advanced solid tumors.

BGB-21447, a BCL2 Inhibitor

BGB-21447 is an investigational BCL2 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.

BGB-B445, an anti-Claudin 6 x CD3 bispecific antibody

BGB-B445 is an investigational anti-claudin 6 x CD3 bispecific antibody being evaluated in a Phase 1 clinical trial (NCT06803680) as a monotherapy in advanced or metastatic solid tumors.

Immunology & Inflammation

BGB-45035, an IRAK4 targeted CDAC

BGB-45035 is an investigational interleukin-1 receptor-associated kinase 4 ("IRAK4") targeting CDAC being evaluated in a Phase 1 clinical trial (NCT06342713) as monotherapy in healthy participants and patients with atopic dermatitis or prurigo nodularis and in a Phase 2 clinical trial (NCT07100938) in adults with moderate to severe active rheumatoid arthritis.

BGB-16673, a BTK targeted CDAC

BGB-16673 is being evaluated in a Phase 1 clinical trial (NCT07005713) in adults with chronic spontaneous urticaria.

Our Preclinical Programs

We have deep expertise in designing small molecule inhibitors and biologics, and are emerging leaders in protein degradation, bi- and tri-specific antibodies, and ADCs.

In the last decade, our preclinical research and development platform has generated more than 35 clinical stage assets, including four internally-developed molecules that have been commercially approved. In 2024 and 2025, we advanced 18 NMEs into the clinic. Our discovery engine 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. 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 assets within our pipeline. 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 of contract manufacturing organizations ("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") 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. manufacturing 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. This site is now fully online with the successful technology transfer and qualification of our TEVIMBRA process, marking our first U.S.-based expected commercial manufacturing.

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 approximately 600 million tablets and capsules. The facility meets or exceeds design criteria of the U.S., EU, and China regulatory requirements, and has been in operation for clinical product supply since the beginning of 2024, with commercial supply in operation since May 2025. The biologics manufacturing business at the former site in Suzhou concluded in January 2025, with some quality control testing expected to continue until the second quarter of 2026.

Our commercial-scale large-molecule biologics manufacturing facility in Guangzhou is approximately 158,000 square meters. Phases 1 and 2 (completed in September 2019 and December 2020, respectively) provide 24,000 liters of single-use bioreactor capacity and are approved for end-to-end commercial manufacturing of TEVIMBRA for the China market. In 2024, we qualified Phase 3 capacity consisting of eight 5,000-liter bioreactors, increasing total capacity to 64,000 liters. Additionally, in April 2024, we commissioned a new campus that includes an ADC manufacturing facility and 1,000 liters of biologics clinical production capacity. The campus also includes reserved land for future expansion to support pipeline development. Following this expansion, total biologics manufacturing capacity at the Guangzhou facility will be approximately 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, supported by our established strategy to maintain sufficient safety stock of our products, do not anticipate any disruptions to supply. We have commercial supply and related agreements with our manufacturing service providers. An ex-China active pharmaceutical ingredients ("API") source was approved by both FDA and EMA in 2025. For our commercial and clinical stage products in-licensed from Amgen 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 include APIs custom-made by our third-party CMOs 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, BeOne Medicines I GmbH, 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) ("Collaboration Territory"), with the commercialization period for XGEVA® commencing following the transition of operational responsibilities for the product. The parties have agreed to equally share profits and losses for the products in the Collaboration Territory during each product's commercialization period. We entered into an amendment to the Amgen Collaboration Agreement in November 2025 to extend our commercialization rights to these products in the Collaboration Territory for so long as each product is sold in the Collaboration Territory following each product's regulatory approval in the Collaboration Territory.

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 BeOne 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 the Collaboration Territory 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 the Collaboration Territory, we will have the right to commercialize the product for seven years, with the parties sharing profits and losses for the product in the Collaboration Territory equally. After the expiration of the seven-year commercialization period, each product will be transitioned back to Amgen and we will be eligible to receive tiered mid-single to low-double digit royalties on net sales in the Collaboration Territory for an additional five years. The parties are subject to specified exclusivity requirements in the Collaboration Territory and the rest of the world. For more information regarding our rights to royalties from sales of IMDELLTRA®, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Business Developments—Royalty Purchase Agreement."

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.

BeOne Medicines Ltd. has guaranteed certain obligations of BeOne Medicines I GmbH 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 the Collaboration Territory.

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 BeOne Medicines 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 BeOne Medicines 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, BeOne Medicines 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, BeOne Medicines 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 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, Japan 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 13, 2026, we owned 68 issued U.S. patents, 16 issued European patents, 34 issued Japanese patents, 72 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 13, 2026, are summarized below:

Molecule	Territory	General Subject Matter	Expiration[1]
BRUKINSA® (zanubrutinib)	U.S.	Composition of matter	2034
	U.S.	Crystalline forms	2037
	U.S.	Method of treatment	2037
	U.S.	Combination use	2039
	U.S.	Method of treatment	2043
	U.S.	Formulation	2040
	Europe	Composition of matter	2034[2]
	Europe	Combination use	2037[3]
	Europe	Crystalline form	2037
	Japan	Composition of matter	2034[4]
	Japan	Crystalline forms	2037[4]
	China	Composition of matter	2034[5]
	China	Crystalline forms	2037
	China	Combination use	2037
TEVIMBRA® (tislelizumab)	U.S.	Composition of matter	2033[6]
	U.S.	Method of treatment	2039
	Europe	Composition of matter	2033[7]
	Japan	Composition of matter	2033
	China	Composition of matter	2033[8]
PARTRUVIX® (pamiparib)	China	Composition of matter	2031
Sonrotoclax	U.S.	Composition of matter	2039
	Europe	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 UK, 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. Three PTE applications have been filed in Japan.
5. An application for PTE has been filed in China.
6. An application for PTE has been filed and if granted, will extend the original patent term to 2038.
7. SPCs have been pending or have been granted in various European countries, extending the original patent term in those countries, where granted, to 2038.
8. Multiple PTE applications have been filed in China.

Under our license and collaboration agreement with Zymeworks Inc. ("Zymeworks"), we have the right to develop and commercialize ZIIHERA® in certain Asian pacific countries. The key patents for it in China as of February 13, 2026 are summarized below:

Product	Territory	General Subject Matter	Expiration
ZIIHERA®	China	Composition of matter	2031
	China	Composition of matter	2032
	China	Composition of matter	2034
	China	Method of use	2039

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 13, 2026 are summarized below:

Product	Territory	General Subject Matter	Expiration
BLINCYTO® (blinatumomab)	China	Method of use	2029
	China	Combination use	2031

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 13, 2026 is summarized below:

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

Under our license and collaboration agreement with Zymeworks, Zymeworks retains the responsibility, but is not obligated, to prosecute, defend and enforce the patents for the corresponding in-licensed product. Under our license agreement with Amgen, Amgen retains the responsibility, but is 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 are 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., Europe, China & Japan
	Innocare	YINUOKAI	China, Singapore
TEVIMBRA	Merck	KEYTRUDA	U.S., Europe, Asia Pacific & China
	Bristol Myers 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 & Middle Eastern
	Henlius	HANSIZHUANG	U.S., Europe, India, Peru & China
	Various Chinese companies	20+ products including PD-1/L1, IO BsAb	China
Sonrotoclax	AbbVie & Roche	VENCLEXTA	China
	Ascentage Pharma	Lisaftoclax	China

In addition, we have several promising candidates in the pivotal development stage, including BGB-16673, a BTK-targeted 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	Ascentage Pharma	Lisaftoclax	Phase 3	Global
	Innocare	Mesutoclax	Pivotal Phase 2/3	China
			Phase 1	U.S. & Europe
BGB-16673	Nurix Therapeutics	NX-5948	Pivotal Phase 2	Global

Furthermore, we are advancing several promising candidates through pivotal programs, including ADCs, multispecific antibodies, and targeted therapies for lung, breast, and gastrointestinal cancers. 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 inspection of some clinical trial sites to ensure compliance with GCPs;
- FDA Sponsor/Monitor inspections;
- FDA review and approval of the NDA or licensing of the BLA and labeling; and
- Alignment on post-marketing requirements/commitments (if applicable).

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 amendments that significantly affect the safety of subjects, the scope of the investigation, or the scientific quality of the protocol must be filed with the FDA as an IND protocol 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 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 annually (or possibly twice 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. 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 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 ensure 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 as well as conduct a Sponsor/Monitor Inspection.

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 which could potentially delay the FDA Prescription Drug User Fee Act goal date. 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 ensure 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. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct any post-approval confirmatory study with due diligence or to submit timely reports to the agency on their progress. It is important to note that per the FDA requirements, unless otherwise informed by the FDA, all promotional materials to be used need to be submitted 120 days prior to approval.

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.

For oncology products, PREA requirements are further modified by the Research to Accelerate Cures and Equity ("RACE") for Children Act of 2017, enacted as part of the FDA Reauthorization Act ("FDARA"), which removed the exemption for orphan-designated oncology indications. Under RACE, unless waived or deferred, pediatric assessments are required if the molecular target of the product is substantially relevant to the growth or progression of a pediatric cancer, regardless of whether the adult indication has orphan designation or does not occur in the pediatric population. These requirements apply to applicable original NDAs and BLAs submitted on or after August 18, 2020.

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, certain types of 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. Although sponsors are obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to public notification of noncompliance, civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. 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. Under the IRA, an orphan drug is exempt from the Medicare drug price negotiation program only if it has a single orphan designation and its sole approved indication is for that disease or condition. The One Big Beautiful Bill Act of 2025 ("OBBBA") removes this limitation. Beginning with the 2028 initial price applicability year, all orphan drugs—regardless of the number of orphan designations or approved indications—are exempt from the Medicare drug price negotiation program. However, an orphan drug loses this exemption once it receives approval for any non-orphan indication, at which point it becomes eligible for selection for Medicare drug price negotiation. 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. Although certain provisions of the IRA remain subject of ongoing litigation, the Centers for Medicare and Medicaid Services ("CMS") has started implementing key components of the law, including inflation-based rebates and the Medicare drug price negotiation program, and these provisions are expected to have an impact on our business and the healthcare industry in general.

On November 6, 2025, CMS announced a new drug payment model designed to make Most Favored Nation ("MFN")-level prices available to state Medicaid programs via manufacturer rebates. Referred to as the "GENErating cost Reductions fOr U.S. Medicaid Model" ("GENEROUS"), the initiative is designed to run from 2026 through 2030 and is voluntary for both manufacturers and state Medicaid programs. Under the model, participating states will be able to access MFN-level prices for participating manufacturers' drugs through CMS-negotiated supplemental rebates tied to an MFN net price benchmark.

On December 19, 2025, CMS proposed a mandatory Center for Medicare and Medicaid Innovation ("CMMI") drug payment model to test whether alternative methods for calculating Medicare rebates, based on international pricing metrics rather than inflation-based metrics, reduce costs for Medicare fee-for-service ("FFS") beneficiaries and the Medicare program while preserving quality of care. The Guarding U.S. Medicare Against Rising Drug Costs ("GUARD") Model, would test an alternative approach to calculating rebates for certain Medicare Part D products using international pricing benchmarks. The GUARD Model would begin on January 1, 2027, and run through December 31, 2033. Further, on December 19, 2025, CMS proposed the Global Benchmark for Efficient Drug Pricing Model ("GLOBE") for Medicare Part B, would require manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. As proposed, GLOBE would begin a five-year performance period on October 1, 2026.

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. Further, CMS issued the CY 2026 Medicare Physician Fee Schedule final rule, effective January 1, 2026, which, among other things, restricts whether certain fees should be considered bona fide service fees, increases bona fide service fee documentation requirements, defines "bundled arrangement," requires "unbundling" of both contingent and non-contingent discounts and includes sales of Part B units at the Maximum Fair Price in average sales price calculations. These changes may reduce reimbursement for Medicare Part B utilization and require manufacturers to comply with new, complex and potentially uncertain reporting obligations and drug pricing documentation practices.

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.

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 November 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. In December 2025, the U.S. District Court of Maine issued a preliminary injunction blocking HHS from implementing the 340B rebate model pilot program, and HHS subsequently agreed to vacate the existing program so it could consider whether to proceed with a new administrative process for such a program.

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. Additionally, certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards ("PDABs") and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits (UPLs) on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues.

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 or 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 Regulation

EU Product Approval

The EMA is a decentralized scientific agency of the EU which coordinates the scientific evaluation and monitoring of centrally authorized medicinal products and is responsible for the scientific evaluation of applications for EU marketing authorizations, as well as the development of technical guidance and the provision of scientific advice to sponsors. The EMA decentralizes its scientific assessment of medicines by working through a network of experts throughout the EU, nominated by the EU Member States. The EC is responsible for formally granting centralized marketing authorizations in the EU, following the scientific opinion from the EMA.

The process regarding approval of medicinal products in the EU is similar to the process in the U.S. and generally involves completing each of the following:

- preclinical laboratory tests, animal studies and formulation studies performed in accordance with the applicable EU GLP regulations;
- submission of a clinical trial authorization application ("CTA") for each trial in humans through the EU Clinical Trials Information System ("CTIS") to the competent authorities of the EU Member States concerned, which must be approved before the trial may begin in each EU Member State where patient enrollment is planned;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a Marketing Authorization Application ("MAA"), which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMP;
- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Preclinical Studies and Clinical Trials

The conduct of preclinical tests and formulation of compounds for testing in the EU must comply with the relevant international, EU and national legislation, regulations and guidelines. The results of the preclinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical trials of medicinal products conducted in the EU must comply with the harmonized regulatory framework provided by Regulation (EU) No 536/2014 ("Clinical Trials Regulation"), and the International Conference on Harmonization ("ICH") guidelines on GCP. A clinical trial to be conducted in an EU Member State must be authorized by the competent authority of the EU Member State concerned and given a positive opinion by an independent ethics committee in accordance with the Clinical Trials Regulation and applicable national laws. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation, and data derived from non-clinical studies and from its clinical use (if any).

The Clinical Trials Regulation, which became applicable in January 2022, establishes the procedure to enable sponsors to submit one CTA for it to be approved in a more streamlined and coordinated manner by two or more countries in the EU or European Economic Area ("EEA") where the clinical trial is to be performed. Sponsors are required to submit an application through an online platform known as the Clinical Trials Information System for approval. To make it more efficient to carry out such multinational trials, one EU Member State assumes the role as the reporting Member State to lead the scientific review of the assessment, for agreement by the EU Member States concerned within the timeframe stipulated by the Clinical Trials Regulation. Each concerned Member State is responsible for assessing country-specific issues concerning the clinical trial, including those related to adequacy of the trial sites, facilities and recruitment details.

One of the key objectives of the Clinical Trial Regulation is to strengthen the transparency of clinical trial related information. Clinical trial data and information submitted to the CTIS are subject to public disclosure in accordance with the Clinical Trials Regulation, subject to defined exceptions, including for the protection of personal data, commercially confidential information, and confidential communications between Member States during the assessment process.

Manufacturers are afforded the opportunity to seek scientific advice from regulatory authorities to guide their research and development programs. A request for scientific advice can be made nationally by engaging the national competent authorities or centrally, which is coordinated by the EMA at different stages of product development in relation to questions concerning an assessment of the product quality, non-clinical testing and clinical development. Scientific advice is not binding with regard to any future MAA of the product concerned, but departure from the advice should be justified in the MAA.

Marketing Authorizations

After completion of the required clinical testing, we must obtain a marketing authorization before we can place a medicinal product on the market in the EU. There are various marketing authorization procedures available, depending on the type of product involved. All procedures require an application to be presented in the internationally harmonized Common Technical Document format, which includes the submission of detailed information about the manufacturing and quality of the product, and nonclinical testing and clinical trials, to inform the benefit-risk assessment.

The centralized procedure results in marketing authorizations that are valid throughout the EU and, by extension (after national implementing decisions), in Norway, Iceland and Liechtenstein, which, together with the EU Member States, comprise the EEA. Applicants submit MAAs to the EMA, where they are reviewed by relevant scientific committees, including the Committee for Medicinal Products for Human Use ("CHMP"). The EMA forwards the CHMP opinion to the EC, which adopts a decision granting or refusing a marketing authorization. The centralized procedure is compulsory for medicinal products that (1) are developed by biotechnology processes, (2) are an advanced therapy medicinal product (i.e., gene therapy, somatic cell therapy or tissue-engineered medicines), (3) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, viral diseases or autoimmune diseases and other immune dysfunctions or (4) are orphan medicinal products. For medicines that do not fall within these categories, an applicant may voluntarily submit an application for a centralized marketing authorization to the EMA, provided that the medicine concerned contains a new active substance and the CHMP agrees that (i) the medicine is a significant therapeutic, scientific, or technical innovation, or (ii) the authorization of the medicine under the centralized procedure would be in the interest of public health at the EU level.

For those medicinal products for which the centralized procedure is not available, the applicant must submit MAAs to the national competent authorities of the EU Member States through one of three procedures: (1) a national procedure, which results in a marketing authorization in a single EU Member State; (2) the decentralized procedure, in which applications are submitted simultaneously in two or more EU Member States and a reference Member State is appointed to lead the scientific assessment; or (3) the mutual recognition procedure, which is used when the product has already been nationally authorized in at least one EU Member State (the reference Member State), and the marketing authorization holder seeks recognition of that authorization for the same product in at least one other EU Member State (concerned Member States). A concerned Member State may refuse to recognize the assessment of the reference Member State in the decentralized procedure or the mutual recognition procedure on grounds of potential serious risk to public health.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically may take a year or more. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of major interest for public health and therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

Data Exclusivity

MAAs for generic medicinal products do not need to include the results of preclinical studies and clinical trials but instead can refer to such data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. Where a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic MAAs referring to the data of that product will not be accepted by the regulatory authorities, and a further two years of marketing protection, during which such generic products, even if approved, may not be placed on the market until the full 10-year protection period has expired. The 10-year protection period may be extended to 11 years if, during the first eight years of the product's authorization, one or more new therapeutic indications with significant clinical benefit over existing therapies are approved.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical studies or clinical trials must be provided, and guidelines from the EMA detail the type of supplementary data to be provided for different types of biological product.

Orphan Designation

In the EU, an orphan medicinal product designation may be granted, following recommendation by the EMA's Committee for Orphan Medicinal Products ("COMP"), for products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU. Additionally, designation may be granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the medicinal product. The COMP may only recommend orphan designation when the product in question offers a significant clinical benefit over existing approved products for the relevant indication or where no satisfactory method of diagnosis, prevention or treatment of such condition exists. Following a positive opinion by the COMP, the EC adopts a decision granting orphan status. The COMP will reassess orphan status in parallel with EMA review of an MAA, and orphan status may be withdrawn at that stage if the product no longer fulfills the orphan criteria.

Orphan designation entitles a party to financial incentives such as reduction of fees or fee waivers, and 10 years of market exclusivity is granted following marketing authorization. During this period, the EU competent authorities may not accept or approve a marketing authorization application for a similar medicinal product, meaning a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product and which is intended for the same approved therapeutic indication, unless: (i) the second medicinal product is safer, more effective or otherwise clinically superior to the authorized orphan product; (ii) the marketing authorization holder for the authorized product consents to a second application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan product. This period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of orphan designation.

PRIME Designation

The PRIority MEdicines ("PRIME"), scheme is intended to encourage product development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Eligible products must target conditions for which there is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of therapeutic candidates with PRIME designation, including but not limited to early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated EMA contact and rapporteur from the CHMP are appointed early in the PRIME scheme facilitating increased understanding of the product at the EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Post-Approval Controls

The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan describing the risk management system that the company will put in place and documenting measures that will be taken to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited in the EU. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by national law in each Member State and may differ between Member States.

Manufacturing

Medicinal products may only be manufactured in the EU, or imported into the EU from another country, by the holder of a manufacturing authorization from the competent national authority. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with EU standards of cGMP before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with cGMP. Testing and certification on importation is exempted where there exists a Mutual Recognition Agreement between the exporting country and the EU.

Pricing and Reimbursement

Governments influence the price of medicinal products in the EU through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some EU Member States operate positive or negative list systems under which reimbursed products may only be placed on the market once a reimbursement price has been agreed. 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. Other EU Member States allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription medicines, has become intense. In addition to an assessment of cost-effectiveness, the national health systems may consider whether market access is affordable. As a result, increasingly high barriers are being erected to the entry of new products.

Reform of the Regulatory Framework in the EU

The EC introduced legislative proposals in April 2023 that, if implemented, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). In April 2024, the European Parliament adopted its position on the legislative proposals, and in June 2025, the Council of the European Union adopted its position. A common position on the text was agreed upon in December 2025, in the context of subsequent inter-institutional trilogue negotiations. The proposed revisions remain to be adopted and are not expected to become applicable before 2028. The aforementioned EU rules are generally applicable in the EEA.

Brexit and the Regulatory Framework in the UK

Following the end of the Brexit transition period on January 1, 2021 and the implementation of the Windsor Framework on January 1, 2025, the UK is not generally subject to EU laws in respect of medicines. EU laws that were transposed into UK law through secondary legislation continue to apply in the UK as retained EU law (as amended), but new EU legislation, such as the Clinical Trials Regulation, does not apply in the UK. Since January 1, 2021, the Medicines and Healthcare products Regulatory Agency ("MHRA") has been the UK's standalone medicines and medical devices regulator.

Under the Medicines and Medical Devices Act 2021, the Secretary of State or an "appropriate authority" has delegated powers to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

The UK regulatory framework in relation to clinical trials is governed by the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, which is derived from the EU Clinical Trial Directive, as implemented into UK national law through secondary legislation. In April 2025, the UK introduced the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025. These changes, which will take full effect from April 2026, aim to create a streamlined, risk-proportionate system that accelerates approvals while maintaining robust safety standards.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. All existing EU marketing authorizations for centrally authorized products were automatically converted or grandfathered into UK marketing authorizations, effective in Great Britain only, on January 1, 2021, unless the marketing authorization holder chose to opt-out. Under the terms of the Windsor Framework, these licenses became valid for the whole of the UK from January 1, 2025. In order to use the centralized procedure to obtain a marketing authorization that will be valid throughout the EEA, companies must be established in the EEA. Therefore, after Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized marketing authorizations. In order to obtain a UK marketing authorization to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures.

In the UK, the initial duration of a marketing authorization is five years and, following renewal, it will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance to proceed with only one additional five-year renewal. Any authorization which is not followed by the actual placing of the medicine on the market in the UK within three years shall cease to be in force.

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, including requirements to have legal basis for processing certain 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 where there is no other 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 includes substantial penalties to which we could become 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

Our China operations are conducted by our Chinese subsidiaries owned by BeOne Medicines (Hong Kong) Co., Limited, one of our wholly owned subsidiaries. We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. As a result of our operations in China, the Chinese regulatory authorities have significant influence over our conduct of business and may influence our operations as they deem appropriate to further economic, regulatory, political and societal goals. This section summarizes the principal PRC laws, rules and regulations that we believe are relevant to our business and operations. For a detailed description of risks related to our doing business in China, please refer to "Risk Factors—Risks Related to Our Doing Business in the PRC".

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 advertising activities related to pharmaceutical products.

The DAL

The DAL 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, including establishing a quality assurance system and being responsible for 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.

The DAL requires drug manufacturers and drug distributors to comply with current GMP and good supply practice ("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. A drug pharmacovigilance system will also be established to monitor, identify, evaluate and control adverse drug reactions and other possible drug-related problems.

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, revocation of required business and operating licenses, certificates or approval documents for drugs, suspension of business, temporary 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 over time. 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 drug regulation, consumer protection, advertising, anticorruption, antitrust, fair competition and intellectual property.

The NMPA regulates almost all 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, 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.

A Certificate for Use of Laboratory Animals is required for performing experimentation on animals under various regulations. Applicants for this certificate must satisfy a number of conditions relating to facilities, sourcing, feeding and experimentation for lab animals.

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 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-marketing 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 impacts 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 data requirements and materials required for this application 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 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. In September 2025, the NMPA issued the Announcement on Optimizing the Review and Approval of Clinical Trial Applications for Innovative Drugs, which formally established an accelerated approval pathway for innovative drugs. Under this regulation, the review timeline is compressed to 30 working days for certain innovative drugs that are designated as national priorities (including those for pediatric use or rare diseases) or are part of global simultaneous development programs. This policy significantly expedites the regulatory timeline for eligible global innovative drug candidates.

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 we are a Swiss 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, and temporary 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 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 industry guidance provides more clarifications from the practice perspective, including: (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. Data from foreign clinical trials must meet authenticity, completeness and accuracy requirements. 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.

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 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 to further monitor and obtain safety and efficacy data of the drug.

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, or marketing approval of the drug, to the applicant, 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. 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.

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. 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.

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. 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; an advertisement can be any media that directly or indirectly introduces the product to end users. 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 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") provide 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 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.

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 basic medical insurance sub-programs: (1) 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) 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. 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.

China has been pursuing a policy of expediting the addition of innovative oncology drugs to this list. 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 the beginning of 2023. SYLVANT and BAITUOWEI have been included in the NRDL since the end of 2023. To allow patients with commercial insurance earlier access to advanced treatments, the NHSA also introduced a Commercial Health Insurance Innovative Drug List ("CHIIDL", effective as of January 1, 2026) in December 2025, which includes 19 high-value treatments not currently covered by the basic medical insurance fund. ZIIHERA and QARZIBA have been included in CHIIDL since 2025.

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.

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.

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 national, provincial and municipal governmental authorities, some of which are or may become applicable to our business. For example, we are subject to regulations relating to labor and social insurance, product liability and 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 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") 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, fines, 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 areas 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.

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. 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, issued in December 2023, included "cell cloning and gene editing technologies used in humans" into the prohibited list. It 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

In January 2025, SAMR launched a first-of-its-kind Compliance Guidelines for Healthcare Companies to Prevent Commercial Bribery Risks, which provide guidance for managing commercial bribery risks for healthcare and pharmaceutical companies and reflect the SAMR's enforcement priorities and high-risk areas of focus observed in recent years.

Subject to the Credit Evaluation System for Pharmaceutical Pricing, Bidding and Procurement, the National Healthcare Security Administration has established a catalog of dishonest practices related to drug pricing and procurement through bidding, which will be dynamically adjusted. The dishonest practices included in this catalog primarily encompass kickbacks or other improper benefits in the buying and selling of drugs, tax-related violations, monopolistic behaviors, improper pricing practices, disruption of centralized procurement processes, malicious breach of contracts, and other acts that contravene good faith principles. Provincial centralized procurement agencies will take action against pharmaceutical companies based on their trustworthiness ratings.

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; or extending loans to non-related parties, unless permitted by the scope of business or located in the designated area.

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.

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., the EU 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 BeOne Medicines 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 Switzerland with operations primarily conducted through direct and indirect subsidiaries in the U.S., China, the UK 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, BeOne Medicines Ltd. has raised over $10.8 billion in various public and private stock offerings, and has raised additional amounts from various borrowings, and beginning in Q3 2024, from cash flows from operations. Of the amounts raised, (1) $2.1 billion and RMB20 billion have been transferred as capital contributions to its operating subsidiaries and (2) $1.2 billion and RMB1.9 billion are outstanding intercompany loans due from its operating subsidiaries as of December 31, 2025. All biopharmaceutical patents previously owned by BeOne Medicines Ltd. have been transferred to operating subsidiaries for further development and commercialization. As of December 31, 2025, BeOne Medicines Ltd. held $584 million in cash and cash equivalents which are available for future investment in its programs and operating subsidiaries. The Company's subsidiaries outside of China have cash and cash equivalents of $3.2 billion that may be permanently transferred to BeOne Medicines 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, BeOne Medicines Ltd. has not received any dividends or distributions from its operating subsidiaries. For further information on our intercompany flow of funds, please refer to (i) the sections titled "Liquidity and Capital Resources" and "Risk Factors—Risks Related to Our Doing Business in the PRC—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," and (ii) our consolidated financial statements and the related notes included herein.

As of December 31, 2025, the Company has established a deferred tax liability of $30 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 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 articles of association, any future determination to pay dividends must be approved in advance by our shareholders. Our board of directors may propose a dividend to shareholders but cannot itself authorize the dividends. Such recommendation by our board of directors 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, 2025, these restricted assets totaled $2.0 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 BeOne Medicines 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 BeOne Medicines (Hong Kong) Co., Limited ("BeOne HK"). BeOne 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.

BeOne Medicines 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 BeOne Medicines Ltd. or between subsidiaries to supply additional liquidity using capital contributions, intercompany advances or loans, as follows:

- Cash may be transferred between BeOne HK and its operating subsidiaries in mainland China through intercompany loans and capital contributions. Cash generated from BeOne HK is used to fund operations of its subsidiaries, and no funds were transferred from BeOne HK's subsidiaries in mainland China to fund operations of other BeOne subsidiaries outside of mainland China for the years ended December 31, 2025 and 2024. For the years ended December 31, 2025 and 2024, the amount of cash transferred between BeOne HK and its subsidiaries in mainland China was $95 million and $106 million, respectively.

- Cash may be transferred between BeOne Medicines UK, Ltd. ("BeOne UK") and/or BeOne Medicines I GmbH ("BeOne Switzerland") and their respective operating subsidiaries through intercompany fund advances and capital contributions. There are currently no restrictions on transferring funds between BeOne UK or BeOne Switzerland and their respective operating subsidiaries. Cash generated from BeOne UK and BeOne Switzerland may be used to fund operations of their respective subsidiaries, and no funds were transferred from BeOne UK's subsidiaries or from BeOne Switzerland's subsidiaries to fund operations of other BeOne subsidiaries (such as BeOne HK and its subsidiaries in mainland China) for the years ended December 31, 2025 and 2024. For the years ended December 31, 2025 and 2024, the amount of cash transferred between BeOne UK to its respective subsidiaries was $5 million and $142 million, respectively. For the years ended December 31, 2025 and 2024, the amount of cash transferred between BeOne Switzerland to its respective subsidiaries was nil.

Seasonality of Business

Our global business has historically been subject to seasonality due to the dynamics of each market. For example, in the U.S., our fourth quarter results are affected by customer buying patterns influenced by pricing dynamics, with a corresponding offset to our first quarter results from these inventory management practices by our distributors. Net pricing and demand are also impacted in the U.S. in the first quarter due to patient co-pays and deductibles resetting at the beginning of each year. However, there are no assurances that these historical trends will continue in the future.

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 BeOne, 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 13, 2026, we had nearly 12,000 full-time employees worldwide, across six continents, with approximately 1,900 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 to 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 and have set targets where meaningful and appropriate. These 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 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 a Swiss corporation with our registered office in Switzerland located at Basel, Canton of Basel-Stadt, Switzerland. Our website address is www.beonemedicines.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 "BeOne" 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 SSE. 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 our website, our X account at x.com/BeOneMedicines, our LinkedIn account at linkedin.com/company/BeOneMedicines, our Facebook account at facebook.com/BeOneMedicines, and our Instagram account at instagram.com/BeOneMedicines to disclose material information and to comply with our disclosure obligations under Regulation FD. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.beonemedicines.com. 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.
- Restrictive covenants in our facilities agreements may limit our ability to respond to changes in market conditions or pursue business opportunities.
- 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 changed following the Continuation.
- As a Swiss corporation, our flexibility will be limited with respect to certain aspects of capital management.
- The Continuation has resulted in and may continue to result in additional direct and indirect costs.

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®, TEVIMBRA®, 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—U.S. 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 April 2025, the Trump administration published Executive Order 14273 (90 Fed. Reg. 16441), "Lowering Drug Prices by Once Again Putting Americans First," which generally directs the U.S. Department of Health and Human Services ("HHS") to take steps to reduce drug prices. In May 2025, the administration published Executive Order 14297 (90 Fed. Reg. 20749), "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients" which generally, among other things, directs certain executive officials to "communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations" and facilitate direct-to-consumer and direct-to-business purchasing programs and directs the Secretary of Commerce and the U.S. Trade Representative to "take all necessary and appropriate action to ensure foreign countries are not engaged in any act, policy, or practice that may be unreasonable or discriminatory or that may impair United States national security . . . including by suppressing the price of pharmaceutical products below fair market value in foreign countries." Subsequently, some pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices or reached agreement with the federal government regarding prices for prescription drugs sold to U.S. patients and through Medicaid programs, and in February 2026, the Trump administration announced the launch of TrumpRx, a website operated by the federal government that is intended to redirect consumers to pharmaceutical companies' direct-to-consumer channels. Additionally, in December 2025, the Centers for Medicare and Medicaid Services ("CMS") proposed a rule to implement the Global Benchmark for Efficient Drug Pricing (GLOBE) Model and the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model – both are new Medicare payment models under section 1115A of the Social Security Act. The scope, timing, and implementation details of these policies remain uncertain and may be subject to legal challenges, regulatory rulemaking, and changes in administrative priorities. If implemented, these policies could have a material impact on the pricing and reimbursement of our products in the United States, particularly those covered under Medicare Part B or Part D. Potential effects include reduced pricing flexibility, downward pressure on reimbursement rates and changes to market access dynamics and to pricing negotiations with commercial payors and international markets. Because the outcome, timing, and specifics of these policies are uncertain, we cannot predict the effect on our business, financial condition, results of operations, or prospects, but the impact could be material and adverse.

In addition, at the state level, legislatures have increasingly passed legislation and implemented regulations similar to those under consideration at the federal level, as well as laws designed to control pharmaceutical and biotherapeutic product pricing, including restrictions on pricing or reimbursement at the state government level, limitations on discounts to patients, marketing cost disclosure and transparency measures, restrictions or other limitations on patient assistance, and, in some cases, policies to encourage importation from other countries (subject to federal approval) and bulk purchasing. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards and similar entities.

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, TEVIMBRA, 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, accounting 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 trade policy, including tariffs that have been or may in the future be imposed by the U.S. or other countries, trade disputes, 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 our employees;
- 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, in 2025, the U.S. imposed tariffs on imports on its trading partners, including Canada, Mexico, the EU and China, and has subsequently proposed additional or alternative tariffs. While certain tariffs have been subsequently invalidated, suspended, modified or temporarily reduced, their impact has already been seen, and we expect will continue to be seen, in global markets, and we cannot predict the results of the U.S. government's trade negotiations or the outcome of ongoing legal challenges to specific tariff policies. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. 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. Furthermore, increased tariffs may make certain products no longer commercially viable. 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.

Furthermore, on April 1, 2025, the Bureau of Industry and Security of the U.S. Department of Commerce ("BIS") initiated an investigation into whether imports of pharmaceutical products present a risk to the national security of the U.S. This investigation could result in BIS recommending additional tariffs on imports of pharmaceutical products into the U.S. The scope or scale of any resulting tariffs as well as their secondary effects could adversely impact our business.

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, and we cannot predict with any certainty the success of any clinical trial or whether or when we might complete a given clinical trial. We may also experience delays in initiating and conducting clinical trials of our drug candidates, and we do not know whether our clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all.

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—U.S. 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.

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 were originally due. Such restatements increase our costs and could result in an overage or underage in our rebate liability for past quarters. Price recalculations may also 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.

Federal legislative and regulatory efforts to implement reference pricing or most-favored-nation pricing models could impact our product revenues and materially harm our business.

On May 12, 2025, President Trump issued an executive order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the U.S. and directing the Secretary of HHS to communicate MFN price targets to pharmaceutical manufacturers to align prices with those in comparably developed nations and, in the event significant progress towards MFN pricing is not delivered, to propose rulemaking to impose MFN pricing.

Since the May 12, 2025 order, the Trump administration has continued to exert pressure on drug manufacturers to implement MFN pricing, including by suggesting that the administration may impose significant tariffs on pharmaceuticals if such manufacturers do not reach agreements to implement MFN pricing. Further, in November 2025, the Centers for Medicare & Medicaid Services (CMS) introduced the GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model, a voluntary Medicaid payment initiative under which participating drug manufacturers may voluntarily offer supplemental rebates to participating state Medicaid programs that are intended to provide such Medicaid programs with an MFN price for the manufacturers' products. Additionally, in December 2025, CMS announced proposals for new mandatory demonstration payment models through two proposed rules under its Center for Medicare and Medicaid Innovation ("CMMI") authority, the Global Benchmark for Efficient Drug Pricing (GLOBE) for Medicare Part B and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) for Medicare Part D. If finalized, these models would impose additional mandatory rebates on manufacturers of certain Medicare Part B and Medicare Part D drugs, for select Medicare populations intended to represent 25% of Medicare patients, if the Medicare prices for such products exceed those paid in economically comparable countries. Both the GLOBE and GUARD models have proposed seven-year testing periods, with the GLOBE model proposed to begin on October 1, 2026 and the GUARD model proposed to begin on January 1, 2027.

If the GLOBE and GUARD models are finalized as proposed under CMMI authority, we could be required to pay additional rebates on products reimbursed by Medicare for the covered populations during the applicable model periods. In addition, if MFN pricing or similar reference pricing policies are enacted or implemented in the U.S. outside of the CMMI framework and applied more broadly, we could be required to pay rebates on products on utilization by a broader portion of U.S. patients to align with prices in certain reference countries. We currently derive the substantial portion of our revenue from U.S. sales, and any requirement to pay additional rebates in the U.S. to match international reference prices would impact our overall net revenue.

MFN pricing models in the U.S. could also affect our international pricing strategy and future decisions on reimbursement and commercialization in certain jurisdictions. If our U.S. pricing becomes tied to international reference prices, we may face decisions regarding pricing in foreign markets that could result in reduced patient access internationally, affect our relationships with foreign regulatory authorities and payers, or impact our ability to obtain or maintain reimbursement approvals in ex-U.S. markets.

These reforms remain subject to change, potential legal challenges, or expansion through additional rulemaking or sub regulatory guidance, creating uncertainty for our overall pricing strategy. It remains to be seen whether and how these drug pricing initiatives will apply to our products, how they will affect the broader pharmaceutical industry, and whether similar reform measures may be adopted in the future.

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.

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, European Medicines Agency ("EMA") and Medicines and Healthcare products Regulatory Agency ("MHRA"), 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, NMPA, EMA, MHRA 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 TEVIMBRA 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. 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 experiencing development delays or not receiving approval for commercialization in the applicable jurisdictions. Additionally, recent policy proposals in the U.S., if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of foreign data more difficult or costly.

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 the NMPA, EMA, MHRA and other 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, MHRA 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, MHRA 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, MHRA 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, MHRA 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-marketing 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, MHRA 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, MHRA and other regulatory authorities strictly regulate the marketing, labeling, advertising and promotion of products that are placed on the market. For example, in September 2025, the FDA and HHS announced reforms to limit the use of misleading direct-to-consumer pharmaceutical advertisements and increased enforcement activity, including through the issuance of dozens of publicly-posted untitled and warning letters, regarding direct-to-consumer advertising. Subsequently, in December 2025 and January 2026, we received untitled letters from the FDA relating to certain promotional communications relating to BRUKINSA® and TEVIMBRA®. We submitted responses to the FDA regarding the untitled letters. 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, MHRA 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, MHRA 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 TEVIMBRA, 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 TEVIMBRA, 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, in August 2022, the Inflation Reduction Act of 2022 (the "IRA") was signed into law. The IRA includes several provisions that may impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our medicines and drug candidates. For additional information, please see the section of this Annual Report titled "Part I – Item 1 – Business – Government Regulation – U.S. Regulation – Healthcare Reform."

In addition, in July 2025, the OBBBA was signed into law. This legislation reduces funding to federal healthcare programs and imposes additional requirements to be eligible for healthcare, and, to the extent the OBBBA reduces the number of enrollees in federal healthcare programs and covered services, our business could be adversely impacted.

Furthermore, the Creating and Restoring Equal Access to Equivalent Samples 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—U.S. 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, with exceptions in 2025 and 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, 2025, we had an accumulated deficit of $8.3 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 have achieved positive GAAP operating income and net income for full year 2025 as product sales growth exceeded 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 not be profitable in future periods. To the extent we achieve profitability in any future periods, we may not be able to sustain profitability in subsequent periods. Our failure to sustain profitability 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 provided $1.1 billion, and used $0.1 billion and $1.2 billion of net cash during the years ended December 31, 2025, 2024 and 2023, respectively. We recorded positive net cash flows from operating activities in 2025 and negative net cash flows from operating activities in 2024 and 2023 primarily due to our net income of $0.3 billion, and net losses of $0.6 billion and $0.9 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 may not be 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, and our ability to obtain additional financing may be subject to shareholder approval requirements or other regulatory approvals and requirements.

We have indebtedness outstanding and may incur additional short-term and long-term debt in the future. In November 2025, we and certain of our subsidiaries, as guarantors, entered into the Facilities Agreement with Hongkong and Shanghai Banking Corporation Limited and certain financial institutions, as lenders (the "Facilities Agreement"). 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 possibly 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 of 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. As of December 31, 2025, we had approximately $2.4 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 $4.5 billion and restricted cash of $62.1 million as of December 31, 2025, 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, 2025, 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 vary in scope and enforceability. 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 February 25, 2026, our subsidiaries, BeOne Medicines USA, Inc. and BeOne Medicines I GmbH, filed a patent infringement suit against Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Zydus") in the U.S. District Court for the District of New Jersey, in response to Zydus's notice informing its filing of an ANDA with the FDA in connection with BRUKINSA® (zanubrutinib) tablets. For additional information on this litigation, please see "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 product 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. Our medicines and drug candidates have and may in the future, given rise to claims of infringement of the patent rights of others, and 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 and suffer reputational harm.

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 TEVIMBRA, 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 TEVIMBRA 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;
- a dispute may arise with one or more of our third-party manufacturers;
- 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 TEVIMBRA in certain territories, but that agreement was terminated in September 2023 and we regained full, global rights to develop, manufacture and commercialize TEVIMBRA. 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. 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 2025, we had approximately 11,000 employees, and we ended the year with nearly 12,000 employees, an increase of approximately 9%. As of the date of this Annual Report, we had nearly 12,000 employees worldwide. 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 options, restricted share units and restricted shares that vest over time or are 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 requires 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, and now include potential attacks enhanced or facilitated by artificial intelligence.

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 widespread adoption of artificial intelligence impacting the attack surfaces targeted by threat actors or by other 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. If a material cyber incident or data breach 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 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 reputational 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. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, artificial intelligence hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies. 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, disclosure, or compromise of confidential information or other proprietary intellectual property through the use of generative artificial intelligence tools, or other cybersecurity incidents which may impact our ability to realize the benefit of our intellectual property.

A growing number of laws and regulations are being adopted which focus 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., dozens of states have passed laws to regulate various uses and applications of artificial intelligence, including addressing deployment of artificial intelligence in healthcare settings. At the federal level, the FDA has advanced guidance and proposed frameworks for regulating AI in drug discovery, marketing submissions, and medical device development. At the same time, the Trump administration has endorsed a federal moratorium on enforcement of certain state-level AI regulation, including through a December 11, 2025 Executive Order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork that may be litigated in state and federal courts. 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 or is use of such technologies results in harms or other causes of actions we did not predict.

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 China's Measures on National Cybersecurity Incident Reporting), health information privacy laws (such as the United States' Health Insurance Portability and Accountability Act ("HIPAA")), 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, in the U.S., in early 2025, the U.S. Department of Justice ("the DOJ") issued a January 8, 2025 rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," to prohibit certain 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 instance, the DOJ's 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. Additionally, numerous U.S. states now have passed or proposed privacy laws that add complexity, variation in requirements, restrictions and potential legal risk requiring additional investment of resources in compliance programs. For example, state laws regulating consumer personal information may impact clinical trial recruitment, marketing, and other activities, and state laws regulating health and genetic information may restrict access to data from outside the U.S. and our ability to collaborate with certain institutions. For example, Texas passed the Texas Genomic Act of 2025, which regulates access by "Foreign adversaries" to genomic data or biosamples collected in Texas and forbids use of genetic sequencers or associated software made or developed by Foreign Adversaries. 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. Despite our best efforts and those of our outside counsel, regulators and courts may disagree with our interpretation of the regulations, which may impact how we operate and result in penalties being imposed on us. 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, which was amended effective January 1, 2026, requires companies to take certain organizational, technical and administrative measures to ensure the security of their networks and data stored on their networks. Specifically, the Cyber Security Law provides that companies adopt a multi-level protection scheme ("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 which became effective in January 2025, impose detailed and prescriptive requirements for protecting network security. In addition, the Administrative Measures on National Cybersecurity Incident Reporting which became effective in November 2025, define the levels of cybersecurity incidents and the corresponding reporting requirements. 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), as well as further question-and-answer guidance issued in April and May 2025 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. The CAC has also issued new and updated regulatory measures focused on data security and cross-border data flows, and increased its enforcement activity. We expect the CAC and additional Chinese regulators to maintain a high level of scrutiny in the data security, cross-border data transfer and artificial intelligence space. 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. Certain industry-specific laws and regulations may also affect our collection and transfer of data. For example, the HGR Regulation and the Biosecurity Law of the PRC stipulate that foreign organizations, individuals, and the entities established or actually controlled by foreign organizations or individuals are forbidden to collect, preserve and export China's human genetic resources.

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 our business 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. While 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. In February 2025, the CAC finalized the Administrative Measures on Personal Information Protection Compliance Audit, which specifies the requirements on companies to implement and conduct the compliance audit under the PIPL. 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 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 the 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 the 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 the 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 the 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, such as occurred in October 2025, or if staffing changes prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, 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, government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Without appropriation of necessary funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The Trump administration has issued executive orders seeking to greatly reduce the size of the federal workforce, including through layoffs and severance packages offered to employees of federal agencies within the executive branch and independent agencies, including the FDA. Any such reduction in personnel may result in longer review times by the FDA and other agencies. In addition, U.S. state governments may seek to address or react to changes at the federal level with changes to their regulatory frameworks in a manner that could impact our operations.

Furthermore, 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 compliance 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, which 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 a 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 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. 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. For example, along with other recent U.S. federal tax reforms, the IRA and recently-enacted OBBBA have resulted in significant changes to the taxation of business entities including, among other changes, the imposition of a minimum tax on the book income of certain large corporations, changes to the taxation of income derived from international operations, changes in the deduction and amortization of research and development expenditures, and limitations on the deductibility of business interest. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified or sunset in future years. 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.

In addition, we evaluate our deferred income tax assets and record a valuation allowance if it is "more likely than not" that all or a portion of the deferred tax asset will not be realized. The assessment of the appropriate amount of a valuation allowance against the deferred tax assets is dependent upon several factors, including estimates of the realization of deferred income tax assets, which realization will be primarily based on future taxable income, including the reversal of existing taxable temporary differences. Given our recent history of earnings, our management believes that there is a reasonable possibility that, within the next twelve months, sufficient positive evidence may become available to allow management to reach a conclusion that a significant portion of the valuation allowance recorded against the deferred tax assets held will be reversed. We will continue to monitor the likelihood of a reversal, and the exact timing and amount of a valuation allowance release are subject to change based on the level of profitability that we actually achieve. Moreover, if actual results differ significantly from these estimates of future taxable income, we may need to maintain the valuation allowance for all or a significant portion of our deferred tax assets. Changes in the amount of any valuation allowance could materially increase or decrease our provision for income taxes in a given period.

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.

Restrictive covenants in our facilities agreements may limit our ability to respond to changes in market conditions or pursue business opportunities.

The Facilities Agreement and our other facilities agreements contain restrictive covenants that, among other things, limit certain activities or actions, including incurring additional indebtedness or liens, dispositions of assets, making certain fundamental changes, entering into restrictive agreements, making certain investments, entering into certain joint ventures, making certain loans, advances, guarantees or acquisitions, prepaying certain indebtedness, paying dividends or making certain other distributions or redemptions/repurchases on certain equity interests, and engaging in transactions with affiliates or amending certain material documents. As a result of these covenants, we are limited in the manner in which we conduct our business and we may be unable to react to changes in market conditions, take advantage of business opportunities we believe to be desirable, obtain future financing, fund needed capital expenditures or withstand a continuing or future downturn in our business.

In addition, the Facilities Agreement and our other facilities agreements require us to maintain certain financial ratios and to make certain required payments of principal, premium, if any, and interest. If we fail to comply with these provisions or other financial and operating covenants in such agreements, we could be in default under the terms of such agreements. In the event of such default and we were unable to cure such default, the holders of such indebtedness could elect to declare all the funds borrowed thereunder to be due and payable, together with accrued and unpaid interest, and the lenders thereunder could elect to terminate their commitments thereunder, cease making further loans and institute foreclosure proceedings against our assets. If any of these events occurred, then our business, operating results and financial condition could be materially and adversely affected.

We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under applicable debt instruments, which may not be successful.

Our ability to make scheduled payments on or to refinance our indebtedness obligations depends on our financial condition and operating performance, which are subject to financial, macroeconomic, competitive and other factors, some of which may be beyond our control. We may not be able to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness.

If our cash flows and capital resources are insufficient to fund debt service obligations, we may be forced to reduce or delay investments and R&D expenditures, sell assets, seek additional capital or restructure or refinance indebtedness. These alternative measures may not be successful and may not permit us to meet scheduled debt service obligations. Our ability to restructure or refinance indebtedness will depend on the condition of the capital markets and our financial condition at such time. Also, we may not be able to consummate dispositions at such time on terms acceptable to us or at all, and the proceeds of any such dispositions may not be adequate to meet such debt service obligations. Furthermore, any refinancing of indebtedness could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict business operations. In addition, the terms of existing or future debt instruments may restrict us from adopting some of these alternatives. For example, the Facilities Agreement may restrict our ability to dispose of assets under certain circumstances and our use of the proceeds from such disposition. Our inability to generate sufficient cash flows to satisfy our debt obligations, and resulting actions we may be forced to take or restricted from taking pursuant to our debt instruments, would have a material adverse effect on our business, results of operations, financial condition and prospects.

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 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.

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.

In January 2023, the National Development and Reform Commission (the "NDRC") promulgated the Administrative Measures for Examination and Registration of Medium and Long-term Foreign Debts of Enterprises (the "Foreign Debts Measures"), which became effective as of February 10, 2023. According to the Foreign Debts Measures, overseas enterprises that have material business operations in Chinese mainland may be required to complete applications for registration of foreign debts with the NDRC prior to the borrowing of foreign debts with a term of over one year. If any of our debt financing is subject to the Foreign Debt Measures and we fail to successfully complete such registrations or obtain approval from the NDRC in a timely manner or at all, we may need to seek alternative, shorter-term financing, and our ability to finance strategic transactions may be limited, which could adversely affect our business.

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, and our ability to incur debt. 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 U.S. may not be efficient in the absence of a mutual and practical cooperation mechanism. For risks associated with investing in us as a Swiss company, see the risk factor titled *"As we are now a Swiss company, our shareholders have broader rights in certain aspects than they would have under Hong Kong law, Chinese law, U.S. law, or previously applicable Cayman Islands law. While these enhanced rights offer increased shareholder participation, our flexibility to swiftly implement certain initiatives or strategies may be limited, and situations may arise where greater flexibility could otherwise provide meaningful benefits to our shareholders."*

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 Switzerland, 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, 2025, these restricted assets totaled $2.0 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 BeOne Medicines (Hong Kong) Co., Limited ("BeOne HK"), a company incorporated under the laws of Hong Kong on November 22, 2010 and a wholly-owned subsidiary of the Company. BeOne 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 BeOne Medicines 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 BeOne Medicines 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 Swiss 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, 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 pharmaceutical 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 or investor 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 U.S., 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 13, 2026, 1,442,259,810 ordinary shares, par value $0.0001 per share, were outstanding, of which 714,971,127 ordinary shares were held in the form of 54,997,779 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, as amended by the Post-Effective Amendment No. 1 filed with the SEC on May 27, 2025, registering 183,209,748 ordinary shares, including 128,104,537 ordinary shares in the form of 9,854,195 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 ordinary shares maintained on our Swiss share register in Switzerland and Hong Kong share 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 have 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 investors with respect to 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 our ordinary shares, ADSs and/or RMB Shares as a source for any future dividend income.

Any future distribution of dividends will be subject to approval by shareholders at a general meeting based on a proposal by the board of directors in accordance with Swiss law. The proposal by the board of directors to shareholders to approve a declaration of a dividend will depend, among other things, upon then existing conditions, including our financial condition, results of operations, contractual and other relevant legal or regulatory restrictions, capital requirements, business prospects and other factors deemed relevant by our board of directors.

Even if our board of directors decides to propose to shareholders to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend, among other things, on 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. In addition, payment of future dividends, if any, is subject to certain limitations pursuant to Swiss law or by our Swiss articles of association (as may be amended from time to time) (the "Swiss Articles"). Accordingly, the return on your investment in our ordinary shares, ADSs and/or RMB Shares will likely depend entirely upon any future price appreciation of our ordinary shares, ADSs and/or RMB Shares. There is no guarantee that our ordinary shares, ADSs and/or RMB Shares will appreciate in value or even maintain the price at which you purchased our ordinary shares, ADSs and/or RMB Shares. You may not realize a return on your investment in our ordinary shares, ADSs and/or RMB Shares and you may even lose your entire investment in our 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 our 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 our ordinary shares, ADSs and/or RMB Shares or publishes inaccurate or unfavorable research about our business, the market price for our 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 our ordinary shares, ADSs and/or RMB Shares to decline significantly.

As we are now a Swiss company, our shareholders have broader rights in certain aspects than they would have under Hong Kong law, Chinese law, U.S. law, or previously applicable Cayman Islands law. While these enhanced rights offer increased shareholder participation, our flexibility to swiftly implement certain initiatives or strategies may be limited, and situations may arise where greater flexibility could otherwise provide meaningful benefits to our shareholders.

We are now a corporation (Aktiengesellschaft) organized under Swiss law. Our corporate affairs are governed by Swiss Articles, our organizational regulations (as may be amended from time to time), and the laws of Switzerland, in particular the Swiss Code of Obligations (Obligationenrecht).

Under Swiss law, shareholder rights are broader than those under Cayman Islands law previously applicable to us before the Continuation. Swiss law reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. For example, shareholder approval is required for all dividend distributions, subject to the Company having sufficient distributable reserves. The board of directors cannot unilaterally declare dividends, unlike under Hong Kong, Delaware, or Cayman Islands law, which give the board of directors discretion to directly declare dividends, providing more flexibility. Actions for which our shareholders must vote will require that we file a proxy statement with the SEC and convene a shareholders' meeting that could delay the timing to execute such actions.

Furthermore, under Swiss law, a staggered or classified board is not permitted and all directors are elected or re-elected annually, which could increase board turnover and potentially reduce continuity and stability in management. Under Hong Kong, Delaware, and Cayman Islands law, staggered boards are allowed, which may provide greater stability. These and other Swiss law requirements could limit our flexibility to swiftly implement certain initiatives or strategies that could otherwise provide meaningful benefits to our shareholders.

As we are a Swiss company, our shareholders may face difficulties in enforcing their interests.

As we are a Swiss company, our shareholders 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 Hong Kong, mainland China, or U.S. federal court.

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 domiciled in China. Even if shareholders are successful in bringing an action, the laws of Switzerland and China may render them unable to enforce a judgment against our assets or the assets of our directors and officers. Swiss courts may recognize judgments obtained in the U.S., Hong Kong, or mainland China under certain conditions, but may not fully enforce punitive damages awarded.

The enforceability in Switzerland of a foreign judgment rendered against the Company or our directors and officers is subject to applicable international treaties by which Switzerland is bound and the Swiss Federal Private International Law Act. A foreign judgment may only be enforced in Switzerland if the foreign court had jurisdiction, such judgment became final and non-appealable, the court procedures leading to such judgment following the due process of law (including proper service of process), and such judgment does not violate Swiss legal principles of public policy. We have been advised that the U.S. and Switzerland currently do not have a treaty providing for reciprocal recognition and enforcement of judgments in civil and commercial matters. Some remedies available under the laws of U.S. jurisdictions, including under U.S. federal securities laws, may not be recognized in Swiss courts as they are contrary to Swiss public policy.

In view of the above, our shareholders may have more difficulty protecting their interests regarding actions taken by management or members of the board of directors, compared to 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 the Swiss Articles, the minimum notice period required for convening an annual general meeting or an extraordinary general meeting is 21 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 Swiss Articles include provisions that could limit the ability of others to acquire control of our Company, which could discourage third parties from seeking to obtain control in a tender offer or similar transaction, which may deprive our shareholders of an opportunity to sell their shares, at a premium over prevailing market prices.

For example, in new share issuances, our board of directors has the authority, without further action by our shareholders, to limit or withdraw subscription rights of existing shareholders and allocate such rights to third parties, the Company, or its group companies for various reasons, including raising equity capital quickly, acquiring enterprises or products, expanding the shareholder base, or defending against a takeover bid.

Further, our Swiss Articles require a majority of all shares entitled to vote at the relevant general meeting of shareholders to pass resolutions on the removal of board members during their one-year term of office. This threshold makes it difficult for a potential acquirer to remove existing directors during their one-year term and replace them with their own nominees.

Our Swiss Articles designate specific courts as the exclusive forum for certain disputes initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us, our directors, officers, or other employees.

Our Swiss Articles provide that our place of incorporation in Basel, Switzerland will be the exclusive forum for any disputes arising under, out of, in connection with, or related to the corporate relationship. As a result, any derivative action or proceeding brought on behalf of us asserting a claim of breach of a fiduciary duty owed by any director or officer of us to the Company and our shareholders, can only be brought in the courts of Basel, Switzerland. Our Swiss Articles 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 bound by 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.

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, registration of ADS transfers, conversion of ADSs of one series for ADSs of another series, 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 37% of our outstanding ordinary shares as of February 13, 2026. 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" (a "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, 2025. 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 changed following the Continuation.

Effective May 27, 2025, we changed 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 Act on Private International Law (such transaction, the "Continuation"). Because of differences in Swiss law and Cayman Islands law and certain changes that were made to our governing documents in connection with the Continuation, your rights as a shareholder have changed. For a description of these differences, see "Proposal No. 1: Approval of the Continuation — Comparison of Shareholder Rights" in the proxy statement/prospectus filed with the SEC on March 10, 2025.

As a Swiss corporation, our flexibility will be limited with respect to certain aspects of capital management.

Swiss law regulates a corporation's ability to hold, purchase or repurchase its own shares. We and our subsidiaries may only purchase or repurchase our own shares (the "treasury shares") to the extent that sufficient freely available equity is available. The aggregate par value of the treasury shares may not exceed 10% of our stated share capital, unless our shareholders authorize (including through the capital band) our board of directors to purchase or repurchase our registered shares in an amount in excess of 10% and the treasury shares are dedicated for cancellation to effect a capital reduction.

Swiss law allows our shareholders to authorize the board of directors to issue shares without additional shareholder approval, but this authorization is limited to (i) 50% of our stated share capital (among other things, for the issuance of shares in connection with an acquisition or to raise new equity capital, subject to compliance with shareholders' preemptive rights, unless withdrawn for the reasons specified in the Swiss Articles) (the "capital band"), and (ii) an additional 20% of our stated share capital for the issuance of shares in connection with convertible or similar financial instruments and our equity incentive plans (the "conditional share capital"). The authority of the board of directors to issue shares based on the capital band must be renewed by our shareholders every five years. The Swiss Articles provide for a capital band authorizing the board of directors to issue or increase the nominal value of up to 770,487,949 shares or to cancel or reduce the nominal value of up to 154,097,590 shares up until April 28, 2029. After April 28, 2029, the capital band will only be available to the board of directors for issuance or cancellation of registered shares if a renewed authorization is approved by shareholders.

Additionally, Swiss law grants existing shareholders preemptive rights to subscribe for newly issued shares and advance subscription rights to subscribe for convertible and similar financial instruments. Preemptive rights and advance subscription rights may be limited or withdrawn only for valid reasons. In connection with share issuances based on the capital band and the conditional share capital, the preemptive rights and the advance subscription rights may only be limited or withdrawn for the reasons specified in the Swiss Articles.

In comparison to Cayman Islands law, Swiss law does not provide as much flexibility in the various terms that can attach to different classes of shares. Further, Swiss law also reserves for approval by shareholders many corporate actions, including the declaration and approval of dividends under certain circumstances. While we do not believe that the differences between Cayman Islands law and Swiss law relating to our capital management will have an adverse effect on our company, Swiss law requirements may limit our flexibility to swiftly implement certain initiatives or strategies and situations may arise where greater flexibility would have provided substantial benefits to our shareholders.

The Continuation has resulted in and may continue to result in additional direct and indirect costs.

The Continuation has resulted in and may continue to result in additional direct costs. Following the Continuation, we expect to hold a large portion of meetings of our board of directors, management strategy meetings as well as our annual general meetings 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. We may continue to experience indirect costs if management and employees' attention is diverted from our business or if the administrative complexity associated with the new structure leads to 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 Continuation, even though you will not have realized any income or liquidity as a result of the Continuation. For a more detailed description of the tax consequences associated with the Continuation, see "Proposal No. 1: Approval of the Continuation — Material Tax Considerations — United States Tax Considerations" in the proxy statement/prospectus filed with the SEC on March 10, 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 had qualifying capital contribution reserves in the amount of approximately US$11-12 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 change 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 amount tax must be withheld from the gross dividend distribution and paid to the Swiss Federal Tax Administration. A U.S. holder that qualifies for benefits under the Convention between the U.S. 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 amount withheld in excess of the U.S.-Swiss Treaty 15% rate (or for a full refund in the case of qualified pension funds, or a refund in excess of the 5% U.S.-Swiss Treaty rate if you are a corporate shareholder that directly holds at least 10% of our share capital). A shareholder domiciled in China 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 (the "PRC-Swiss Treaty") may apply for a refund of the tax amount withheld in excess of the 10% or 5% PRC-Swiss 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 (the "Hong Kong-Swiss Treaty") may apply for a refund of the tax amount withheld in excess of the 10% Hong Kong-Swiss Treaty rate (or a full refund in the case of specific qualified persons, including a pension fund or a corporate shareholder that directly holds at least 10% our share capital). Subject to applicable laws and regulations, this may also apply to other shareholders entitled to a dividend withholding tax rate lower than the Swiss withholding tax rate under 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, share repurchases for capital reduction are treated as a partial liquidation subject to 35% Swiss withholding tax on the difference between the par value plus qualifying capital contributions reserves and the repurchase price, irrespective of the shareholder's tax residency. Share repurchases for purposes other than capital reduction, such as for retention 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, provided the total treasury shares do not exceed 10% or 20% (as applicable) of the share capital. Any portion of the share 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 proxy statement/prospectus filed with the SEC on March 10, 2025.

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 program, we adhere to our Information Security Management System Policy ("ISMS 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 ISMS 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 ISO 27001:2022 and additionally 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.

To date, cybersecurity threats have 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 reports on a quarterly basis 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 Chief Technology Officer ("CTO"), along with our CISO, is responsible for leading the individuals tasked with maintaining our enterprise-wide cyber resilience strategy, policy, standards, architecture, and processes. Our CTO has over thirty years of experience leading technology organizations and managing information security across multiple industries and programs, including SOX 404 compliance, GxP audit and compliance, NIST Cybersecurity Framework assessments, managing incident response and communication with executives and board of directors. 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.

Item 2. Properties

We lease all of our facilities, excluding the following owned facilities: our offices and laboratories in Changping, Beijing; our manufacturing facility in Guangzhou, China; our manufacturing facility and CMC laboratories in the Industrial Park of Suzhou; our offices and laboratories in Zhangjiang, Shanghai; our innovation center on "Bio-Island" in Guangzhou; and our manufacturing facility and clinical R&D center at the Princeton Innovation Park in Hopewell, New Jersey. We lease a total of approximately 130,000 square meters of office space at around 51 other locations across the United States, Europe, China, the Middle East and North Africa (MENA), South Africa, and South America, in cities such as Cambridge, Massachusetts, and San Carlos, California in the United States; Beijing, Shanghai, Wuhan, and Chengdu in China; and Basel, Switzerland. These leased spaces are primarily used for our offices and the manufacturing facility in Suzhou, China, under leases with various expiration dates, the latest of which expires in 2031. We consider that our current facilities are suitable and sufficient to meet our requirements. We plan to add new facilities or expand existing ones as we recruit more employees and enter new regions. Moreover, we believe that appropriate additional or substitute space will be available as necessary to support the 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.

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.

ANDA Litigation

On February 25, 2026, our subsidiaries, BeOne Medicines USA Inc. and BeOne Medicines I GmbH, filed a patent infringement suit under the Hatch-Waxman Act against Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Zydus") in the United States District Court for the District of New Jersey. The patent infringement suit is in response to Zydus' notice to BeOne concerning the filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA"), seeking FDA approval to market a generic version of BRUKINSA® (zanubrutinib) tablets along with "Paragraph IV certifications" challenging certain BRUKINSA® Orange Book patents for invalidity and/or non-infringement. According to the notice, Zydus has not challenged BRUKINSA's composition of matter patent, which remains intact and protects BRUKINSA® from generic competition until its expiration in 2034.

BeOne's complaint alleges that by filing the ANDA, Zydus infringes certain of BRUKISNA's Orange Book patents and seeks a permanent injunction to prevent Zydus from commercializing a generic version of BRUKINSA® tablets until the expiration of the asserted patents.

ANDA litigation is common in the U.S. pharmaceutical industry. We may receive additional notices from other generic drug companies and may file additional ANDA lawsuits in the future.

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, 2026, we had approximately 31,846 holders of record of our ordinary shares, 31,697 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

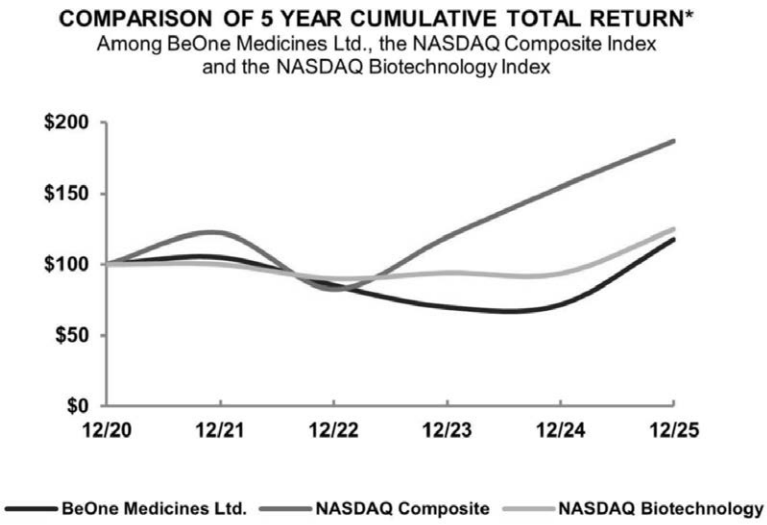
We have never declared or paid any dividends on our ordinary shares or any other securities. We currently intend to retain all available funds and earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. If 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 articles of association, any future determination to pay dividends must be approved in advance by our shareholders. Our board of directors may propose a dividend to shareholders but cannot itself authorize the dividends. Such recommendation by our board of directors 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, 2020 through December 31, 2025 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.



($ in dollars)	12/31/20	12/31/21	12/31/22	12/31/23	12/31/24	12/31/25
BeOne Medicines Ltd.	**100.00**	**104.85**	**85.12**	**69.80**	**71.48**	**117.58**
Nasdaq Composite	**100.00**	**122.18**	**82.43**	**119.22**	**154.48**	**187.14**
Nasdaq Biotechnology	**100.00**	**100.02**	**89.90**	**94.03**	**93.49**	**124.75**

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

Except as previously reported by us on our current report on Form 8-K, we did not sell any securities during the year covered by this Annual Report that were not registered under the Securities Act.

Issuer Purchases of Equity Securities

None.

Taxation

Swiss Taxation

The tax consequences discussed below are not a complete analysis or description of all the possible tax consequences that may be relevant to you. You should consult your own tax advisor in respect of the tax consequences related to receipt, ownership, purchase or sale or other disposition of registered shares and the procedures for claiming a refund of withholding tax.

Swiss Income Tax on Dividends and Similar Distributions

A non-Swiss holder will not be subject to Swiss income taxes on dividend income and similar distributions in respect of registered shares, unless the shares are attributable to a permanent establishment or a fixed place of business maintained in Switzerland by such non-Swiss holder. However, dividends and similar distributions are subject to Swiss withholding tax. See "—Swiss Withholding Tax—Distributions to Shareholders" below.

Swiss Wealth Tax

A non-Swiss holder will not be subject to Swiss wealth taxes unless the holder's registered shares are attributable to a permanent establishment or a fixed place of business maintained in Switzerland by such non-Swiss holder.

Swiss Capital Gains Tax upon Disposal of Registered Shares

A non-Swiss holder will not be subject to Swiss income taxes for capital gains unless the holder's shares are attributable to a permanent establishment or a fixed place of business maintained in Switzerland by such non-Swiss holder. In such case, the non-Swiss holder is required to recognize capital gains or losses on the sale of such shares, which will be subject to cantonal, communal and federal income tax.

Swiss Withholding Tax—Distributions to Shareholders

A Swiss withholding tax of 35% is due on dividends and similar distributions to our shareholders from BeOne out of available earnings or other non-qualifying reserves for withholding tax purposes, regardless of the place of residency of the shareholder (subject to the exceptions discussed under "—Exemption from Swiss Withholding Tax—Distributions to Shareholders" below). We will be required to withhold at such rate and remit on a net basis any payments made to a holder of registered shares and pay such withheld amounts to the Swiss Federal Tax Administration. See "—Refund of Swiss Withholding Tax on Dividends and Other Distributions" below.

Exemption from Swiss Withholding Tax—Distributions to Shareholders

Distributions to shareholders in relation to a reduction of par value and distributions to shareholders out of qualifying capital contribution reserves recognized by the Swiss Federal Tax Administration are exempt from the Swiss withholding tax. We expect to pay any distributions out of qualifying capital contribution reserves recognized by the Swiss Federal Tax Administration for the foreseeable future, and as a result, any such distributions to shareholders will be exempt from the Swiss withholding tax.

Repurchases of Shares

Repurchases of shares for the purposes of capital reduction are treated as a partial liquidation subject to the 35% Swiss withholding tax. However, for shares repurchased for capital reduction, the portion of the repurchase price attributable to the par value and to the qualifying contribution reserves recognized by the Swiss Federal Tax Administration of the shares repurchased will not be subject to the Swiss withholding tax. We would be required to withhold at such rate the tax from the difference between the repurchase price and the related amount of par value and qualifying contribution reserves. We would be required to remit on a net basis the purchase price with the Swiss withholding tax deducted to a holder of registered shares and pay the withholding tax to the Swiss Federal Tax Administration.

With respect to the refund of Swiss withholding tax from the repurchase of shares, see "—Refund of Swiss Withholding Tax on Dividends and Other Distributions" below.

In many instances, Swiss companies listed on the SIX Swiss Exchange carry out share repurchase programs through a "second trading line" on the SIX Swiss Exchange. Swiss institutional investors (such as Swiss arbitrage banks) typically purchase shares from shareholders on the open market and then sell the shares on the second trading line back to the company. The Swiss institutional investors are generally able to receive a full refund of the withholding tax. Due to, among other things, the time delay between the sale to the company and the institutional investors' receipt of the refund, the price companies pay to repurchase their shares has historically been slightly higher (but less than 1.0%) than the price of such companies' shares in ordinary trading on the SIX Swiss Exchange first trading line.

We do not expect to use the SIX Swiss Exchange second trading line process to repurchase our shares because we do not intend to list our shares on the SIX Swiss Exchange. We may, however, follow an alternative process whereby we expect to be able to repurchase our shares in a manner that should allow Swiss institutional market participants selling the shares to us to receive a refund of the Swiss withholding tax and, therefore, accomplish the same purpose as share repurchases on the second trading line at substantially the same cost to us and such market participants as share repurchases on a second trading line.

The repurchase of shares for purposes other than capital reduction, such as to retain as treasury shares for use in connection with long-term incentive plans, convertible debt or other instruments within certain periods, will generally not be subject to Swiss withholding tax.

Refund of Swiss Withholding Tax on Dividends and Other Distributions

The Swiss-U.S. tax treaty provides that U.S. residents eligible for benefits under the treaty can seek a refund of the Swiss withholding tax on dividends for the portion exceeding 15% (leading to a refund of 20%) or a full refund in the case of qualified pension funds.

As a general rule, the refund will be granted under the treaty if the U.S. resident can show evidence of:

- beneficial ownership;
- U.S. residency; and
- meeting the U.S.-Swiss tax treaty's limitation on benefits requirements.

The claim for refund must be filed with the Swiss Federal Tax Administration (Eigerstrasse 65, 3003 Berne, Switzerland), not later than December 31 of the third year following upon the calendar year in which the dividend payments became due. The relevant Swiss tax form is Form 82C for companies, 82E for other entities and 82I for individuals. These forms can be obtained from any Swiss Consulate General in the United States or from the Swiss Federal Tax Administration at the address mentioned above or online. Each form needs to be filled out in triplicate, with each copy duly completed and signed before a notary public in the United States. You must also include evidence that the withholding tax was withheld at the source.

Swiss Transfer Stamp Tax in Relation to the Transfer of Registered Shares

The purchase or sale of registered shares may be subject to Swiss Transfer Stamp Tax which is due on the transfer of taxable securities (as defined in the Swiss Federal Stamp Tax Act) irrespective of the place of residency of the purchaser or seller if a Swiss or Liechtenstein bank or other Swiss or Liechtenstein securities dealers (as defined in the Swiss Federal Stamp Tax Act of 1973) participate to the transaction as contracting parties or as intermediaries. The applicable stamp tax rate is 0.075% for each of the two parties to a transaction (i.e., 0.15% in total) and is calculated based on the purchase price or sale proceeds. If the transaction does not involve cash consideration, the transfer stamp duty is computed on the basis of the market value of the consideration. No Swiss Transfer Stamp Tax will be due if no Swiss or Liechtenstein bank or other Swiss or Liechtenstein securities dealers (as defined in the Swiss Federal Stamp Tax Act) is involved in a purchase or sale.

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 BeOne Medicines 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 BeOne Medicines 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. BeOne Medicines 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 BeOne Medicines 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.

A discussion of the Company's financial condition and results of operations for the year ended December 31, 2023 and year-to-year comparisons between 2024 and 2023 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, 2024.

Non-GAAP Financial Measures

We provide certain financial measures that are not defined under accounting principles generally accepted in the United States of America ("GAAP"), commonly referred to as non-GAAP financial measures, including Adjusted Operating Expenses, Adjusted Income (Loss) from Operations, Adjusted Net Income (Loss), Adjusted Earnings Per Share, Free Cash Flow 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. Non-GAAP adjustments are tax effected to the extent there is US GAAP current tax effect. The Company currently records a valuation allowance on its net deferred tax assets, so there is no net impact recorded for deferred tax effects in our tax expense. 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 BeOne'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 BeOne 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 show topline growth and a strong liquidity position to support ongoing operations and strategic priorities. BRUKINSA is the global revenue leader in the BTK inhibitor class and TEVIMBRA continues to gain new indications and expanded reimbursement in multiple markets. Our late-stage hematology assets are approaching commercialization and our solid tumor portfolio continues to deliver encouraging data.

Key highlights for the full year 2025 are as follows:

- Total global revenues of $1.5 billion and $5.3 billion, respectively, in the fourth quarter and full year, increases of 32.8% and 40.2%, respectively, compared to the prior year periods;
- Global BRUKINSA revenues of $1.1 billion and $3.9 billion for the fourth quarter and full year 2025, increases of 38.4% and 48.6%, respectively, compared to the prior year periods; and
- GAAP diluted earnings per American Depositary Share ("ADS") of $0.58 and $2.53 for the fourth quarter and full year, non-GAAP diluted earnings per ADS of $1.95 and $8.09 for the fourth quarter and full year.

Recent Business Developments

On December 7, 2025, we announced new data on sonrotoclax, a next-generation investigational BCL2 inhibitor, demonstrating meaningful clinical benefit as monotherapy and in combination across B-cell malignancies, and in January 2026, we received the first approval of sonrotoclax for adult patients with relapsed/refractory ("R/R") mantle cell lymphoma ("MCL") and R/R chronic lymphocytic leukemia ("CLL")/small lymphocytic lymphoma ("SLL").

On November 26, 2025, we announced that the U.S. Food and Drug Administration ("FDA") accepted and granted Priority Review to a New Drug Application ("NDA") for sonrotoclax for the treatment of adult patients with R/R MCL, following treatment with a Bruton's tyrosine kinase ("BTK") inhibitor.

On November 17, 2025, we announced positive top-line results from the Phase 3 HERIZON-GEA-01 trial evaluating ZIIHERA® (zanidatamab), a HER2-targeted bispecific antibody, in combination with chemotherapy, with or without PD-1 inhibitor TEVIMBRA® (tislelizumab), as first-line treatment for HER2-positive ("HER2+") locally advanced or metastatic gastroesophageal adenocarcinoma ("GEA"), including cancers of the stomach, gastroesophageal junction, and esophagus.

On November 13, 2025, we entered into the Facilities Agreement (the "Facilities Agreement") with The Hongkong and Shanghai Banking Corporation Limited ("HSBC") and certain financial institutions listed in the Facilities Agreement as lenders. The Facilities Agreement provides senior secured financing consisting of a U.S. dollar-denominated, B1 revolving loan facility in an aggregate principal amount of $140 million (the "B1 Revolving Loan Facility"), a U.S. dollar-denominated, B2 term loan facility in an aggregate principal amount of $560 million (the "B2 Term Loan Facility" and, together with the B1 Revolving Loan Facility, the "B Loan Facilities"); and a Renminbi-denominated, A term loan facility in an aggregate principal amount of approximately $300 million (the "A Loan Facility") (collectively, the "Loan Facilities"). The A Loan Facility matures 36 months after the first utilization date of such facility and, unless extended, the B Loan Facilities mature 24 months after the first utilization date of a B Loan Facility. Subject to certain limitations, the Loan Facilities are secured on a first priority basis granted in favor of HSBC by a security interest in the equity interests of a number of our subsidiaries and security interests in, and mortgage on, our manufacturing and clinical R&D facility in New Jersey. The Facilities Agreement contains certain affirmative and negative covenants, as well as financing covenants applicable to the Loan Facilities. The A Loan Facility is subject to an interest rate equal to the Reference Rate (RMB) (as defined in the Facilities Agreement) plus a margin of 0.65% per annum. The B Loan Facilities are subject to an interest rate equal to the Reference Rate (USD) (as defined in the Facilities Agreement) plus a margin of 2.40% per annum. Subsequently, on December 16, 2025, we utilized a portion of the proceeds from borrowings under the Facilities Agreement to repay in full all outstanding amounts owed under the Company's Facility Agreement, dated as of December 9, 2024, by and between the Company and China Merchants Bank Co., Ltd. (the "CMB Credit Facility"), and terminated all commitments by the lender to extend further credit under the CMB Credit Facility and all guarantees and security interests granted by the Company to the lender under the CMB Credit Facility.

On August 25, 2025, BeOne Medicines Ltd. entered into a Royalty Purchase Agreement (the "Royalty Agreement") with Royalty Pharma plc ("Royalty Pharma"), pursuant to which we agreed to sell a significant portion of our rights to royalty payments from Amgen based on annual net revenue from sales outside of China of any and all products that consist of Amgen's IMDELLTRA®. Under the terms of the Royalty Agreement, we received a non-refundable upfront payment of $885 million upon the closing of the Royalty Agreement, and subsequently exercised our option to sell to Royalty Pharma an additional portion of our rights to royalty payments for approximately $26 million. We will share in a portion of the royalties on annual ex-China net revenue from IMDELLTRA® above $1.5 billion, and will maintain royalty and all other rights to other assets under the terms of the existing collaboration with Amgen, including xaluritamig, a first-in-class STEAP1 x CD3 XmAb currently being studied in patients with metastatic castration-resistant prostate cancer (mCRPC). The upfront payment received from Royalty Pharma is classified as a financing liability according to ASC 470, *Debt*. The repayment of this obligation to Royalty Pharma will be made upon the receipt of royalties from Amgen throughout the royalty period, which is anticipated to extend at least through 2041.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		Change	
	2025	2024	$	%
	(dollars in thousands)			
Revenues				
Product revenue, net	$ 5,282,061	$ 3,779,546	$ 1,502,515	39.8 %
Other revenue	60,972	30,695	30,277	98.6 %
Total revenues	5,343,033	3,810,241	1,532,792	40.2 %
Cost of sales - product	668,540	594,089	74,451	12.5 %
Gross profit	4,674,493	3,216,152	1,458,341	45.3 %
Operating expenses				
Research and development	2,145,868	1,953,295	192,573	9.9 %
Selling, general and administrative	2,081,489	1,831,056	250,433	13.7 %
Total operating expenses	4,227,357	3,784,351	443,006	11.7 %
Income (loss) from operations	447,136	(568,199)	1,015,335	(178.7)%
Interest income	70,505	69,641	864	1.2 %
Interest expense	(58,234)	(21,805)	(36,429)	167.1 %
Other expense, net	(42,553)	(12,638)	(29,915)	236.7 %
Income (loss) before income tax expense	416,854	(533,001)	949,855	(178.2)%
Income tax expense	129,921	111,785	18,136	16.2 %
Net income (loss)	$ 286,933	$ (644,786)	$ 931,719	(144.5)%

Revenue

Total revenue increased by $1.5 billion to $5.3 billion for the year ended December 31, 2025, from $3.8 billion for the year ended December 31, 2024, primarily due to increased sales of BRUKINSA, TEVIMBRA, as well as increased sales of in-licensed products from Amgen.

Net product revenue consisted of the following:

	Year Ended December 31,		Changes	
	2025	2024	$	%
	(dollars in thousands)			
BRUKINSA®	$ 3,928,489	$ 2,644,226	$ 1,284,263	48.6 %
TEVIMBRA®	737,304	620,836	116,468	18.8 %
XGEVA®	305,979	224,403	81,576	36.4 %
BLINCYTO®	104,224	74,331	29,893	40.2 %
KYPROLIS®	74,974	66,171	8,803	13.3 %
POBEVCY®	47,400	53,509	(6,109)	(11.4)%
Other	83,691	96,070	(12,379)	(12.9)%
Total product revenue	$ 5,282,061	$ 3,779,546	$ 1,502,515	39.8 %

Net product revenue increased for the year ended December 31, 2025, compared to 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 2025 were positively impacted by growth from in-licensed products from Amgen and TEVIMBRA.

Global sales of BRUKINSA totaled $3.9 billion for the year ended December 31, 2025, representing a 48.6% increase compared to the prior year. U.S. sales of BRUKINSA totaled $2.8 billion for the year ended December 31, 2025 compared to $2.0 billion in the prior year, representing growth of 45.1%, driven primarily by robust demand growth across all indications and modest benefit due to net pricing. BRUKINSA continues to maintain its leading new patient share across the BTKi class due to its differentiated, best-in-class clinical profile. BRUKINSA sales in the EU totaled $596.4 million for the year ended December 31, 2025, representing growth of 66.2% compared to the prior-year period, driven by continued gains in market share across all major markets, including Germany, Italy, Spain, France and the UK. BRUKINSA sales in China totaled $344.1 million for the year ended December 31, 2025, representing growth of 33.3% compared to the prior year.

Sales of TEVIMBRA totaled $737.3 million for the year ended December 31, 2025, representing a 18.8% increase compared to the prior year.

Other revenue totaled $61.0 million and $30.7 million for the years ended December 31, 2025 and 2024, respectively, primarily related to royalty revenue under the Amgen collaboration and revenue generated under the Novartis broad markets marketing and promotion agreement.

Gross Margin

Gross margin on global product sales increased to $4.6 billion, or 87.3% as a percentage of sales, for the year ended December 31, 2025, compared to $3.2 billion, or 84.3% as a percentage of sales, for the year ended December 31, 2024. The gross margin percentage increased due to a proportionally higher sales mix of global BRUKINSA compared to other products in our portfolio. Gross margin also benefited from production productivity improvements resulting in lower costs for both BRUKINSA and TEVIMBRA. These increases were slightly offset by period costs of $33.9 million related to the re-positioning of our manufacturing capacity during 2025. On an adjusted basis, which does not include depreciation and amortization, gross margin as a percentage of product sales increased to 87.8% for the year ended December 31, 2025, from 85.5% in the prior year.

Research and Development Expense

Research and development expense increased by $192.6 million, or 9.9%, to $2.1 billion for the year ended December 31, 2025, from $2.0 billion for the year ended December 31, 2024. 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, 2025 and 2024:

	Year Ended December 31,		Changes	
	2025	2024	$	%
	(dollars in thousands)			
External research and development expense:				
Cost of development programs	$ 753,868	$ 539,446	$ 214,422	39.7 %
Upfront license and development milestone fees	709	114,049	(113,340)	(99.4)%
Amgen co-development expenses[1]	104,143	75,165	28,978	38.6 %
Total external research and development expenses	858,720	728,660	130,060	17.8 %
Internal research and development expenses	1,287,148	1,224,635	62,513	5.1 %
Total research and development expenses	$ 2,145,868	$ 1,953,295	$ 192,573	9.9 %
Adjusted research and development expense[2]	$ 1,855,979	$ 1,668,368	$ 187,611	11.2 %

[1.] Our co-funding obligation for the development of the pipeline assets under the Amgen collaboration for the year ended December 31, 2025 totaled $205.2 million, of which $104.1 million was recorded as R&D expense. The remaining $101.1 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, 2025 was primarily attributable to an increase in external costs of development programs primarily due to advancing preclinical programs into the clinic and early clinical programs into late stage, including sonrotoclax (BCL2i), as well as higher Amgen co-development expenses offset by lower development upfront and milestone fees.

Internal research and development expense increased $62.5 million, or 5.1%, to $1.3 billion for the year ended December 31, 2025 from $1.2 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.

Selling, General and Administrative Expense

	Year Ended December 31,		Changes	
	2025	2024	$	%
	(dollars in thousands)			
Selling, general and administrative expense	$ 2,081,489	$ 1,831,056	$ 250,433	13.7 %
Adjusted selling, general and administrative expense[1]	$ 1,743,118	$ 1,549,864	$ 193,254	12.5 %

[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 $250.4 million, or 13.7%, to $2.1 billion for the year ended December 31, 2025, from $1.8 billion for the year ended December 31, 2024. The increase was primarily attributable to continued investment in global commercial expansion primarily in the U.S. and Europe. Selling, general and administrative expenses as a percentage of product sales were 39.4% for the year ended December 31, 2025 compared to 48.4% in the prior-year period.

Interest Income

Interest income increased by $0.9 million, or 1.2%, to $70.5 million for the year ended December 31, 2025, compared to $69.6 million for the year ended December 31, 2024. Interest income remained materially consistent, due to lower interest rates earned on our cash and cash equivalents offset by a higher cash and cash equivalents balance.

Interest Expense

Interest expense increased by $36.4 million, or 167.1%, to $58.2 million for the year ended December 31, 2025, compared to $21.8 million for the year ended December 31, 2024. Interest expense increased resulting from interest expense recorded under the effective interest method related to the sale of future royalty liability, higher interest rates on debt balances and lower interest capitalized related to completion of certain phases of our Hopewell facility.

Other Expense, Net

Other expense, net for the year ended December 31, 2025 was $42.6 million, due to impairment losses recognized on our equity investments partially offset by government subsidy income and foreign exchange gains.

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 BeOne Medicines Ltd. (the “Parent Company”), and unrealized losses on equity investments, partially offset by government subsidy income.

Income Tax Expense

Our total income tax expense is substantially equal to our current tax expense and thus does not reflect any deferred tax benefits related to our net deferred tax assets due to the ASC 740, *Income Taxes* requirement to establish a valuation allowance against all such assets in all jurisdictions, thereby negating the tax benefit in the income statement, due to our three-year cumulative loss position. Our discussion of income tax expense below is thus based on a comparison of our current tax expense in 2025 versus 2024.

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Current tax expense	120,452	85,778	55,185
Net deferred tax benefit	(149,347)	(131,279)	(845,124)
Increase in valuation allowance	158,816	157,286	845,811
Total income tax expense	129,921	111,785	55,872

Income tax expense was $129.9 million ($120.5 million current tax) for the year ended December 31, 2025 compared with $111.8 million ($85.8 million current tax) for the year ended December 31, 2024. The current income tax expense for the year ended December 31, 2025 was primarily attributable to higher currently taxable income primarily in China, Australia, and Italy, that resulted in an increase of $52.6 million offset with lower current tax in the U.S. of $17.9 million. The decrease in the U.S. was driven by positive impacts of OBBBA, while the increase in other jurisdictions' higher current taxable income was driven by (a) the increase in current year valuation allowances on short-term deferred tax assets that are triggered by our three-year cumulative loss position at a consolidated level, (b) increase in uncertain tax liabilities and (c) return to provision adjustments.

Given the Company's recent history of earnings, management believes that there is a reasonable possibility that, within the next twelve months, sufficient positive evidence may become available to allow management to reach a conclusion that a significant portion of the valuation allowance recorded against the deferred tax assets held will be reversed. The reversal would result in an income tax benefit for the quarterly and annual fiscal period in which the Company releases the valuation allowance. However, the exact timing and amount of the valuation allowance release are subject to change on the basis of the level of profitability that the Company actually achieves. Prior to reversal, income tax expense should trend with earnings per historical relationship.

On July 4, 2025, the reconciliation bill (H.R. 1), commonly referred to as the OBBBA, was signed into law and includes a broad range of tax reform provisions. The OBBBA allows an elective deduction for domestic research and development expenses and, a reinstatement of elective 100% first-year bonus depreciation effective in tax year 2025, and a more favorable tax rate on foreign-derived deduction eligible income effective in tax year 2026. The impact of certain elective provisions of the OBBBA has been included in the 2025 tax provision, resulting in a reduction of U.S. income tax expense within our consolidated financial statements.

Non-GAAP Reconciliation

	Year Ended December 31,	
	2025	2024
	(in thousands, except for per share data)	
Reconciliation of GAAP to adjusted cost of sales - products:		
GAAP cost of sales - products	$ 668,540	$ 594,089
Less: Depreciation	13,669	42,707
Less: Amortization of intangibles	10,004	4,729
Less: Other	893	—
Adjusted cost of sales - products	$ 643,974	$ 546,653
Reconciliation of GAAP to adjusted research and development:		
GAAP research and development	$ 2,145,868	$ 1,953,295
Less: Share-based compensation expenses	217,440	186,113
Less: Depreciation	72,449	98,814
Adjusted research and development	$ 1,855,979	$ 1,668,368
Reconciliation of GAAP to adjusted selling, general and administrative:		
GAAP selling, general and administrative	$ 2,081,489	$ 1,831,056
Less: Share-based compensation expenses	292,807	255,680
Less: Depreciation	45,497	25,417
Less: Amortization of intangibles	67	95
Adjusted selling, general and administrative	$ 1,743,118	$ 1,549,864
Reconciliation of GAAP to adjusted operating expenses		
GAAP operating expenses	$ 4,227,357	$ 3,784,351
Less: Share-based compensation expenses	510,247	441,793
Less: Depreciation	117,946	124,231
Less: Amortization of intangibles	67	95
Adjusted operating expenses	$ 3,599,097	$ 3,218,232
Reconciliation of GAAP to adjusted income (loss) from operations:		
GAAP income (loss) from operations	$ 447,136	$ (568,199)
Plus: Share-based compensation expenses	510,247	441,793
Plus: Depreciation	131,615	166,938
Plus: Amortization of intangibles	10,071	4,824
Plus: Other	893	—
Adjusted income from operations	$ 1,099,962	$ 45,356
Reconciliation of GAAP to adjusted net income (loss):		
GAAP net income (loss)	$ 286,933	$ (644,786)
Plus: Share-based compensation expenses	510,247	441,793
Plus: Depreciation	131,615	166,938
Plus: Amortization of intangibles	10,071	4,824
Plus: Other	893	—
Plus: Impairment of equity investments	75,626	6,838
Plus: Discrete tax items	24,778	18,597
Plus: Income tax effect of non-GAAP adjustments	(122,562)	(49,123)
Adjusted net income (loss)	$ 917,601	$ (54,919)

	Year Ended December 31,	
	2025	2024
	(in thousands, except for per share data)	
Reconciliation of GAAP to adjusted EPS - basic		
GAAP earnings (loss) per share - basic	$ 0.20	$ (0.47)
Plus: Share-based compensation expenses	0.36	0.32
Plus: Depreciation	0.09	0.12
Plus: Amortization of intangibles	0.01	0.00
Plus: Other	0.00	0.00
Plus: Impairment of equity investments	0.05	0.00
Plus: Discrete tax items	0.02	0.01
Plus: Income tax effect of non-GAAP adjustments	(0.09)	(0.04)
Adjusted earnings (loss) per share - basic	$ 0.65	$ (0.04)
Reconciliation of GAAP to adjusted EPS - diluted		
GAAP earnings (loss) per share - diluted	$ 0.19	$ (0.47)
Plus: Share-based compensation expenses	0.35	0.32
Plus: Depreciation	0.09	0.12
Plus: Amortization of intangibles	0.01	0.00
Plus: Other	0.00	0.00
Plus: Impairment of equity investments	0.05	0.00
Plus: Discrete tax items	0.02	0.01
Plus: Income tax effect of non-GAAP adjustments	(0.08)	(0.04)
Adjusted earnings (loss) per share - diluted	$ 0.62	$ (0.04)
Reconciliation of GAAP to adjusted earnings (loss) per ADS - basic		
GAAP earnings (loss) per ADS - basic	$ 2.63	$ (6.12)
Plus: Share-based compensation expenses	4.68	4.20
Plus: Depreciation	1.21	1.59
Plus: Amortization of intangibles	0.09	0.05
Plus: Other	0.01	0.00
Plus: Impairment of equity investments	0.69	0.06
Plus: Discrete tax items	0.23	0.18
Plus: Income tax effect of non-GAAP adjustments	(1.12)	(0.47)
Adjusted earnings (loss) per ADS - basic	$ 8.41	$ (0.52)
Reconciliation of GAAP to adjusted earnings (loss) per ADS - diluted		
GAAP earnings (loss) per ADS - diluted[1]	$ 2.53	$ (6.12)
Plus: Share-based compensation expenses	4.50	4.20
Plus: Depreciation	1.16	1.59
Plus: Amortization of intangibles	0.09	0.05
Plus: Other	0.01	0.00
Plus: Impairment of equity investments	0.67	0.06
Plus: Discrete tax items	0.22	0.18
Plus: Income tax effect of non-GAAP adjustments	(1.08)	(0.47)
Adjusted earnings (loss) per ADS - diluted	$ 8.09	$ (0.52)

	Year Ended December 31,	
	2025	2024
Free Cash Flow (Non-GAAP):	(in thousands)	
Net cash provided by (used in) operating activities (GAAP)	$ 1,127,580	$ (140,631)
Less: Purchases of property, plant and equipment	(185,839)	(492,663)
Free Cash Flow (Non-GAAP)	$ 941,741	$ (633,294)

Liquidity and Capital Resources

The following table represents our cash and debt balances as of December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Cash, cash equivalents and restricted cash	$ 4,609,647	$ 2,638,747
Total debt	$ 1,019,206	$ 1,018,013

We have generated positive cash flow from operations since the third quarter of 2024. We generated cash flows from operations of $1.1 billion for the year ended December 31, 2025, which is $1.3 billion higher than the year ended December 31, 2024.

Based on our recent and expected performance, we expect that our operating cash flows and existing cash and cash equivalents as of December 31, 2025 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. In 2025 we generated proceeds from long-term debt of $855.0 million which was used to pay off all existing short-term working capital loans, and include certain restrictive covenants as laid out further below with respect to certain coverage ratios and maximum investment amounts. 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 as they become due principally in 2027 and 2028.

Facilities Agreement

In November 2025, we entered into a Facilities Agreement (the "Facilities Agreement") with a syndicate of banks. The Facilities Agreement provides for a $140 million U.S. dollar-denominated, 2-year, B1 revolving credit facility (the "B1 Revolving Loan Facility"), a $560 million U.S. dollar-denominated, 2-year, B2 term loan facility (the "B2 Term Loan Facility" and, together with the B1 Revolving Loan Facility, the "B Loan Facilities"), and a RMB 2.15 billion Renminbi-denominated, or approximately $300 million, 3-year, A term loan facility (the "A Loan Facility") (collectively, the "Loan Facilities"). Subsequently, we consummated the refinancing of our short-term (1 year tenor) working capital loans of approximately $768 million in aggregate through the proceeds from the B2 Term Loan Facility and A Loan Facility. We paid $23 million in debt issuance costs for the Facilities Agreement from available cash and cash equivalents.

The refinancing extended the maturity of our working capital loans. The A Loan Facility requires repayment of 4% of the aggregate amount outstanding every six months beginning on November 24, 2026, with all remaining principal outstanding due on November 24, 2028. The B2 Term Loan Facility requires repayment of 10% of the aggregate amount outstanding every three months beginning on June 15, 2027, with all remaining principal outstanding due on December 15, 2027, unless the final repayment date is extended.

The A Loan Facility is subject to an interest rate equal to the Reference Rate (RMB) (as defined in the Facilities Agreement) plus a margin of 0.65% per annum. The B Loan Facilities are subject to an interest rate equal to the Reference Rate (USD) (as defined in the Facilities Agreement) plus a margin of 2.40% per annum. In addition to paying interest on the outstanding principal, we are also required to pay a commitment fee of 0.85% on the undrawn and uncancelled amounts under the Loan Facilities.

The Facilities Agreement contains certain affirmative and negative covenants customary for financings of this type. In addition, the Facilities Agreement contains financial covenants applicable to the Loan Facilities, including covenants requiring the maintenance of: (i) a minimum cash interest coverage ratio of not less than 5.00 to 1.00; (ii) a net leverage ratio of not greater than 2.50 to 1.00; (iii) a minimum total consolidated shareholders' equity of the Group of not less than $2.7 billion; (iv) a minimum cash balance held outside the PRC by the Company and the Guarantors of $500.0 million; (v) a maximum financial indebtedness of the Company and its subsidiaries not to exceed $2.0 billion; and (vi) a maximum financial indebtedness of the Company's subsidiaries that are incorporated or registered in the PRC not to exceed $500.0 million. We were compliant with the required covenants as of December 31, 2025.

Sale of Future Royalties

The upfront payment from Royalty Pharma of $885 million in the third quarter of 2025 and the subsequent payment of $26 million in the fourth quarter of 2025 increased our cash and cash equivalents through financing cash inflows. However, the repayment of this obligation to Royalty Pharma will be made upon the receipt of royalties from Amgen throughout the royalty period; therefore, it has not been included in the total debt balance above, as there is no claim on unrestricted cash. Our classification of the liability between current and non-current is based on our expectations of royalty revenue from Amgen over the next 12 months, which will be paid to Royalty Pharma in accordance with the terms of the Royalty Agreement. Cash inflows from Amgen are classified as operating cash inflows, while the corresponding payments to Royalty Pharma are allocated between interest cash outflows within operating cash flows and a portion to reduce the liability, classified as a financing cash outflow. Pursuant to the Royalty Agreement, in 2025, we paid to Royalty Pharma an aggregate of $9.6 million, of which $5.6 million was allocated as interest expense and recognized within operating cash flows, and $4.0 million was recorded as a reduction to the liability recorded within financing activities. An additional $14.2 million of interest expense was accrued as of December 31, 2025. Any cash received from Amgen but not yet remitted to Royalty Pharma as of the balance sheet date will be reflected as restricted cash in the Consolidated Balance Sheet. There was no such restricted cash as of December 31, 2025.

The following table summarizes our cash and cash equivalent balances, cash flows and unused borrowing capacity available under our Facilities Agreement for the years indicated:

	Year Ended December 31,	
	2025	2024
	(in thousands)	
Cash, cash equivalents and restricted cash at beginning of period	$ 2,638,747	$ 3,185,984
Net cash provided by (used in) operating activities	1,127,580	(140,631)
Net cash used in investing activities	(276,155)	(548,350)
Net cash provided by financing activities	1,059,451	193,449
Net effect of foreign exchange rate changes	60,024	(51,705)
Net increase (decrease) in cash, cash equivalents and restricted cash	1,970,900	(547,237)
Cash, cash equivalents and restricted cash at end of period	$ 4,609,647	$ 2,638,747
Unused borrowing capacity available under the Facilities Agreement, at end of year	$ 140,000	$ —

Operating Activities

Cash provided by operating activities increased by $1.3 billion versus the prior year due to our significantly improved revenue and $1.5 billion of increase in gross margin in the current year, offset by continued funding of our development pipeline and commercial operations, and positive cash flows from changes in working capital due to timing of accounts receivable collections and payments on accrued expenses.

Investing Activities

Investing activities used $276.2 million of cash for the year ended December 31, 2025, compared to $548.4 million of cash used in the prior year due primarily to a decrease in capital expenditures, partially offset by an increase in acquired in-process research and development and regulatory milestone payments.

Financing Activities

Financing activities provided $1.1 billion of cash for the year ended December 31, 2025, compared to $193.4 million of cash provided in the prior year period due primarily to $911.0 million of proceeds from sale of future royalties and higher proceeds from option exercises and employee share purchase plan, partially offset by a net reduction in debt borrowings in the current year period and higher payroll tax payments upon vesting of share-based compensation awards.

In 2026, we expect to repay approximately $60.5 million of outstanding bank loans.

Effects of Exchange Rates on Cash

As noted above, we hold RMB denominated cash in our Parent Company and incur foreign currency gains or losses when remeasuring such cash to the U.S. dollar. In the year ended December 31, 2025, we incurred realized gains on cash of $4.2 million that is included in the reconciling items between net income and net cash provided by 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 have substantial operations in China and Europe, where the functional currency is the RMB and EUR 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 non-USD denominated cash held in those currency markets 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, 2025:

		Payments Due by Period	
	Total	Short-term	Long-term
		(in thousands)	
Contractual obligations:			
Operating lease commitments	$ 80,569	$ 23,653	$ 56,916
Purchase commitments	205,175	202,833	2,342
Debt obligations	1,041,224	60,528	980,696
Interest on debt	110,322	50,722	59,600
Co-development funding commitment	130,393	130,393	—
Funding commitments	5,241	5,186	55
Capital commitments	46,431	46,431	—
Total	$ 1,619,355	$ 519,746	$ 1,099,609

Operating Lease Commitments

We lease office facilities in California and Massachusetts 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, 2025, purchase commitments amounted to $205.2 million, of which $24.9 million related to non-utilization fees and minimum purchase requirements for supply purchased from CMOs and $180.3 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 $60.5 million. Total long-term debt obligations are $980.7 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. As of December 31, 2025, 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.

Royalty Sale Liability

As described above, we have a contractual commitment to pay Royalty Pharma amounts received from Amgen related to Amgen's sales of IMDELLTRA® in certain markets outside of China. While we have classified the upfront payment and the option exercise payment received from Royalty Pharma as a liability, the repayment of this obligation to Royalty Pharma will be made upon the receipt of royalties from Amgen throughout the royalty period, which is anticipated to extend at least through 2041. We have not included this liability in the table above because it does not constitute a fixed contractual obligation or a cancellable commitment from which the upfront payment and option exercise payment could be demanded for refund.

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, 2025, our remaining co-development funding commitment was $130.4 million.

Funding Commitments

Funding commitments represent our committed capital related to equity investments. As of December 31, 2025, our remaining capital commitment was $5.2 million and is expected to be paid from time to time over the investment period.

Capital Commitments

We had capital commitments amounting to $46.4 million for the acquisition of property, plant and equipment as of December 31, 2025, 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, 2025, our existing deferred revenue balance related to collaborative arrangements 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. If and when we are no longer in a three-year cumulative loss position, the subsequent measurement of our deferred tax assets will subject to the estimation process noted above.

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, 2025, 2024 and 2023, 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 $1.0 billion of outstanding floating rate debt as of December 31, 2025. A 100-basis point increase in interest rates as of December 31, 2025 would increase our annual pre-tax interest expense by approximately $10.4 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 4.4% for the year ended December 31, 2025, and depreciated approximately 2.8% for both the years ended December 31, 2024 and 2023, 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. We recognized foreign exchange gains of $4.2 million during the year ended December 31, 2025 and foreign exchange losses of $16.0 million and $64.8 million for the years ended December 31, 2024 and 2023, respectively, resulting from changes in the value 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.

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, 2025.

Item 8. Financial Statements and Supplementary Data

BEONE MEDICINES LTD.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of BeOne Medicines Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BeOne Medicines Ltd. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and cash flows for each of the three years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, 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, 2025, 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 26, 2026 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.

Gross-to-Net U.S. Accruals for Sales Chargebacks and Third-Party Managed Rebates

Description of the Matter

At December 31, 2025, the Company recorded $79.1 million of contra AR accruals and $398.5 million of accrued 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 sales chargebacks and rebates 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, and channel inventory levels. 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 sales chargebacks and rebates using the expected value method.

Auditing the Company's United States accrued sales chargebacks and rebates owed pursuant to definitive contractual agreements or legal requirements with distributors, private (Managed Care and Group Purchasing Organizations) and public (Medicaid, Tricare, and Manufacturer's Discounts) benefit providers was challenging due to the extent of effort required to audit the significant number of sales chargeback and rebate programs, as the terms vary by distributor and program and by benefit provider. Additionally, due to the volume of sales chargebacks and rebates, third-party processing and the timing of invoicing received from distributors and benefit providers, the actual amounts incurred for all distributors and benefit providers are not known at the time the financial statements are issued.

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 sales chargebacks and rebates in the United States. This included testing controls over management's review of contractual sales chargebacks and rebates and other inputs used in the estimation of accrued sales chargebacks and rebates in the United States, including but not limited to the Company's historical results, current contractual and statutory requirements, channel inventory levels, and projected subsequent period invoicing. 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 sales chargebacks and 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 sales chargebacks and rebates and evaluating the assumptions and inputs used by management. To evaluate the measurement and completeness of the accruals, 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 sales chargebacks and rebates estimates by comparing prior period accrued sales chargebacks and 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 independently calculated the sales chargeback and rebate accruals using actual invoicing, executed third party contracts, current period expense activity, and projected subsequent period invoicing. 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 26, 2026

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of BeOne Medicines Ltd.

Opinion on Internal Control Over Financial Reporting

We have audited BeOne Medicines Ltd.'s internal control over financial reporting as of December 31, 2025, 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, BeOne Medicines Ltd. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, 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, 2025 and 2024, the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and cash flows for each of the three years in the period ended December 31, 2025, and the related notes and our report dated February 26, 2026 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 26, 2026

BEONE MEDICINES LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Note	Year Ended December 31, 2025	2024	2023
		$	$	$
Revenues				
Product revenue, net	13	5,282,061	3,779,546	2,189,852
Other revenue	3	60,972	30,695	268,927
Total revenues		5,343,033	3,810,241	2,458,779
Cost of sales - product		668,540	594,089	379,920
Gross profit		4,674,493	3,216,152	2,078,859
Operating expenses				
Research and development		2,145,868	1,953,295	1,778,594
Selling, general and administrative		2,081,489	1,831,056	1,508,001
Total operating expenses		4,227,357	3,784,351	3,286,595
Income (loss) from operations		447,136	(568,199)	(1,207,736)
Interest income		70,505	69,641	78,373
Interest expense		(58,234)	(21,805)	(4,364)
Other (expense) income, net	6	(42,553)	(12,638)	307,891
Income (loss) before income taxes		416,854	(533,001)	(825,836)
Income tax expense	10	129,921	111,785	55,872
Net income (loss)		286,933	(644,786)	(881,708)
Earnings (loss) per share				
Basic	14	0.20	(0.47)	(0.65)
Diluted	14	0.19	(0.47)	(0.65)
Weighted-average shares outstanding—basic		1,417,803,727	1,368,746,793	1,357,034,547
Weighted-average shares outstanding—diluted		1,474,829,908	1,368,746,793	1,357,034,547
Earnings (loss) per American Depositary Share ("ADS")				
Basic	14	2.63	(6.12)	(8.45)
Diluted	14	2.53	(6.12)	(8.45)
Weighted-average ADSs outstanding—basic		109,061,825	105,288,215	104,387,273
Weighted-average ADSs outstanding—diluted		113,448,454	105,288,215	104,387,273

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

BEONE MEDICINES LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

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

	Note	Year Ended December 31, 2025	2024	2023
		$	$	$
Net income (loss)		286,933	(644,786)	(881,708)
Other comprehensive income (loss), net of tax of nil:				
Foreign currency translation adjustments	16	69,300	(47,565)	(25,464)
Other adjustments	16	1,504	(1,977)	3,435
Comprehensive income (loss)		357,737	(694,328)	(903,737)

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

BEONE MEDICINES 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, 2025	As of December 31, 2024
		$	$
Assets			
Current assets:			
Cash and cash equivalents		4,547,530	2,627,410
Accounts receivable, net		865,080	676,278
Inventories, net	11	608,227	494,986
Prepaid expenses and other current assets	11	212,752	192,919
Total current assets		6,233,589	3,991,593
Property, plant and equipment, net	8	1,641,678	1,578,423
Operating lease right-of-use assets	7	148,184	139,309
Intangible assets, net	9	62,704	51,095
Other non-current assets	11	102,418	160,490
Total non-current assets		1,954,984	1,929,317
Total assets		8,188,573	5,920,910
Liabilities and shareholders' equity			
Current liabilities:			
Accounts payable		479,035	404,997
Accrued expenses and other payables	11	1,109,120	803,713
Tax payable	10	41,625	25,930
Operating lease liabilities, current portion	7	20,698	17,576
Research and development cost share liability, current portion	3	64,345	111,154
Sale of future royalty liability, current portion	4	56,714	—
Short-term debt	12	57,293	851,529
Total current liabilities		1,828,830	2,214,899
Non-current liabilities:			
Long-term debt	12	961,913	166,484
Sale of future royalty liability, non-current portion	4	850,242	—
Operating lease liabilities, non-current portion	7	52,940	44,277
Deferred tax liabilities	10	53,209	42,007
Research and development cost share liability, non-current portion	3	—	54,286
Other long-term liabilities	11	80,245	66,735
Total non-current liabilities		1,998,549	373,789
Total liabilities		3,827,379	2,588,688
Commitments and contingencies	20		
Shareholders' equity:			
Ordinary shares, $0.0001 par value per share; 1,540,975,898 and 1,387,367,704 shares issued and 1,441,075,618 and 1,387,367,704 shares outstanding as of December 31, 2025 and 2024, respectively		144	138
Additional paid-in capital		12,759,137	12,087,908
Accumulated other comprehensive loss	16	(78,184)	(148,988)
Accumulated deficit		(8,319,903)	(8,606,836)
Total shareholders' equity		4,361,194	3,332,222
Total liabilities and shareholders' equity		8,188,573	5,920,910

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

BEONE MEDICINES LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

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

	Note	Year Ended December 31, 2025	2024	2023
		$	$	$
Cash flows from operating activities:				
Net income (loss)		286,933	(644,786)	(881,708)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:				
Depreciation and amortization expense		141,686	171,762	87,675
Share-based compensation expense	15	510,857	441,618	367,618
Acquired in-process research and development	3	691	60,000	46,800
Amortization of research and development cost share liability	3	(101,095)	(73,226)	(55,294)
Impairment of equity investments		75,626	6,838	7,529
Loss on long-term investments	6	596	17,184	8,692
Non-cash interest expense		14,872	—	—
Deferred income tax expense		9,469	25,983	689
Gain on BMS termination settlement		—	—	(362,917)
Other items, net		(2,953)	11,163	(5,998)
Changes in operating assets and liabilities:				
Accounts receivable		(164,954)	(329,443)	(188,306)
Inventories		(93,168)	(91,496)	(140,948)
Other assets		37,164	45,126	12,120
Accounts payable		79,833	121,497	21,484
Accrued expenses and other payables		311,762	111,354	180,111
Deferred revenue		1,293	633	(255,587)
Other liabilities		18,968	(14,838)	587
Net cash provided by (used in) operating activities		1,127,580	(140,631)	(1,157,453)
Cash flows from investing activities:				
Purchases of property and equipment		(185,839)	(492,663)	(561,896)
Purchase of in-process research and development		(60,691)	(31,800)	(15,000)
Purchase of intangible assets	3	(20,000)	(4,674)	(19,365)
Purchase of long-term investments	6	(11,834)	(19,006)	(14,900)
Proceeds from sale or maturity of short-term investments		3,446	2,655	673,240
Other investing activities		(1,237)	(2,862)	(2,075)
Net cash (used in) provided by investing activities		(276,155)	(548,350)	60,004
Cash flows from financing activities:				
Proceeds from sale of future royalties	4	911,000	—	—
Proceeds from long-term loan	12	850,586	9,053	22,502
Repayment of long-term loan	12	(35,680)	(28,031)	(13,690)
Proceeds from short-term loans	12	233,676	868,270	661,530
Repayment of short-term loans	12	(1,044,781)	(704,216)	(309,576)
Payments of debt issuance costs	12	(23,392)	—	—
Payments of withholding taxes from share-based awards		(24,195)	—	—
Proceeds from option exercises and employee share purchase plan		196,281	45,373	55,712
Repayment of sale of future royalties liability	4	(4,044)	—	—
Other financing activities		—	3,000	—
Net cash provided by financing activities		1,059,451	193,449	416,478
Effect of foreign exchange rate changes, net		60,024	(51,705)	(8,082)
Net increase (decrease) in cash, cash equivalents, and restricted cash		1,970,900	(547,237)	(689,053)
Cash, cash equivalents, and restricted cash, beginning of year		2,638,747	3,185,984	3,875,037
Cash, cash equivalents, and restricted cash, end of year		4,609,647	2,638,747	3,185,984
Supplemental cash flow disclosures:				
Cash and cash equivalents		4,547,530	2,627,410	3,171,800
Short-term restricted cash		41,284	9,312	11,473
Long-term restricted cash		20,833	2,025	2,711
Interest paid		52,452	51,175	19,753
Supplemental non-cash activities:				
Accruals for capital expenditures		57,283	70,314	91,804
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.

BEONE MEDICINES LTD.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

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

	Ordinary Shares Issued	Effect of Redomiciliation[1]	Total Outstanding Shares	Ordinary Shares Issued	Additional Paid-In Capital	Accumulated Other Comprehensive Income/(Loss)	Accumulated Deficit	Total
	Shares			$	$	$	$	$
Balance at December 31, 2022	1,356,140,180	—	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	—	84,227	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	26,561,925	—	26,561,925	2	53,006	—	—	53,008
Cancellation of ordinary shares	(23,273,108)	—	(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	—	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)	—	(2,258,161)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	30,112,641	—	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	—	1,387,367,704	138	12,087,908	(148,988)	(8,606,836)	3,332,222
Issuance of shares reserved for share option exercises	109,709,434	(112,772,594)	(3,063,160)	—	—	—	—	—
Exercise of options, ESPP and release of RSUs	43,898,760	12,872,314	56,771,074	6	195,895	—	—	195,901
Share-based compensation	—	—	—	—	510,857	—	—	510,857
Withholding taxes from share-based awards	—	—	—	—	(35,523)	—	—	(35,523)
Other comprehensive income	—	—	—	—	—	70,804	—	70,804
Net income	—	—	—	—	—	—	286,933	286,933
Balance at December 31, 2025	1,540,975,898	(99,900,280)	1,441,075,618	144	12,759,137	(78,184)	(8,319,903)	4,361,194

1. Upon effectiveness of the Continuation, ordinary shares (including in the form of ADS) held by the Company or one of its controlled subsidiaries immediately prior to the effective date of the Continuation became part of the Company's issued but not outstanding share capital and are considered ordinary shares of the Company, or "treasury shares" under Swiss law. The Company expects to use these treasury shares in the future to satisfy obligations to deliver shares in connection with awards granted under the Company's equity incentive plans and agreements.

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

1. Description of Business

Formerly known as BeiGene, Ltd., BeOne Medicines Ltd. (the "Company" or "BeOne") is a global oncology company focused on discovering and developing innovative treatments that are more affordable and accessible to cancer patients worldwide.

Effective May 27, 2025, the Company changed its 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 Act on Private International Law (such transaction, the "Continuation"), The Continuation did not change the accounting basis under U.S. generally accepted accounting principles ("GAAP") of any of the Company's consolidated assets, liabilities, equity, or any previous results of operations or cash flows.

In connection with the Continuation, ordinary shares held by the Company or one of its controlled subsidiaries immediately prior to the effective date of the Continuation became part of the Company's issued share capital and are considered ordinary shares of the Company, or "treasury shares" under Swiss law. See the Company's final prospectus filed with the U.S. Securities and Exchange Commission pursuant to Rule 424(b)(3) on March 10, 2025 for a full description of the changes related to the Company's ordinary shares following the Continuation.

Since its inception in 2010, the Company has become a fully integrated global organization with nearly 12,000 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, assessing the impairment of long-lived assets, valuation and recognition of share-based compensation expenses, realizability of deferred tax assets, estimating uncertain tax positions, valuation of inventory, estimating the allowance for credit losses, determining defined benefit pension plan obligations, measurement of right-of-use assets and lease liabilities, estimates related to research and development accruals, estimates related to the sale of future royalty liability 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 and reported amounts of revenues and expenses. 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 letters of credit and cash used to settle employee benefit obligations and related taxes. 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 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.

- 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 for impairment. The Company recognized impairment losses from observable price changes in orderly transactions for a similar investment of $75,626, $7,635 and $7,529 related to its investments in equity during the years ended December 31, 2025, 2024 and 2023, respectively.

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

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 to 30 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, 2025. 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 in 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, 2025, the Company held land use rights in the following regions:

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

	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, 2025, 2024 and 2023, the Company determined that there were no indicators of impairment of its 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, 2025, 2024 and 2023, 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.

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

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, 2025 and 2024:

As of December 31, 2025	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	2,384,656	—	—
Other non-current assets:			
Equity securities with readily determinable fair values	—	2	—
Convertible debt instrument	—	—	6,135
Other	1,271	—	—
Total	2,385,927	2	6,135

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

The Company's cash equivalents are highly liquid investments with original maturities of 3 months or less. The Company determines the fair value of cash equivalents using a market approach based on quoted prices in active markets.

The Company's equity securities carried at fair value consisted of holdings in common stock and warrants to purchase additional shares of common stock of a publicly-traded biotechnology company. The common stock investment was 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. In 2025, the Company sold its common stock holdings. Refer to Note 6, *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 gain on fair value adjustments of $1,368 for the year ended December 31, 2025 and losses on fair value adjustments of $4,842 and $1,492 for the years ended December 31, 2024 and 2023, respectively.

There were no transfers of instruments between levels of valuation categories during the years ended December 31, 2025 and 2024.

As of December 31, 2025 and 2024, 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 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, 2025, 2024 and 2023, the Company recognized other income of $22,718, $22,326, and $23,989, 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 recognize the payment as a liability and amortize it within 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, 2025 and 2024, other long-term liabilities related to the Guangzhou manufacturing facility build-out totaled $28,900 and $30,235, respectively. For the years ended December 31, 2025, 2024 and 2023, depreciation expense is presented net of amortization of government assistance of $2,587, $3,053 and $2,938, 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, 2025 and 2024, other long-term liabilities related to research and development programs totaled $79 and $89, respectively. No income was recognized during the three years ended December 31, 2025 related to grants received for research and development programs.

Comprehensive Income (Loss)

Comprehensive income (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 income (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 income (loss) includes net income (loss), foreign currency translation adjustments and pension liability adjustments, and is presented in the consolidated statements of comprehensive income (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.

Sale of Future Royalty Liability

The Company records upfront payments received from the sale of future royalties as a liability. Royalty payments made to the purchaser are recorded as a reduction of the liability or accrued interest. The Company accounts for the associated interest expense under the effective interest rate method, while continuing to recognize the full amount of royalty revenue in the period in which the counterparty sells the related product and recognizes the related revenue.

The Company calculates the liability related to the sale of future royalties, effective interest rate and the related interest expense using the current estimate of anticipated future royalty payments under the arrangement, which is periodically reassessed based on internal projections of future royalty revenues and information from partners who are responsible for commercializing the medicines. If there is a material change in the estimate, the Company will prospectively adjust the effective interest rate and the related interest expense.

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.

Earnings (Loss) Per Share

Basic earnings (loss) per share is calculated in accordance with ASC 260, *Earnings per Share*. Basic earnings (loss) per ordinary share is computed by dividing net earnings (loss) attributable to ordinary shareholders by the weighted average number of ordinary shares outstanding during the period.

Diluted earnings (loss) per share is calculated by dividing net earnings (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 ordinary shares issuable upon the conversion of the share options, and unvested employee share purchase plan, restricted shares units, employee share purchase plan ("ESPP") shares 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 earnings (loss) per share if their effects would be anti-dilutive. Basic and diluted earnings (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, 2025 and 2024, $4,547,530 and $2,627,410 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, 2025 and 2024, the Company had accounts receivable, net of $865,080 and $676,278, 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, 2025, sales to the Company's three largest product distributors, ASD Specialty Healthcare (Cencora), McKesson and Shanghai Pharmaceutical represented approximately 18.5%, 17.5% and 10.1% of product revenue, respectively, and collectively, represented approximately 37.1% of trade accounts receivable as of December 31, 2025.

For the year ended December 31, 2024, sales to the Company's three largest product distributors, ASD Specialty Healthcare (Cencora), 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.

Recent Accounting Pronouncements

New accounting standards which have been adopted

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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. The Company adopted ASU 2023-09 effective December 31, 2025 on a prospective basis. Refer to Footnote 10 for income taxes related disclosures.

New accounting standards which have not yet been adopted

In December 2025, the FASB issued ASU 2025-10, *Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities* (ASU 2025-10), which establishes authoritative guidance on the recognition, measurement, presentation, and disclosure of government grants. Under ASU 2025-10, government grants are recognized when it is probable that the entity will both comply with the conditions of the grant and the grant will be received. The ASU provides specific accounting models for grants related to assets and grants related to income, including options to recognize government grants as deferred income or as a reduction of the asset's cost basis. The ASU also requires enhanced disclosures regarding the nature of government grants, significant terms and conditions, accounting policies applied, and amounts recognized in the financial statements. ASU 2025-10 is effective for fiscal years beginning after December 15, 2028, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of adopting ASU 2025-10 on its consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software* (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software. This update removes all references to prescriptive and sequential software development stages throughout Subtopic 350-40. The update requires an entity to start capitalizing software costs when management has authorized and committed to funding the software project, and it is probable that the project will be completed and the software will be used to perform the function intended. The update further specifies that the disclosures in Subtopic 360-10 are required for all capitalized internal-use software costs. This update is effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods. Early adoption is permitted. The guidance can be applied using a prospective transition approach, a modified transition approach that is based on the status of the project and whether software costs were capitalized before the date of adoption, or a retrospective transition approach. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

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.

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

3. Collaborative, Licensing and Other 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.

During the three years ended December 31, 2025, the Company's other revenue consisted primarily of royalty revenue from IMDELLTRA® sales outside of China under the Amgen collaboration agreement, revenue generated under the Novartis broad markets agreement, and research and development services revenue and right to access intellectual property revenue from its former collaboration agreements with Novartis for tislelizumab and ociperlimab.

The following table summarizes total other revenue recognized for the years ended December 31, 2025, 2024 and 2023:

	Year Ended December 31,		
	2025	2024	2023
Other Revenue	$	$	$
Amgen royalty revenue	40,733	7,841	—
Novartis broad markets revenue	17,598	18,259	8,859
Research and development service revenue	—	—	79,431
Right to access intellectual property revenue	—	—	104,477
Material rights revenue	—	—	71,980
Other	2,641	4,595	4,180
Total	60,972	30,695	268,927

In-Licensing Arrangements - Commercial

Amgen

In October 2019, the Company entered into a global strategic oncology collaboration with Amgen (as amended, the "Amgen Collaboration Agreement") for the commercialization and development in China (excluding Hong Kong, Macao and Taiwan) (the "Collaboration Territory"), of Amgen's XGEVA®, KYPROLIS®, and BLINCYTO®, and the joint global development of a portfolio of oncology assets in Amgen's pipeline, with the Company responsible for development and commercialization in the Collaboration Territory. 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 the Collaboration Territory for so long as each product is sold in the Collaboration Territory following each product's regulatory approval in the Collaboration Territory. 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 Collaboration Territory commercial profits and losses during the commercialization period.

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 the Collaboration Territory 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 the Collaboration Territory. For each pipeline asset that is approved in the Collaboration Territory, 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 the Collaboration Territory. The Company and Amgen will share equally in the Collaboration Territory commercial profits and losses during the commercialization period. The Company is entitled to receive royalties from sales in the Collaboration Territory 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 the Collaboration Territory (with the exception of AMG 510).

In April 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 connection 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 the Company. 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.

In October 2025, the parties entered into the Third Amendment to Amgen Collaboration Agreement, which amends certain terms and conditions relating to financial responsibility for early access programs in certain regions of the Collaboration Territory and commercial supply of IMDELLTRA® (tarlatamab-dlle). In November 2025, the parties entered into the Fourth Amendment to the Amgen Collaboration Agreement, which extends the Company's commercialization rights to certain products in the Collaboration Territory.

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 the Collaboration Territory 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.

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

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, 2025, 2024 and 2023 were as follows:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
BeOne's portion of the development funding	205,238	148,391	108,608
Less: Amortization of research and development cost share liability	101,095	73,226	55,294
Research and development expense	104,143	75,165	53,314

	As of December 31, 2025
Remaining portion of development funding cap	130,393

As of December 31, 2025 and 2024, the research and development cost share liability recorded in the Company's balance sheet was as follows:

	As of December 31,	
	2025	2024
	$	$
Research and development cost share liability, current portion	64,345	111,154
Research and development cost share liability, non-current portion	—	54,286
Total research and development cost share liability	64,345	165,440

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, 2025 as follows:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Cost of sales - product	35,985	37,150	8,358
Selling, general and administrative	(99,448)	(83,674)	(60,917)
Research and development	(3,115)	(2,438)	1,688
Total	(66,578)	(48,962)	(50,871)

The Company purchases commercial inventory from Amgen to distribute in the Collaboration Territory. Total inventory purchases amounted to $263,896, $247,655 and $108,691, respectively, during the years ended December 31, 2025, 2024 and 2023. Net amounts payable to Amgen as of December 31, 2025 and 2024 were $79,097 and $116,563, respectively.

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

Out-Licensing Arrangements

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 the Company's approval. The Company 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, 2025, 2024 and 2023:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Research and development service revenue	—	—	72,278
Other [1]	—	2,113	5,067
Total	—	2,113	77,345

[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.

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

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, 2025, 2024 and 2023:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Research and development service revenue	—	—	7,153
Right to access intellectual property revenue	—	—	104,477
Material rights revenue	—	—	71,980
Novartis broad markets revenue	17,598	18,259	8,859
Total	17,598	18,259	192,469

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, 2025, 2024 and 2023 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,		
		2025	2024	2023
Payments due to collaboration partners	**Classification**	$	$	$
Upfront payments	Research and development expense	691	60,027	46,800
Development milestone payments	Research and development expense	—	54,000	—
Regulatory and commercial milestone payments	Intangible asset	20,000	—	24,365
Total		20,691	114,027	71,165

The Company has entered into a number of in-licensing collaborative arrangements during the years ended December 31, 2025, 2024 and 2023. 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.

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

4. Sale of Future IMDELLTRA® Royalties

On August 25, 2025, the Company entered into an agreement ("Royalty Agreement") to sell its royalty rights on the worldwide sales, excluding China, of Amgen's IMDELLTRA® (tarlatamab-dlle) for up to $950,000 to Royalty Pharma Investments 2023 ICAV ("Royalty Pharma"). Under the terms of the Royalty Agreement, the Company received a non-refundable upfront payment of $885,000 upon closing of the Royalty Agreement. Subsequently, the Company exercised its option to sell additional royalties to Royalty Pharma and received $26,000 in the fourth quarter of 2025. The Company will share in a portion of the royalty on annual sales above $1.5 billion, and will maintain royalty and all other rights to other assets under the terms of its collaboration agreement with Amgen.

The Company evaluated the arrangement and determined that the proceeds from the sale of future IMDELLTRA® royalties, as well as the option to sell remaining royalties when and if exercised, should be treated as a financing liability according to ASC 470, *Debt* due to the Company's continuing involvement with the Amgen collaboration. At the transaction date, the Company recognized the upfront proceeds of $885,000 and, subsequently, the option proceeds of $26,000, as liabilities and is amortizing them using the effective interest method over the life of the arrangement. The Company imputes interest expense associated with the liability using the effective interest rate method. The effective interest rate is the rate that equates the present value of the estimate of remaining royalty revenues payable to Royalty Pharma with the carrying amount of the liability. The interest rate on the sale of future royalty liability may vary during the term of the agreement depending on a number of factors, including the royalty revenues forecast. The Company evaluates the interest rate quarterly based on its expectations of future royalty revenues, historical experience and current market conditions using the prospective method. A significant increase or decrease in future royalty revenues will materially impact the timing of royalty sale liability amortization, interest expense and the time period for repayment. The Company will assess the expected payments to Royalty Pharma quarterly, and, to the extent the amount or timing of such payments is materially different than its initial estimates, the Company will prospectively adjust the amortization of the liability and the related interest expense.

The repayment of this obligation to Royalty Pharma will be made upon the receipt of royalties from Amgen throughout the royalty period. The repayment does not follow a fixed repayment schedule and will be recognized over the life of the royalty stream, which is expected to occur through at least 2041. The Royalty Agreement also contains customary representations, warranties, covenants, and indemnification provisions.

As of December 31, 2025, the royalty financing obligation recorded in the Company's balance sheet was as follows:

	As of December 31, 2025
	$
Sale of future royalty liability, current portion	56,714
Sale of future royalty liability, non-current portion	850,242
Total sale of future royalty liability	906,956

The following table summarizes the sale of future royalty liability activity during the year ended December 31, 2025:

	Royalty Sale Liability
	$
Balance at August 25, 2025	885,000
Proceeds from option exercise	26,000
Payments to Royalty Pharma, excluding effective interest payments	(4,044)
Balance at December 31, 2025	906,956

The carrying value of the sale of future royalty liability approximates fair value as of December 31, 2025 and is based on the Company's current estimates of future royalties expected to be paid to Royalty Pharma over the life of the royalty stream, which are considered Level 3 inputs. The Company recognized interest expense of $19,760 related to this arrangement for the year ended December 31, 2025, of which $14,180 was accrued as of December 31, 2025. The effective annual imputed interest rate was 6.4% as of December 31, 2025.

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

5. 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 and cash used to settle employee benefit obligations and related taxes. The Company classifies restricted cash as current or non-current based on term of restriction. Restricted cash as of December 31, 2025 and 2024 was as follows:

	As of December 31,	
	2025	2024
	$	$
Short-term restricted cash	41,284	9,312
Long-term restricted cash	20,833	2,025
Total	62,117	11,337

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, 2025, the Company had cash remaining related to the STAR Offering proceeds of $146,253.

6. Investments

The following table summarizes the Company's investments in equity securities:

	As of December 31,	
	2025	2024
	$	$
Equity securities with readily determinable fair values [1]	2	2,281
Equity securities without readily determinable fair values		
Pi Health, Inc. [2]	422	40,798
Other[3]	32,732	48,157
Equity-method investments [4]	22,387	33,081
Total	55,543	124,317

[1] Represents common stock and warrants to purchase additional shares of common stock of a publicly-traded biotechnology company. 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. In the fourth quarter of 2025, the Company sold its common stock holdings.

[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 accounts for its investment as a private equity security without a readily determinable fair value, and the divestiture was 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. In the fourth quarter of 2025, the Company recognized an impairment loss of $40,376 within other (expense) income, net resulting from a decline in enterprise value in business reorganization.

[3] In the third quarter of 2025, the Company recognized an impairment loss of $15,552 within other (expense) income, net, resulting from a decline in the enterprise value related to a business acquisition of one of its investees.

[4] In the first quarter of 2025, as a result of the wind-down of the operations and related financial obligations of one of the Company's equity-method investments, the investment's fair value was assessed to be zero. The Company recognized an other-than-temporary impairment loss of $12,376 within unrealized losses from equity-method investments.

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

The following table summarizes realized and unrealized losses related to investments in equity securities recorded in other (expense) income, net:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Equity securities with readily determinable fair values	(1,252)	(1,307)	(425)
Equity securities without readily determinable fair values	(58,282)	(7,596)	(6,448)
Equity-method investments	(14,982)	(10,275)	(7,856)

The following table summarizes the portion of unrealized losses that relates to equity securities still held by the Company as of December 31, 2025:

	Year Ended December 31,
	2025
	$
Net losses recognized on equity securities	(74,516)
Less: net losses recognized on equity securities sold	(16,638)
Net unrealized losses on equity securities held at end of period	(57,878)

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 five years, some of which include options to extend the leases that have not been included in the calculation of the Company's lease liabilities and ROU assets. The Company has land use rights, which represent land acquired for the biologics manufacturing facility in Guangzhou, 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,		
	2025	2024	2023
	$	$	$
Operating lease cost	24,899	26,575	25,978
Variable lease cost	4,282	4,580	6,101
Short-term lease cost	1,804	2,897	1,683
Total lease cost	30,985	34,052	33,762

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

Supplemental balance sheet information related to leases was as follows:

	As of December 31,	
	2025	2024
	$	$
Operating lease right-of-use assets	69,306	60,639
Land use rights, net	78,878	78,670
Total operating lease right-of-use assets	148,184	139,309
Current portion of operating lease liabilities	20,698	17,576
Operating lease liabilities, non-current portion	52,940	44,277
Total lease liabilities	73,638	61,853

Maturities of operating lease liabilities are as follows:

	Amounts
	$
Year ending December 31, 2026	23,653
Year ending December 31, 2027	21,761
Year ending December 31, 2028	16,453
Year ending December 31, 2029	11,173
Year ending December 31, 2030	6,641
Thereafter	888
Total lease payments	80,569
Less imputed interest	(6,931)
Present value of lease liabilities	73,638

Other supplemental information related to leases is summarized below:

	Year ended December 31,		
	2025	2024	2023
	$	$	$
Operating cash flows used in operating leases	24,000	56,005	27,985
ROU assets obtained in exchange for new operating lease liabilities	29,826	47,066	11,854

	As of December 31,	
	2025	2024
Weighted-average remaining lease term (years)	4	4
Weighted-average discount rate	5.02 %	5.23 %

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

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,	
	2025	2024
	$	$
Land	71,434	65,485
Building	1,187,836	607,857
Manufacturing equipment	273,769	244,255
Laboratory equipment	309,471	240,885
Software, electronics and office equipment	124,136	100,348
Leasehold improvements	76,568	64,680
Property and equipment, at cost	2,043,214	1,323,510
Less: Accumulated depreciation	(528,695)	(399,105)
Construction in progress	127,159	654,018
Property, plant and equipment, net	1,641,678	1,578,423

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, 2025, $469,006 of assets were placed into service. As of December 31, 2025, the Company had construction in progress of $91,390 related to the Hopewell facility, the majority of which will be put into service in 2026.

Construction in progress ("CIP") as of December 31, 2025 and 2024 primarily related to the Hopewell facility and the research and development facility acquired in 2024. CIP by fixed asset class are summarized as follows:

	As of December 31,	
	2025	2024
	$	$
Manufacturing equipment	92,673	89,897
Laboratory equipment	7,997	9,805
Building	16,442	528,629
Other	10,047	25,687
Total	127,159	654,018

Depreciation expense for the years ended December 31, 2025, 2024 and 2023 were $131,615, $166,938 and $80,436, 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 TEVIMBRA.

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

9. Intangible Assets

Intangible assets as of December 31, 2025 and 2024 are summarized as follows:

	December 31, 2025			December 31, 2024		
	Gross carrying amount	Accumulated amortization	Intangible assets, net	Gross carrying amount	Accumulated amortization	Intangible assets, net
	$	$	$	$	$	$
Finite-lived intangible assets:						
Developed products	77,486	(15,291)	62,195	62,889	(12,370)	50,519
Other	8,987	(8,478)	509	8,987	(8,411)	576
Total finite-lived intangible assets	86,473	(23,769)	62,704	71,876	(20,781)	51,095

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 10 years. Amortization expense is as follows:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Amortization expense - Cost of sales - product	10,004	4,729	3,739
Amortization expense - Selling, general and administrative	67	95	3,500
Total	10,071	4,824	7,239

Estimated amortization expense for each of the five succeeding years and thereafter, as of December 31, 2025 is as follows:

Year Ending December 31,	Cost of Sales - Product	Selling, General and Administrative Expense	Total
	$		
2026	6,226	67	6,293
2027	6,226	67	6,293
2028	6,226	67	6,293
2029	6,226	67	6,293
2030	6,226	67	6,293
2031 and thereafter	31,065	174	31,239
Total	62,195	509	62,704

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

10. Income Taxes

The components of income (loss) before income taxes are as follows:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Switzerland	189,967	277,710	(21,368)
U.S.	203,189	201,516	117,446
PRC	(66,300)	(263,159)	(315,852)
Other	89,998	(749,068)	(606,062)
Total	416,854	(533,001)	(825,836)

The current and deferred components of the income tax expense (benefit) from continuing operations are as follows:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Current tax expense			
Switzerland	82	2	88
U.S.	39,305	57,222	25,170
PRC	23,133	12,331	24,956
Other	57,932	16,223	4,971
Total	120,452	85,778	55,185
Deferred tax expense (benefit)			
Switzerland	—	—	—
U.S.	6,039	23,556	—
PRC	5,450	180	687
Other	(2,020)	2,271	—
Total	9,469	26,007	687
Income tax expense	129,921	111,785	55,872

The Company established tax residency in Switzerland upon the Continuation and adopted ASU 2023-09 on a prospective basis beginning with the year ended December 31, 2025. The following table presents the required disclosure pursuant to ASC 2023-09 and reconciles the Switzerland federal statutory tax amount and rate to the Company's actual global effective income tax amount and rate for the year ended December 31, 2025:

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

	Year Ended December 31,	
	2025	
	$	Percent
Income before income taxes	416,854	
Switzerland federal statutory tax rate	35,433	8.5 %
State and local income tax, net of federal income tax effect[1]	(1,789)	(0.4)%
Foreign tax effects		
United States		
Statutory tax rate difference between the U.S. and Switzerland	25,399	6.1 %
State and local income tax, net of federal income tax effect[2]	9,610	2.3 %
Share-based payment awards	(17,702)	(4.2)%
Foreign-derived intangible income	(15,337)	(3.7)%
Unremitted earnings	6,039	1.4 %
Research tax credits and incentives	(35,048)	(8.4)%
Changes in valuation allowances	47,084	11.3 %
Other	960	0.2 %
China		
Statutory tax rate difference between China and Switzerland	(2,122)	(0.5)%
Share-based payment awards	37,822	9.1 %
Non-deductible business expenses	12,676	3.0 %
Research tax credits and incentives	(23,404)	(5.6)%
Effect of changes in tax rates	5,283	1.3 %
Deferred asset adjustment	10,239	2.5 %
Changes in valuation allowances	(19,272)	(4.6)%
Other	3,839	0.9 %
Australia		
Statutory tax rate difference between Australia and Switzerland	9,089	2.2 %
Share-based payment awards	3,076	0.7 %
Changes in valuation allowances	16,013	3.8 %
Other	421	0.1 %
Germany		
Statutory tax rate difference between Germany and Switzerland	2,453	0.6 %
Share-based payment awards	2,158	0.5 %
Other	(2,671)	(0.6)%
Italy		
Changes in valuation allowances	4,260	1.0 %
Other	2,360	0.6 %
Cayman Islands		
Statutory tax rate difference between Cayman Islands and Switzerland	4,253	1.0 %
Other	59	0.0 %
Japan	1,928	0.5 %
Brazil	1,827	0.4 %
Other foreign jurisdictions	3,055	0.7 %

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

Changes in valuation allowance	(12,725)	(3.1)%
Changes in unrecognized tax benefits	16,208	3.9 %
Other adjustments	(1,553)	(0.4)%
Effective tax rate	129,921	31.2 %

1. Local taxes in Basel-Stadt canton made up the majority (greater than 50%) of the tax effect in this category.
2. State taxes in Kentucky, Tennessee, New York, and New York City made up the majority (greater than 50%) of the tax effect in this category.

The following table presents the required disclosures prior to the adoption of ASU 2023-09 and reconciles the U.S. statutory tax rate to the Company's effective income tax rate for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	$	$
Loss before tax	(533,001)	(825,836)
U.S. statutory tax rate	21 %	21 %
Expected taxation at U.S. statutory tax rate	(111,930)	(173,426)
Foreign and preferential tax rate differential	93,741	144,310
Non-deductible expenses	1,130	19,134
Share-based payment awards	53,446	32,581
State tax (benefit)	(7,988)	(5,872)
Change in valuation allowance	157,286	845,811
Tax relief credits	—	(704,928)
Research tax credits and incentives	(43,602)	(64,343)
Deductible research expenses	(13,644)	—
Tax on unremitted earnings	23,743	—
Foreign-derived intangible income	(40,397)	(37,395)
Taxation for the year	111,785	55,872
Effective tax rate	(21.0)%	(6.8)%

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

Significant components of deferred tax assets (liabilities) are as follows:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Accruals and reserves	168,454	121,549	106,708
Net operating losses carryforward	1,338,800	1,137,890	996,588
Share-based compensation	42,236	38,397	26,687
Research tax credits	40,224	34,561	68,117
Tax relief credits	704,928	704,928	704,928
Intangible asset amortization	1,020,858	1,081,442	699,974
Lease liability	14,960	11,882	7,893
R&D and other capitalized costs	361,557	277,061	164,190
Total gross deferred tax assets	3,692,017	3,407,710	2,775,085
Less: valuation allowance	(3,648,017)	(3,403,505)	(2,771,470)
Net deferred tax assets	44,000	4,205	3,615
Property, plant and equipment, net	(53,199)	(10,795)	(12,374)
Tax on unremitted earnings	(29,995)	(23,735)	—
Right of use asset	(14,015)	(11,682)	(7,735)
Total gross deferred tax liabilities	(97,209)	(46,212)	(20,109)
Net deferred tax assets/(liabilities)	(53,209)	(42,007)	(16,494)

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, 2025, it is more likely than not that certain deferred tax assets will not be realized for the Company's subsidiaries in Australia, Switzerland, the U.S. and certain subsidiaries in China. For the years ended December 31, 2025 and 2024, there was an increase in the valuation allowance of $158,816 and $157,286, respectively. Adjustments could be required in the future if the Company estimates that the amount of deferred tax assets to be realized is more or less than the net amount recorded.

During 2025, the Company reevaluated its indefinite reinvestment assertions and concluded that a portion of earnings from certain subsidiaries, primarily in the U.S., Canada, Argentina and Israel, are no longer indefinitely reinvested. Accordingly, the Company recognized a deferred tax liability of $29,995, representing the estimated withholding taxes that would be incurred upon the future distribution of these earnings. The Company continues to assert that earnings in its other jurisdictions remain indefinitely reinvested. The Company has not recorded a deferred tax liability for these jurisdictions because the determination of the amount of the associated unrecognized deferred tax liability is not practicable, as it depends on the timing, manner, and tax consequences of potential future distributions, all of which remain uncertain.

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

The valuation allowances for the years ended December 31, 2025, 2024 and 2023 were as follows:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Beginning balance, as of January 1	3,403,505	2,771,470	1,943,775
Additions/(subtractions) charged to income tax provision	158,816	157,286	845,811
Additions/(subtractions) charged to equity	50,721	497,823	—
Currency translation and other	34,975	(23,074)	(18,116)
Ending balance, as of December 31	3,648,017	3,403,505	2,771,470

As of December 31, 2025 and 2024, the Company had net operating losses of approximately $7,598,546 and $6,720,659, respectively. As of December 31, 2025, net operating losses were primarily comprised of: $2,239,157 from entities in the PRC which expire in years 2026 through 2035; and $5,359,251 derived from Switzerland which expires in years 2026 through 2032. The Company has approximately $50,843 of U.S. research tax credits which will expire between 2037 and 2045 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, 2025, 2024 and 2023 were as follows:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Beginning balance, as of January 1	17,239	14,264	11,555
Additions based on tax positions related to prior tax years	5,957	—	—
Reductions based on tax positions related to prior tax years	—	—	—
Additions based on tax positions related to the current tax year	4,639	2,975	2,709
Reductions based on lapse of statute of limitations	—	—	—
Ending balance, as of December 31	27,835	17,239	14,264

Current and prior year additions include assessment of U.S. federal and state tax credits and incentives and intercompany positions taken in China. As of December 31, 2025, the Company had $27,835 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, 2025, the Company's accrued interest and penalties were $2,676 related to positions taken in the U.S. and $3,264 related to positions taken in China. For the years ended December 31, 2024 and 2023, 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, 2025, Australia tax matters are open to examination for the years 2014 through 2025, China tax matters are open to examination for the years 2015 through 2025, Switzerland tax matters are open to examination for the years 2021 through 2025, and U.S. federal tax matters are open to examination for years 2016 through 2025. Other U.S. states and non-US tax jurisdictions in which the Company files tax returns remain open to examination for 2015 through 2025. Various U.S., foreign and state income tax returns are currently under examination by taxing authorities, with potential income tax liabilities estimated and updated in light of available facts and circumstances. Due to the uncertain and complex application of income tax regulations globally, it is possible that the ultimate resolution of audits may result in liabilities that could be materially different from original estimates. In such an event, the Company will record additional income tax expense or income tax benefit in the period in which such resolution occurs.

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

The following table summarizes income taxes paid, net of refunds received, for the year ended December 31, 2025, as required by ASU 2023-09:

	Year Ended December 31,
	2025
	$
U.S. federal	40,500
U.S. state and local	
Kentucky	6,065
Other	3,831
Foreign	
China	15,472
Australia	14,575
Italy	5,691
Other	14,547
Total income taxes paid	100,681

The following table presents income taxes paid for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
	$	$
Income taxes paid	69,430	56,003

The Company qualifies for the Technology Advanced Service Enterprises and High and New Technology Enterprise status for certain subsidiaries in China, which began to expire at the end of 2025. The income tax benefits attributable to this status for the year ended December 31, 2025 is approximately $5,953, or less than $0.01 per share outstanding.

11. Supplemental Balance Sheet Information

Inventories, net consisted of the following:

	As of December 31,	
	2025	2024
	$	$
Raw materials	236,190	170,584
Work in process	122,681	60,118
Finished goods	249,356	264,284
Total inventories, net	608,227	494,986

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

Prepaid expenses and other current assets consist of the following:

	As of December 31,	
	2025	2024
	$	$
Prepaid research and development costs	52,594	64,277
Short-term restricted cash	41,284	9,312
Prepaid taxes	42,232	23,792
Other receivables	21,781	32,828
Prepaid general and administrative expenses	22,209	21,253
Prepaid insurance	9,759	6,242
Prepaid manufacturing cost	3,935	19,333
Other current assets	18,958	15,882
Total	212,752	192,919

Other non-current assets consist of the following:

	As of December 31,	
	2025	2024
	$	$
Long-term investments	61,678	128,933
Long-term restricted cash	20,833	2,025
Rental deposits and other	10,470	8,481
Prepayment of property and equipment	4,964	5,927
Prepaid VAT	3,504	2,875
Prepaid supply cost	969	12,249
Total	102,418	160,490

Accrued expenses and other payables consisted of the following:

	As of December 31,	
	2025	2024
	$	$
Compensation related	305,055	248,348
Sales rebates and returns related	398,533	235,600
External research and development activities related	156,525	154,269
Commercial activities	118,449	77,530
Accrued general and administrative expenses	36,635	31,106
Individual income tax and other taxes	60,359	34,904
Other	33,564	21,956
Total	1,109,120	803,713

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

Other long-term liabilities consist of the following:

	As of December 31,	
	2025	2024
	$	$
Deferred government grant income	28,979	30,324
Pension liability	18,170	16,405
Asset retirement obligation	3,565	3,794
Other	29,531	16,212
Total	80,245	66,735

12. Debt

Facilities Agreement

In November 2025, BeOne Medicines Ltd. entered into the Facilities Agreement (the "Facilities Agreement"), by and among certain subsidiaries of the Company, as guarantors, the Hongkong and Shanghai Banking Corporation Limited ("HSBC"), as global coordinator, original mandated lead arranger and bookrunner, agent and security agent, and certain financial institutions listed in the Facilities Agreement, as lenders. The Facilities Agreement provides for a $140,000 U.S. dollar-denominated, 2-year, B1 revolving credit facility (the "B1 Revolving Loan Facility"), a $560,000 U.S. dollar-denominated, 2-year, B2 term loan facility (the "B2 Term Loan Facility" and, together with the B1 Revolving Loan Facility, the "B Loan Facilities"), and a RMB 2,150,000 Renminbi-denominated, 3-year, A term loan facility (the "A Loan Facility") (collectively, the "Loan Facilities"). Subsequently, the Company consummated the refinancing of its short-term working capital loans of $768,375 in aggregate through the proceeds from the B2 Term Loan Facility and A Loan Facility.

The following table presents outstanding borrowings under the Facilities Agreement:

	As of December 31,
	2025
	$
A Loan Facility	12,298
Less: unamortized debt issuance costs	(3,235)
Total short-term debt	9,063
A Loan Facility	295,152
B2 Term Loan Facility	560,000
Less: unamortized debt issuance costs	(18,783)
Total long-term debt	836,369

The A Loan Facility requires repayment of 4% of the aggregate amount outstanding every six months beginning on November 24, 2026, with all remaining principal outstanding due on November 24, 2028. The B2 Term Loan Facility requires repayment of 10% of the aggregate amount outstanding every three months beginning on June 15, 2027, with all remaining principal outstanding due on December 15, 2027, unless the final repayment date is extended. The Company may voluntarily prepay borrowings, in whole or in part, under the Facilities Agreement without premium or penalty. The Facilities Agreement also contains certain customary mandatory prepayment provisions in the event that the Company undergoes a change of control and in relation to disposal and insurance proceeds.

The A Loan Facility is subject to an interest rate equal to the Reference Rate (RMB) (as defined in the Facilities Agreement) plus a margin of 0.65% per annum. The B Loan Facilities are subject to an interest rate equal to the Reference Rate (USD) (as defined in the Facilities Agreement) plus a margin of 2.40% per annum. In addition to paying interest on the outstanding principal, the Company is also required to pay a commitment fee of 0.85% on the undrawn and uncancelled amounts under the Loan Facilities.

As of December 31, 2025, the B1 Revolving Loan Facility was available for borrowing. Excluding commitment fees, the interest rate for the A Loan Facility and B2 Term Loan Facility was 3.65% and 6.10%, respectively, as of December 31, 2025.

The Loan Facilities are guaranteed by BeOne Medicines UK, Ltd., BeOne Medicines US Holdings, LLC, BeOne Medicines I GmbH, BeOne Medicines (Hong Kong) Co., Limited, BeOne Medicines Aus Pty Ltd, BG NC, Ltd., BG NC, Ltd., BeOne Medicines Hopewell Urban Renewal, LLC, BeOne Medicines US Manufacturing Co., Inc., BeOne Medicines Treasury Ltd., and BeOne Medicines USA, Inc. (collectively, "Guarantors"). Except as otherwise provided by applicable law, all obligations under the Loan Facilities are unconditionally guaranteed jointly and severally by the Guarantors.

Subject to certain limitations, the Loan Facilities are secured on a first priority basis granted in favor of HSBC (as security agent on behalf of the secured parties) by: (a) a security interest in the equity interests of a member of the Company and its subsidiaries and (b) security interests in, and mortgage on, the Company's manufacturing and clinical R&D facility in New Jersey.

The Facilities Agreement contains various customary representations, warranties and covenants applicable to the Company and its subsidiaries. In addition, the Facilities Agreement contains financial covenants, including covenants requiring the maintenance of: (i) a minimum cash interest coverage ratio of not less than 5.00 to 1.00; (ii) a net leverage ratio of not greater than 2.50 to 1.00; (iii) a minimum total consolidated shareholders' equity of not less than $2.7 billion; (iv) a minimum cash balance held outside the PRC by the Company and the Guarantors of $500.0 million; (v) a maximum financial indebtedness of the Company and its subsidiaries not to exceed $2.0 billion; and (vi) a maximum financial indebtedness of the Company's subsidiaries that are incorporated or registered in the PRC not to exceed $500.0 million. The Company was compliant with the required covenants as of December 31, 2025.

In connection with the execution of the Facilities Agreement, the Company capitalized $23,392 of debt issuance costs. The Company allocated these costs among the Loan Facilities based on the maximum borrowing capacity and amortizes the costs using the effective interest method for the A Loan Facility and B2 Term Loan Facility and on a straight-line basis for the B1 Revolving Loan Facility. Non-cash interest expense related to the amortization of the debt issuance costs for the year ended December 31, 2025 was $692.

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

Other Bank Loans

The following table summarizes the Company's short-term working capital loans and project loans of December 31, 2025 and 2024:

Lender	Borrower	Term	Maturity Date	Note	As of December 31, 2025	As of December 31, 2024
					$	$
China Construction Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	June 11, 2027	1	21,450	16,440
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	January 20, 2029	2	8,989	8,611
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	November 8, 2029	3	8,497	8,148
China CITIC Bank	BeOne Pharmaceutical (Suzhou) Co., Ltd.	10-year	July 28, 2032	4	9,294	1,384
China Merchants Bank	BeOne Medicines Ltd.	1-year	January 21, 2026	5	—	380,000
China Minsheng Bank	BeOne Medicines Ltd.	1-year	December 16, 2025	6	—	150,000
China Industrial Bank	BeOne Medicines USA, Inc.	364-days	June 28, 2026	7	—	—
China Industrial Bank	BeOne Medicines Ltd.	364-days	March 27, 2025	8	—	92,475
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	1-year	June 5, 2025	9	—	54,800
HSBC Bank	BeOne Medicines Ltd.	1-year	June 17, 2026	10	—	46,580
Shanghai Pudong Development Bank	BeOne Medicines Ltd.	1-year	November 24, 2025	11	—	93,091
Total short-term debt					48,230	851,529
China Construction Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	June 11, 2027	1	21,450	41,100
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	January 20, 2029	2	20,224	27,987
China Merchants Bank	BeOne Guangzhou Biologics Manufacturing Co., Ltd.	9-year	November 8, 2029	3	25,970	33,020
China CITIC Bank	BeOne Pharmaceutical (Suzhou) Co., Ltd.	10-year	July 28, 2032	4	57,900	64,377
Total long-term debt					125,544	166,484

1. The credit facility offers a borrowing capacity of RMB 580,000, denominated in RMB, and bears 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, 2025. The outstanding principal balance is payable in semi-annual installments. The Company repaid $17,225 (or RMB 120,000) during the year ended December 31, 2025. The loan is secured by BeOne Guangzhou Biologics Manufacturing Co., Ltd.'s property ownership certificate and fixed assets.

2. The credit facility offers a borrowing capacity of RMB 350,000, denominated in RMB, and bears floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.4% as of December 31, 2025. The outstanding principal balance is payable in quarterly installments. The Company repaid $8,726 (RMB 62,857) during the year ended December 31, 2025. The loan is secured by Guangzhou Factory's south district land use right and certain fixed assets.

3. The credit facility offers a borrowing capacity of RMB 378,000, denominated in RMB, and bears floating interest rates benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.2% as of December 31, 2025. The outstanding principal balance is payable in quarterly installments. The Company repaid $8,287 (RMB 59,475) during the year ended December 31, 2025. The loan is secured by fixed assets placed into service in the third phase of the Guangzhou manufacturing facility's buildout.

4. The credit facility offers a borrowing capacity of RMB 480,000, denominated in RMB, and bears floating interest rate benchmarking RMB loan interest rates of financial institutions in the PRC. The loan interest rate was 3.3% as of December 31, 2025. The outstanding principal balance is payable in semi-annual installments. The Company repaid $1,442 (RMB 10,100) during the year ended December 31, 2025. The loan is secured by BeOne Pharmaceutical (Suzhou) Co., Ltd.'s property ownership certificate of the small molecule manufacturing campus in Suzhou, China.

5. The working capital loan facility offers a borrowing capacity of up to $380,000, denominated in USD, and bears floating interest rates benchmarking the secured overnight financing rate. The Company repaid the loan with the proceeds from the Loan Facilities in the fourth quarter of 2025.

6. The working capital loan facility offers a borrowing capacity of up to $150,000, denominated in USD. The Company repaid the loan with the proceeds from the Loan Facilities in the fourth quarter of 2025.

(Amounts in thousands of U.S. Dollar ("$") and Renminbi ("RMB"),
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7. The working capital loan facility offered a borrowing capacity of up to RMB 675,000, denominated in RMB. The Company drew down the facility in the second quarter of 2025 and repaid the loan with the proceeds from the Loan Facilities in the fourth quarter of 2025.

8. The working capital loan facility offered a borrowing capacity of up to RMB 675,000, denominated in RMB. The Company repaid the loan during the year ended December 31, 2025.

9. The working capital loan facility offers a borrowing capacity of up to RMB 400,000, denominated in RMB. The Company repaid the loan during the year ended December 31, 2025.

10. The working capital loan facility offers a borrowing capacity of up to RMB 340,000, denominated in RMB, and bears floating interest rates benchmarking Hong Kong interbank market rate for RMB. The Company repaid the loan with the proceeds from the Loan Facilities in the fourth quarter of 2025.

11. The working capital loan facility offers a borrowing capacity of up to RMB 700,000, denominated in RMB. The Company repaid the loan with the proceeds from the Loan Facilities in the fourth quarter of 2025.

The Company has numerous financial and non-financial covenants on its debt obligations with the lenders above. Some of these covenants include default and/or cross-default provisions that could require acceleration of repayment of loans in the event of default. As of December 31, 2025, the Company was in compliance with all covenants of its material debt agreements.

Contractual Maturities of Debt Obligations

The aggregate contractual maturities of all borrowings due subsequent to December 31, 2025 are as follows:

Maturity dates	Amounts
	$
Year ending December 31, 2026	60,528
Year ending December 31, 2027	632,825
Year ending December 31, 2028	297,337
Year ending December 31, 2029	20,518
Year ending December 31, 2030	9,295
Thereafter	20,721
Total	1,041,224

Interest Expense

Interest on bank loans is paid quarterly until the respective loans are fully settled. Excluding the amortization of debt issuance costs, interest expense on bank loans for the years ended December 31, 2025, 2024 and 2023 amounted to $49,950, $46,894 and $20,800, respectively, among which, $12,443, $32,158 and $16,571 was capitalized, respectively. Interest paid for the years ended December 31, 2025, 2024 and 2023, net of amounts capitalized, amounted to $34,428, $19,723 and $3,484, 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.

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

The table below presents the Company's net product sales for the years ended December 31, 2025, 2024 and 2023.

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Product revenue - gross	6,730,957	4,786,744	2,718,969
Less: Rebates and sales returns	(1,448,896)	(1,007,198)	(529,117)
Product revenue - net	5,282,061	3,779,546	2,189,852

The following table disaggregates net product revenue by product for the years ended December 31, 2025, 2024 and 2023.

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
BRUKINSA®	3,928,489	2,644,226	1,290,396
TEVIMBRA®	737,304	620,836	536,620
XGEVA®	305,979	224,403	92,828
BLINCYTO®	104,224	74,331	54,342
KYPROLIS®	74,974	66,171	39,799
POBEVCY®	47,400	53,509	56,547
Other	83,691	96,070	119,320
Total product revenue - net	5,282,061	3,779,546	2,189,852

The following table presents the roll-forward of accrued sales chargebacks, rebates, returns and other deductions for the years ended December 31, 2025 and 2024.

	Rebates, Returns and Other Deductions	Contra AR Accruals	Total
	$	$	
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
Amounts charged against product revenue	657,138	791,758	1,448,896
Payments and credits	(494,205)	(763,331)	(1,257,536)
Balance at December 31, 2025	398,533	79,126	477,659

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

14. Earnings (Loss) Per Share/ADS

The following table reconciles the numerator and denominator in the computations of earnings (loss) per share/ADS:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Numerator:			
Net income (loss)	286,933	(644,786)	(881,708)
Denominator:			
Weighted-average shares outstanding—basic	1,417,803,727	1,368,746,793	1,357,034,547
Dilutive common shares equivalents	57,026,181	—	—
Weighted-average shares outstanding—diluted	1,474,829,908	1,368,746,793	1,357,034,547
Antidilutive common share equivalents excluded from above	1,089,967	—	—
Earnings (loss) per share:			
Basic	0.20	(0.47)	(0.65)
Diluted	0.19	(0.47)	(0.65)
Earnings (loss) per ADS:			
Basic	2.63	(6.12)	(8.45)
Diluted	2.53	(6.12)	(8.45)

For the year ended December 31, 2025, diluted earnings per share was computed using the weighted-average number of ordinary shares and the effect of potentially dilutive shares outstanding during the periods. Potentially dilutive shares consist of stock options, restricted stock units and ESPP shares. The dilutive effect of outstanding stock options, restricted stock units and ESPP shares is reflected in diluted net earnings per share using the treasury stock method.

For the years ended December 31, 2024 and 2023, the Company was in a net loss position and the effects of all share options, restricted share units and ESPP shares were excluded from the calculation of diluted loss per share, as their effect would have been anti-dilutive.

Each ADS represents 13 ordinary shares. Basic and diluted earnings (loss) per ADS was derived from the basic and diluted earnings (loss) per share, respectively.

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 were cancelled or forfeited without issuance of ordinary shares. As of December 31, 2025, ordinary shares cancelled or forfeited under the 2011 Plan that were carried over to the 2016 Plan totaled 5,167,238. 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, 2025, share-based awards to acquire 60,641,671 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.

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

2018 Employee Share Purchase Plan

In June 2018, the shareholders of the Company approved the 2018 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:

Issuance Date	Number of Ordinary Shares Issued	Market Price[1]		Purchase Price[2]		Proceeds
		ADS	Ordinary	ADS	Ordinary	
August 31, 2025	818,506	$ 245.53	$ 18.89	$ 208.70	$ 16.05	$ 13,140
February 28, 2025	955,396	$ 188.26	$ 14.48	$ 160.02	$ 12.31	$ 11,760
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

[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, 2025, 3,179,780 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.

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

The following table summarizes the Company's share option activities during the year ended December 31, 2025 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, 2024	77,982,656	9.70			
Granted	2,527,499	19.80	10.44		
Exercised	(30,065,802)	5.61			448,698
Forfeited	(2,211,642)	16.61			
Outstanding at December 31, 2025	48,232,711	12.46		5.03	537,801
Exercisable as of December 31, 2025	37,198,441	11.67		4.09	446,954
Vested and expected to vest at December 31, 2025	46,467,228	12.36		4.91	523,265

As of December 31, 2025, the unrecognized compensation cost related to 9,268,787 unvested share options expected to vest was $63,875. 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, 2025, 2024 and 2023 was $55,954, $68,420 and $61,121, 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,		
	2025	2024	2023
Fair value of ordinary share	$8.79 ~ $10.76	$5.72 ~ $9.19	$7.26 ~ $10.72
Risk-free interest rate	4.2% ~ 4.6%	3.8% ~ 4.6%	3.4% ~ 4.6%
Expected exercise multiple	2.8	2.8	2.8
Expected volatility	56% ~ 57%	57% ~ 58%	58% ~ 60%
Expected dividend yield	0%	0%	0%
Contractual life	10 years	10 years	10 years

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

Restricted share units

The following table summarizes the Company's restricted share unit activities during the year ended December 31, 2025 under the 2016 and 2018 Plans:

	Numbers of Shares	Weighted-Average Grant Date Fair Value
		$
Outstanding at December 31, 2024	83,654,116	13.70
Granted	29,086,395	20.34
Vested	(26,921,973)	14.43
Forfeited	(8,737,846)	14.72
Outstanding at December 31, 2025	77,080,692	15.84
Expected to vest at December 31, 2025	64,747,781	15.84

As of December 31, 2025, the unrecognized compensation cost related to unvested restricted share units expected to vest was $899,790. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 2.7 years.

Performance share units

The following table summarizes the Company's performance share unit activities during the year ended December 31, 2025 under the 2016 Plan:

	Numbers of Shares	Weighted-Average Grant Date Fair Value
		$
Outstanding at December 31, 2024	2,176,551	12.37
Granted	1,876,056	20.38
Performance adjustments[1]	151,567	12.34
Forfeited	(269,542)	13.09
Outstanding at December 31, 2025	3,934,632	16.14
Expected to vest at December 31, 2025	3,305,091	16.14

1. The amount shown represents performance adjustments related primarily to the performance-based awards granted during the year ended December 31, 2024.

As of December 31, 2025, the unrecognized compensation cost related to unvested performance share units expected to vest was $38,878. This unrecognized compensation will be recognized over an estimated weighted-average amortization period of 1.9 years.

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

Share-based compensation expense

The following table summarizes total share-based compensation cost recognized for the years ended December 31, 2025, 2024 and 2023:

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Research and development	217,440	186,113	163,550
Selling, general and administrative	292,807	255,680	204,038
Total	510,247	441,793	367,588

16. Accumulated Other Comprehensive Loss

The movement of accumulated other comprehensive (loss) income was as follows:

	Foreign Currency Translation Adjustments	Other Adjustments	Total
	$	$	$
December 31, 2023	(87,987)	(11,459)	(99,446)
Other comprehensive loss before reclassifications	(47,565)	(2,788)	(50,353)
Amounts reclassified from accumulated other comprehensive loss [1]	—	811	811
Net-current period other comprehensive loss	(47,565)	(1,977)	(49,542)
December 31, 2024	(135,552)	(13,436)	(148,988)
Other comprehensive income before reclassifications	69,300	591	69,891
Amounts reclassified from accumulated other comprehensive loss [1]	—	913	913
Net-current period other comprehensive income	69,300	1,504	70,804
December 31, 2025	(66,252)	(11,932)	(78,184)

[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 three years ended December 31, 2025, 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, 2025, 2024 and 2023, 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, 2025 and 2024, amounts restricted were the net assets of the Company's PRC subsidiaries, which, after intercompany eliminations, amounted to $2,012,019 and $1,709,961, respectively.

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

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 PRC government for these benefits based on certain percentage of employees' salaries. The Company has no legal obligation for such benefits beyond the contributions made. The total amounts for such employee benefits, which were expensed as incurred, were $107,246, $101,779 and $94,358 for the years ended December 31, 2025, 2024 and 2023, 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 pre-tax, Roth or non-Roth after-tax basis. In addition, the Company has a matching contribution to the 401(k) Plan, matched dollar for dollar of eligible contributions up to 6% in the 2025 plan year. Company contributions to the 401(k) Plan totaled $24,494, $20,839 and $15,316 in the years ended December 31, 2025, 2024 and 2023, respectively.

The Company maintains a government mandated program to cover its employees in Switzerland for pension, death, and disability. The program is considered a defined contribution plan under U.S. GAAP. 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 $4,562, $3,825, and $2,710 in the years ended December 31, 2025, 2024 and 2023, 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 Pension Plan"). The Swiss Pension 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, 2025 and 2024, the projected benefit obligations under the Swiss Pension Plan were approximately $105,538 and $80,199, respectively, and the Swiss Pension Plan assets were approximately $87,368 and $63,794, respectively. The funded status of the Swiss Pension Plan is included in other long-term liabilities in the accompanying consolidated balance sheets.

The Company's annual contribution to the Swiss Pension Plan is estimated to be approximately $4,540 in 2026 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 Pension Plan participants in the upcoming 10 years and have been estimated based on the same assumptions used to measure the Company's benefit obligations as of December 31, 2025:

	Amounts
	$
Year ending December 31, 2026	5,766
Year ending December 31, 2027	5,622
Year ending December 31, 2028	5,581
Year ending December 31, 2029	5,734
Year ending December 31, 2030	5,876
Thereafter	29,271
Total	57,850

20. Commitments and Contingencies

Purchase Commitments

As of December 31, 2025, the Company had purchase commitments amounting to $205,175, of which $24,921 related to non-utilization fees and minimum purchase requirements for supply purchased from contract manufacturing organizations and $180,254 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 $46,431 for the acquisition of property, plant and equipment as of December 31, 2025 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, 2025, the Company's remaining co-development funding commitment was $130,393.

Funding Commitment

The Company had committed capital related to equity investments in the amount of $15,891. As of December 31, 2025, the remaining capital commitment was $5,241 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 income (loss). Significant segment expenses reviewed by the CODM on a regular basis included within net income (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 income (loss) include interest income, interest expense, other (expense) income, net and income tax expense.

The Company's long-lived assets are primarily located in the U.S. and China.

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

Net product revenues by geographic area are based upon the location of the customer, and net other 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,		
	2025	2024	2023
	$	$	$
U.S. - total revenue	**2,880,324**	**1,957,498**	**1,128,219**
Product revenue	2,841,246	1,950,530	945,551
Other revenue	39,078	6,968	182,668
China- total revenue	**1,679,531**	**1,411,307**	**1,101,951**
Product revenue	1,659,363	1,390,699	1,093,091
Other revenue	20,168	20,608	8,860
Europe- total revenue	**611,369**	**362,626**	**202,014**
Product revenue	609,643	359,507	122,228
Other revenue	1,726	3,119	79,786
Rest of world- total revenue	**171,809**	**78,810**	**26,595**
Product revenue	171,809	78,810	28,982
Other revenue	—	—	(2,387)
Total Revenue	**5,343,033**	**3,810,241**	**2,458,779**

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, 2025, 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, 2025.

The effectiveness of our internal control over financial reporting as of December 31, 2025, 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, 2025 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)

The following table describes for the fourth quarter ended December 31, 2025 each trading arrangement for the purchase or sale of the Company's securities adopted, modified or terminated by our directors and officers that is either (1) a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), or a "Rule 10b5-1 trading arrangement," or (2) a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K):

Name (*Title*)	**Action Taken (*Date of Action*)**	**Type of Trading Arrangement**	**Nature of Trading Arrangement**	**Duration of Trading Arrangement**	**Aggregate Number of Securities**
Dr. Xiaobin Wu *(President, Chief Operating Officer)*	Adoption *(November 7, 2025)*	Rule 10b5-1 trading arrangement	Sale	Through February 26, 2027	Up to 30,000 ADSs

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, 2025.

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, 2025.

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, 2025.

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, 2025.

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, 2025.

PART IV

Item 15. Exhibits and Financial Statement Schedules

The financial statements listed in the Index to Consolidated Financial Statements beginning on page 141 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, 2025, 2024 and 2023 on page 201. 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

BeOne Medicines Ltd.
Financial Information of Parent Company
Condensed Statements of Operations
(Amounts in thousands of U.S. Dollars ("$"))

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Operating expenses			
Research and development	29,372	427,129	381,854
Amortization of research and development cost share liability	(101,095)	(73,226)	(55,294)
Selling, general and administrative	69,530	357,103	304,543
Total operating expenses	(2,193)	711,006	631,103
Income (loss) from operations	2,193	(711,006)	(631,103)
Interest (expense) income, net	(20,887)	3,101	48,982
Other income (expense), net	305,686	63,522	(297,856)
Income (loss) before income taxes	286,992	(644,383)	(879,977)
Income tax expense	59	403	1,731
Net income (loss)	286,933	(644,786)	(881,708)

BeOne Medicines Ltd.
Financial Information of Parent Company
Condensed Statements of Comprehensive Loss
(Amounts in thousands of U.S. Dollars ("$"))

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Net income (loss)	286,933	(644,786)	(881,708)
Other comprehensive (loss) income, net of tax of nil:			
Foreign currency translation adjustments	69,300	(47,565)	(25,464)
Other adjustments	1,504	(1,977)	3,435
Comprehensive income (loss)	357,737	(694,328)	(903,737)

BeOne Medicines Ltd.
Financial Information of Parent Company
Condensed Balance Sheets
(Amounts in thousands of U.S. Dollars ("$"))

	As of December 31,	
	2025	2024
	$	$
Assets		
Current assets:		
Cash and cash equivalents	584,216	400,135
Prepaid expenses and other current assets	180,495	249,016
Total current assets	764,711	649,151
Loans to subsidiaries	1,710,737	1,731,266
Investment in wholly owned subsidiaries	3,314,162	2,081,335
Other non-current assets	41,658	114,728
Total assets	5,831,268	4,576,480
Liabilities and shareholders' equity		
Current liabilities:		
Accrued expenses and other payables	254,815	312,957
Indebtedness to subsidiaries	253,194	—
Research and development cost share liability, current portion	64,345	111,154
Short-term debt	9,063	762,146
Total current liabilities	581,417	1,186,257
Long-term debt	836,369	—
Research and development cost share liability, non-current portion	—	54,286
Other long-term liabilities	52,288	3,714
Total liabilities	1,470,074	1,244,257
Total shareholders' equity	4,361,194	3,332,223
Total liabilities and shareholders' equity	5,831,268	4,576,480

BeOne Medicines Ltd.
Financial Information of Parent Company
Condensed Statements of Cash Flows
(Amounts in thousands of U.S. Dollars ("$"))

	Year Ended December 31,		
	2025	2024	2023
	$	$	$
Cash flows from operating activities:			
Net income (loss)	286,933	(644,786)	(881,708)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Acquired in-process research and development	—	—	15,000
Amortization of research and development cost share liability	(101,095)	(73,226)	(55,294)
Unrealized (gains) losses in subsidiaries	(484,466)	(85,471)	237,351
Other items, net	81,247	31,651	(374,370)
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	27,544	1,053	30,519
Accrued expenses and other payables	56,259	627,307	(140,126)
Net cash used in operating activities	(133,578)	(143,472)	(1,168,628)
Cash flows from investing activities:			
Proceeds from sale or maturity of short-term investments	954	2,628	552,000
Loans to subsidiaries	—	(442,917)	(53,100)
Repayments from subsidiaries	279,031	423,532	252,662
Investment in subsidiaries	(173,429)	(406,624)	(883,328)
Other investing activities	(9,670)	(17,735)	(27,981)
Net cash provided by (used in) investing activities	96,886	(441,116)	(159,747)
Cash flows from financing activities:			
Proceeds from long-term loan	850,586	—	—
Proceeds from short-term loans	139,453	813,058	547,842
Repayment of short-term loans	(893,987)	(593,898)	(293,002)
Proceeds from option exercises and employee share purchase plan	196,281	45,371	55,712
Other financing activities	(47,587)	—	—
Net cash provided by financing activities	244,746	264,531	310,552
Effect of foreign exchange rate changes, net	6,228	(4,356)	—
Net increase (decrease) in cash, cash equivalents, and restricted cash	214,282	(324,413)	(1,017,823)
Cash, cash equivalents, and restricted cash, beginning of year	400,135	724,548	1,742,371
Cash, cash equivalents, and restricted cash, end of year	614,417	400,135	724,548

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, BeOne Medicines 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, 2025, the Parent Company had a remaining capital commitment of $4,350 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 BeOne Medicines I 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		Articles of Association of BeOne Medicines Ltd., effective May 27, 2025.		8-K12G3 (Exhibit 3.1)	5/27/2025	000-56752
3.2		Organizational Regulations of BeOne Medicines Ltd., effective May 27, 2025.		8-K12G3 (Exhibit 3.2)	5/27/2025	000-56752
4.1	.1	Amended and Restated Deposit Agreement, dated May 27, 2025, by and between the Company and Citibank, N.A., and the Form of American Depositary Receipt thereunder.		8-K12G3 (Exhibit 4.1.1)	5/27/2025	000-56752
	.2	Amended and Restated Restricted ADS Letter Agreement, dated May 27, 2025, by and between the Company and Citibank, N.A.		8-K12G3 (Exhibit 4.1.3)	5/27/2025	000-56752
	.3	Amended and Restated Letter Agreement, dated May 27, 2025, by and between the Company and Citibank, N.A.		8-K12G3 (Exhibit 4.1.4)	5/27/2025	000-56752
	.4	Amended and Restated Supplemental Letter Agreement, dated May 27, 2025, by and between the Company and Citibank, N.A.		8-K12G3 (Exhibit 4.1.5)	5/27/2025	000-56752
4.2		Form of American Depositary Receipt under the Amended and Restated Deposit Agreement (included in Exhibit 4.1.1)		8-K12G3 (Exhibit 4.1.2)	5/27/2025	000-56752
4.3	.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
4.4		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
	.4	Letter Agreement, dated May 9, 2025, regarding the Collaboration Agreement, dated October 31, 2019, by and between BeiGene Switzerland GmbH and Amgen Inc.		10-Q (Exhibit 10.19)	8/6/2025	001-37686
	.5##	Waiver under Collaboration Agreement, dated August 11, 2025, by and between the Registrant, BeOne Medicines I GmbH, and Amgen Inc.		10-Q (Exhibit 10.2)	11/6/2025	001-37686
	.6##	Waiver under Collaboration Agreement, dated October 1, 2025, by and between the Registrant, BeOne Medicines I GmbH, and Amgen Inc.	X			
	.7##	Third Amendment to Collaboration Agreement, dated October 31, 2025, by and among the Registrant, BeOne Medicines I GmbH and Amgen Inc.	X			
	.8##	Fourth Amendment to Collaboration Agreement, dated November 11, 2025, by and among the Registrant, BeOne Medicines I GmbH and Amgen Inc.	X			
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 agreement thereunder		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.1)	5/27/2025	333-279980
10.7†	.1†	Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.1)	5/27/2025	333-279980
	.2†	Form of Global Performance Share Unit Award Agreement for Employees under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.2)	5/27/2025	333-279980
	.3†	Form of Global Restricted Share Unit Award Agreement for Non-Employee Directors under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.3)	5/27/2025	333-279980

Exhibit No.		Exhibit Description	Filed/ Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
	.4†	Form of Global Restricted Share Unit Award Agreement for Employees under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.4)	5/27/2025	333-279980
	.5†	Form of Global Restricted Share Unit Award Agreement for Consultants under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.5)	5/27/2025	333-279980
	.6†	Form of Global Non-Qualified Share Option Agreement for Employees under the Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.6)	5/27/2025	333-279980
	.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 Fourth Amended and Restated 2016 Share Option and Incentive Plan		POS AM No. 1 to Registration Statement on Form S-8 (Exhibit 99.2.8)	5/27/2025	333-279980
10.8†		Fifth Amended and Restated 2018 Employee Share Purchase Plan		10-Q (Exhibit 10.18)	8/6/2025	001-37686
10.9†		Senior Executive Cash Incentive Bonus Plan		S-1 (Exhibit 10.19)	1/19/2016	333-207459
10.10†		Independent Non-Executive Director Compensation Policy, as amended		POS AM No. 1 to Registration Statement on Form S-4 (Exhibit 10.10)	5/27/2025	333-281324
Agreements with Executive Officers and Directors						
10.11†		Form of Indemnification Agreement, entered into between the Registrant and its directors and officers		8-K12G3 (Exhibit 10.6)	5/27/2025	000-56752
10.12†		Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines USA, Inc. and John V. Oyler.		8-K12G3 (Exhibit 10.1)	5/27/2025	000-56752
10.13†		Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines (Beijing) Co., Ltd. and Xiaobin Wu.		8-K12G3 (Exhibit 10.2)	5/27/2025	000-56752
10.14†		Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines USA, Inc. and Aaron Rosenberg.		8-K12G3 (Exhibit 10.3)	5/27/2025	000-56752
10.15†		Consulting Agreement, effective May 27, 2025, by and between BeOne Medicines USA, Inc. and Xiaodong Wang.		8-K12G3 (Exhibit 10.7)	5/27/2025	000-56752
10.16†		Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines (Shanghai) Co., Ltd. and Lai Wang.		8-K12G3 (Exhibit 10.4)	5/27/2025	000-56752

Exhibit No.	Exhibit Description	Filed/ Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
10.17†	Executive Employment Agreement, effective May 27, 2025, by and between BeOne Medicines USA, Inc. and Chan Lee.		8-K12G3 (Exhibit 10.5)	5/27/2025	000-56752
Other Agreements					
10.18##	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
10.19##	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
10.20	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		10-K (Exhibit 10.23)	2/27/2025	001-37686
10.21##	Royalty Purchase Agreement, dated August 25, 2025, by and between the Registrant, BeOne Medicines I GmbH, and Royalty Pharma Investments 2023 ICAV		10-Q (Exhibit 10.1)	11/6/2025	001-37686
10.22##	Facilities Agreement, dated November 14, 2025, by and among the Registrant, as borrower, certain subsidiaries of the Registrant listed in the Facilities Agreement, as guarantors, The Hongkong and Shanghai Banking Corporation Limited, as global coordinator, original mandated lead arranger and bookrunner, agent and security agent, and certain financial institutions listed in the Facilities Agreement, as lenders	X			
19.1	Insider Trading Policy	X			
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			

Exhibit No.	Exhibit Description	Filed/ Furnished Herewith	Incorporated by Reference Herein from Form or Schedule	Filing Date	SEC File/ Reg. Number
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	X			
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				
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.

BEONE MEDICINES LTD.

Date: February 26, 2026

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 26, 2026
/s/ AARON ROSENBERG Aaron Rosenberg	Chief Financial Officer *(Principal Financial Officer)*	February 26, 2026
/s/ TITUS BALL Titus Ball	Chief Accounting Officer *(Principal Accounting Officer)*	February 26, 2026
/s/ OLIVIER BRANDICOURT Olivier Brandicourt	Director	February 26, 2026
/s/ MARGARET DUGAN Margaret Dugan	Director	February 26, 2026
/s/ MICHAEL GOLLER Michael Goller	Director	February 26, 2026
/s/ ANTHONY C. HOOPER Anthony C. Hooper	Director	February 26, 2026
/s/ RANJEEV KRISHANA Ranjeev Krishana	Director	February 26, 2026
/s/ ALESSANDRO RIVA Alessandro Riva	Director	February 26, 2026
/s/ CORAZON (CORSEE) D. SANDERS Corazon (Corsee) D. Sanders	Director	February 26, 2026
/s/ SHALINI SHARP Shalini Sharp	Director	February 26, 2026
/s/ XIAODONG WANG Xiaodong Wang	Director	February 26, 2026
/s/ QINGQING YI Qingqing Yi	Director	February 26, 2026

Shape the future
with confidence

Ernst & Young AG
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CH-4002 Basel

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To the General Meeting of
BeOne Medicines Ltd., Basel

Basel, February 26, 2026

Report of the statutory auditor

Report on the audit of the financial statements

Opinion
We have audited the financial statements of BeOne Medicines Ltd. (the Company), which comprise the balance sheet as of December 31, 2025, the income statement for the period from May 27, 2025 to December 31, 2025, and notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying financial statements comply with Swiss law and the Company's articles of incorporation.

Basis for opinion
We conducted our audit in accordance with Swiss law and Swiss Standards on Auditing (SA-CH). Our responsibilities under those provisions and standards are further described in the "Auditor's responsibilities for the audit of the financial statements" section of our report. We are independent of the Company in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession that are relevant to audits of the financial statements of public interest entities. We have also fulfilled our other ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Key audit matters
Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period. We have determined that there are no key audit matters to communicate in our report.

Other information
The Board of Directors is responsible for the other information. The other information comprises the information included in the annual report, but does not include the consolidated financial statements, the stand-alone financial statements, and our auditor's reports thereon. We expect to obtain the remuneration report after the date of our auditor's report.

Our opinion on the financial statements does not cover the other information and we do not express any form of assurance conclusion thereon.

Shape the future with confidence

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed on the other information obtained prior to the date of the auditor's report, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Board of Directors' responsibilities for the financial statements

The Board of Directors is responsible for the preparation of the financial statements in accordance with the provisions of Swiss law and the Company's articles of incorporation, and for such internal control as the Board of Directors determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board of Directors is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern, and using the going concern basis of accounting unless the Board of Directors either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Swiss law and SA-CH will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on EXPERTsuisse's website at: https://www.expertsuisse.ch/en/audit-report. This description forms an integral part of our report.

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with confidence

Report on other legal and regulatory requirements

In accordance with Art. 728a para. 1 item 3 CO and PS-CH 890, we confirm that an internal control system exists, which has been designed for the preparation of the financial statements according to the instructions of the Board of Directors.

Based on our audit in accordance with Art. 728a para. 1 item 2 CO, we confirm that the proposal of the Board of Directors complies with Swiss law and the Company's articles of incorporation. We recommend that the financial statements submitted to you be approved.

Ernst & Young AG

Licensed audit expert
(Auditor in charge)

Licensed audit expert

Enclosures

- Financial statements (balance sheet, income statement, notes)
- Proposal of the Board of Directors

BeOne Medicines Ltd.

Aeschengraben 27
4501 Basel

Statutory financial statements 2025

Balance sheet as at December 31, 2025

Income statement for the period May 27, 2025 to December 31, 2025

Notes

BeOne Medicines Ltd., Basel

Balance Sheet

		As of December 31, 2025	
		USD in 000'	CHF in 000'
Assets	**Note**		
Current assets:			
Cash and cash equivalents	4.1	614,417	486,803
Other short term receivables			
– from companies in which the entity holds an investment		140,359	111,206
Prepaid expenses and other current assets	4.2	36,198	28,679
		790,974	626,688
Non-current assets:			
Financial assets	4.3	24,654	19,533
Long-term loans (from companies in which the entity holds an investment)		1,714,121	1,358,098
Long-term investments	4.4	7,259,271	5,751,521
Intangible assets		1,776	1,408
Prepaid expenses	4.2	12,561	9,952
		9,012,383	7,140,512
Total assets		9,803,357	7,767,200
Liabilities and shareholders' equity			
Short-term liabilities:			
Trade accounts payable			
– from third parties		1,396	1,106
Short-term interest bearing liabilities			
– from third parties		12,298	9,744
– from companies in which the entity holds an investment		250,000	198,075
Other short-term liabilities			
– from third parties		2,712	2,149
– from companies in which the entity holds an investment		212,733	168,548
Accrued liabilities and deferred revenue		45,734	36,235
		524,873	415,857
Long-term liabilities:			
Long-term interest-bearing liabilities			
– from third parties	4.5	855,151	677,537
Other long-term liabilities			
– from companies in which the entity holds an investment		52,288	41,429
		907,439	718,966
Total liabilities		1,432,312	1,134,823
Shareholders' equity			
Share capital	4.6	154	122
Statutory capital reserve			
– Reserve for capital contributions	4.6	14,377,156	11,391,020
Legal retained earnings			
– Reserve for treasury shares held by subsidiaries	4.6	1,692,901	1,341,285
Loss brought forward	4.6	(7,585,270)	(6,009,810)
Loss for the period	4.6	(113,896)	(90,240)
		8,371,045	6,632,377
Total liabilities and shareholders' equity		9,803,357	7,767,200

The accompanying notes form an integral part of the Financial Statements.

BeOne Medicines Ltd., Basel
Income Statement

	May 27, 2025 - December 31, 2025	
	USD in 000'	**CHF in 000'**
Other operating income	35,599	28,205
Total Income	35,599	28,205
Personnel expenses	(72)	(57)
Other operating expenses	(65,341)	(51,771)
Impairment losses on investments	(40,376)	(31,990)
Impairment losses on financial assets	(21,840)	(17,304)
Amortization on intangible assets	(852)	(674)
Total expenses	(128,481)	(101,796)
Loss from operations	(92,882)	(73,591)
Financial income	19,160	15,181
Financial expenses	(40,174)	(31,830)
Loss before income taxes	(113,896)	(90,240)
Loss for the period	(113,896)	(90,240)

The accompanying notes form an integral part of the Financial Statements.

BeOne Medicines Ltd., Basel
Notes to the financial statements

1 General formation

BeOne Medicines Ltd. (the "Company"), incorporated under Swiss law and headquartered at Aeschengraben 27, 4051 Basel, Switzerland, is the ultimate holding company of the BeOne group of companies, which includes affiliated and associated companies and joint ventures worldwide (the "BeOne Group").

2 Basis of Presentation

On May 27, 2025, BeOne Medicines Ltd. completed its change in jurisdiction of incorporation from the Cayman Islands to Switzerland, and thus became subject to Swiss law on May 27, 2025. Prior to such date, BeOne Medicines Ltd. was organized under the laws of the Cayman Islands under the name of "BeiGene, Ltd.". Because the Company became subject to Swiss law on May 27, 2025, there are no comparative figures to be presented. The statutory financial statements present the results of BeOne Medicines Ltd. on a standalone basis.

The statutory financial statements reflect the results of operations for the period from May 27, 2025 to December 31, 2025 and have been prepared in accordance with the requirements of the Swiss Code of Obligations ("SCO"). They are prepared under the historical cost convention and on an accrual basis.

When referring to fiscal year 2025 in these statutory financial statements, the Company considers the period from its incorporation on May 27, 2025 to December 31, 2025.

3 Accounting Principles

3.1 Information on the annual accounts applied principles

The annual financial statements are prepared in accordance with the valuation principles prescribed by Swiss law (Title Thirty-Two of the Swiss Code of Obligations). In addition, they have been prepared under the historical cost convention, taking into account income and expenses not yet due at the balance sheet date. The main valuation principles applied which are not prescribed by law are described below. It should be noted that to ensure the Company's going concern, the company may create or release hidden reserves.

3.2 Other information required by law

The Company's functional currency is USD. Transactions in foreign currencies are recorded at the rate of exchange at the date of the transaction.

To meet the requirements of SCO, the financial statements are also disclosed in local currency (CHF) by using the closing rate method. Applying this method, all figures in Swiss francs in the balance sheet, income statement and notes are converted at the closing rate at the end of the period (December 31, 2025). At December 31, 2025, the exchange rate was CHF 0.7923 for USD 1. Disclosing the financial statements in CHF is for informative purposes only.

3.3 Interest-bearing liabilities

Interest-bearing liabilities are recognized in the balance sheet at nominal value. Issue costs for the loans are recognized as prepaid expenses and amortized on a straight line basis over the maturity of the loans.

3.4 Foregoing a cash flow statement and additional disclosures in the notes

The Company is integrated into the operations of the BeOne Group, which presents its consolidated financial statements in accordance with US GAAP. In accordance with Article 961d of the Swiss Code of Obligations, the Company has decided not to present additional information in the notes, the cash flow statement and the management report.

4 Information on balance sheet items

4.1 Cash and cash equivalents

Cash and cash equivalents include deposits with maturities of less than three months.

4.2 Prepaid expenses and other current assets

Long-term prepaid expenses contain the non-yet-amortized amount of the issue costs which arose when the loans were drawn. The part to be amortized in the following year is recognized in the short-term prepaid expenses.

4.3 Financial assets

Financial assets include securities with a long-term holding period that have no quoted market price or no other observable market price, as well as convertible notes. Financial assets are valued at their acquisition cost adjusted for impairment losses.

	As of December 31, 2025	
	USD in 000'	CHF in 000'
Convertible Debt Instruments	5,335	4,227
Other Financial Assets	19,319	15,306
	24,654	**19,533**

4.4 Long term investments

(a) Direct investments

Direct shareholdings of BeOne Medicines Ltd. were as follows as at December 31, 2025:

Company	Subsidiary	Domicile	Share in voting and capital rights, in %
			As of December 31, 2025
BeOne Medicines (Hong Kong) Co., Limited	Direct	Hong Kong	100 %
Pi Health Inc.	Direct	Massachusetts, USA	46 %
MapKure, LLC	Direct	Connecticut, USA	53 %
BG NC 1, Ltd.	Direct	Cayman Islands	100 %
BG NC 2, Ltd.	Direct	Cayman Islands	100 %
BeOne Medicines Treasury Ltd.	Direct	Cayman Islands	100 %
Ribonaut Therapeutics, Inc.	Direct	Delaware USA	34 %
Salsola Therapeutics, Inc.	Direct	Delaware USA	30 %

(b) Indirect investments

Significant indirect shareholdings of BeOne Medicines Ltd. were as follows as at December 31, 2025:

Company	Subsidiary	Domicile	Share in voting and capital rights, in %
			As of December 31, 2025
BeiGene 101	Indirect	Cayman Islands	100 %
BeOne Medicines Argentina S.R.L.	Indirect	Argentina	100 %
BeOne Medicines AUS Pty Ltd	Indirect	Australia	100 %
BeOne Medicines Austria GmbH	Indirect	Austria	100 %
BeOne Medicines (Beijing) Co., Ltd.	Indirect	PRC	100 %
BeOne Medicines Belgium SRL	Indirect	Belgium	100 %
BeOne Biologics Co., Ltd.	Indirect	PRC	100 %
BeOne Medicines Brasil Ltda.	Indirect	Brazil	100 %
BeOne Medicines (Canada) ULC	Indirect	Canada	100 %
BeOne Medicines Chile Limitada	Indirect	Chile	100 %
BeOne Medicines Colombia S.A.S.	Indirect	Columbia	100 %
BeOne Medicines ESP, S.L.U. Unipersonal	Indirect	Spain	100 %
BeOne Medicines France Sarl	Indirect	France	100 %
BeOne Medicines Germany GmbH	Indirect	Germany	100 %
BeOne Guangzhou Biologics Manufacturing Co., Ltd.	Indirect	PRC	100 %
BeOne (Guangzhou) Innovation Technology Co., Ltd.	Indirect	PRC	100 %

Company	Subsidiary	Domicile	Share in voting and capital rights, in %
			As of December 31, 2025
BeOne Medicines Hopewell Urban Renewal, LLC	Indirect	New Jersey, USA	100 %
BeOne Medicines International GmbH	Indirect	Switzerland	100 %
BeOne Medicines Ireland Limited	Indirect	Republic of Ireland	100 %
BeOne Medicines (Italy) S.r.l.	Indirect	Italy	100 %
BeOne Medicines Japan, GK	Indirect	Japan	100 %
BeOne Medicines Korea Y.H.	Indirect	South Korea	100 %
BeOne Medicines Malaysia Sdn. Bhd.	Indirect	Malaysia	100 %
BeOne Medicines Mexico S. de R.L. de C.V.	Indirect	Mexico	100 %
BeOne Medicines Netherlands B.V.	Indirect	Netherlands	100 %
BeOne Medicines NZ Unlimited	Indirect	New Zealand	100 %
BeOne Medicines Peru (Sociedad Comercial de Responsabilidad Limitada - S.R.L)	Indirect	Peru	100 %
BeOne Medicines Pharmaceuticals GmbH	Indirect	Switzerland	100 %
BeOne Pharmaceuticals (Guangzhou) Co., Ltd.	Indirect	PRC	100 %
BeOne Medicines Pharmaceuticals Israel Ltd.	Indirect	Israel	100 %
BeOne Medicines (Shanghai) Co., Ltd.	Indirect	PRC	100 %
BeOne Medicines Poland sp. z o.o.	Indirect	Poland	100 %
BeOne Medicines Portugal, Unipessoal Lda.	Indirect	Portugal	100 %
BeiGene Shanghai	Indirect	Cayman Islands	95 %
BeiGene Shanghai 101	Indirect	Cayman Islands	95 %
BeOne Medicines (Shanghai) Development Co., Ltd.	Indirect	PRC	95 %
BeOne Medicines (Shanghai) Management Consulting Co., Ltd.	Indirect	PRC	100 %
BeOne Medicines (Shanghai) Research & Development Co., Ltd.	Indirect	PRC	100 %
BeOne Medicines Shanghai Asset Limited	Indirect	Hong Kong	95 %
BeOne Medicines Singapore Pte. Ltd	Indirect	Singapore	100 %
BeOne Medicines South Africa (PTY) Ltd	Indirect	South Africa	100 %
BeOne Pharmaceutical (Suzhou) Co., Ltd.	Indirect	PRC	100 %
BeOne Medicines Sweden AB	Indirect	Sweden	100 %
BeOne Medicines (Taiwan) Limited	Indirect	Taiwan	100 %
BeiGene (Thailand) Ltd.	Indirect	Thailand	100 %
BeiGene Turkey Medical Products Trade Limited Company	Indirect	Turkey	100 %
BeOne Medicines UK, Ltd.	Indirect	United Kingdom	100 %
BeOne Medicines United Kingdom, Ltd.	Indirect	United Kingdom	100 %
BeOne Medicines USA, Inc.	Indirect	Delaware, USA	100 %
BeOne Medicines US Holdings, LLC	Indirect	Delaware, USA	100 %
BeOne Medicines US Manufacturing Co., Inc.	Indirect	Delaware, USA	100 %
Beijing Innerway Bio-tech Co., Ltd.	Indirect	PRC	100 %
BeOne Medicines Global Business Services Sp. Z o.o.	Indirect	Poland	100 %
BeOne Medicines I GmbH	Indirect	Switzerland	100 %
BeONe Medicines d.o.o. Beograd	Indirect	Serbia	100 %
Newco 101	Indirect	Cayman Islands	100 %
SuGene Pharmaceuticals (Suzhou) Co., Ltd.	Indirect	PRC	100 %

4.5 Long-term interest-bearing liabilities from third party

The long-term interest-bearing liabilities consists of term loans and a revolving credit line from various banks.

4.6 Shareholders's equity

Share capital

The Company was incorporated on May 27, 2025, with a share capital of USD 154,097.5898, corresponding to 1,540,975,898 fully paid-in registered shares with a par value of USD 0.0001 each.

The following table presents the activity related to our equity accounts as at December 31, 2025 in USD:

	Share Capital	Reserve from capital contributions		Legal retained earnings		Total shareholders's equity
		Foreign	*Domestic*	Reserve for treasury shares	Loss brought forward	
Redomiciliation	154	13,784,270	—	2,270,652	(7,585,270)	8,469,806
Share-based compensation	—	577,751	15,135	(577,751)	—	15,135
Loss for the period	—	—	—	—	(113,896)	(113,896)
Balance as at December 31, 2025	**154**	**14,362,021**	**15,135**	**1,692,901**	**(7,699,166)**	**8,371,045**

The following table presents the activity related to our equity accounts as at December 31, 2025 in CHF:

	Share Capital	Reserve from capital contributions		Legal retained earnings		Total shareholders's equity
		Foreign	*Domestic*	Reserve for treasury shares	Loss brought forward	
Redomiciliation	122	10,921,277	—	1,799,037	(6,009,810)	6,710,626
Share-based compensation	—	457,752	11,991	(457,752)	—	11,991
Loss for the period	—	—	—	—	(90,240)	(90,240)
Balance as at December 31, 2025	**122**	**11,379,029**	**11,991**	**1,341,285**	**(6,100,050)**	**6,632,377**

Capital Band

The Company's Articles of Association provides for a capital band between USD 138,687.8308 (lower limit) and USD 231,146.3847 (upper limit). Within this capital band, the Board of Directors is authorized, until April 28, 2029, to increase or decrease the share capital at any time or from time to time and in any (partial) amounts, or to cause the company or one of its group companies to directly or indirectly acquire registered shares with a nominal value of USD 0.0001 each including as part of share buyback programs).

Reserves from capital contributions

Statutory reserves from capital contributions, subject to certain conditions, are distributable reserves.

From a fiscal point of view, any distribution made from reserves from capital contributions are treated the same as a repayment of share capital. The Swiss Federal Tax Administration (SFTA) has not yet confirmed that it will recognize disclosed reserves from capital contribution as a capital contribution as per Article 5(1bis) Withholding Tax Act.

Reserve for treasury shares held by subsidiaries

In 2025, a subsidiary (BG NC 2, Ltd.) acquired 133,000,000 registered shares of BeOne Medicines Ltd. at a price of USD 17 each. A respective reserve for treasury shares was recorded. During the period, 33,840,898 shares were delivered to employees as part of the Company's Third Amended and Restated 2016 Share Option and Incentive Plan (as amended from time to time). As of December 31, 2025, the Company held, through BG NC 2, Ltd., 98,994,284 of its own registered shares with a par value of USD 0.0001 each. The Company has deposited, and will continue to deposit, these treasury shares to the Company's depositary bank to satisfy the Company's obligations to deliver ordinary shares in connection with awards granted under the Company's Third Amended and Restated 2016 Share Option and Incentive Plan (as amended from time to time) within the then-available scheme mandate limit as approved by the Company's shareholders under Chapter 17 of the Listing Rules of The Stock Exchange of Hong Kong Limited.

Bulk shares

Additionally, the Company has deposited bulk shares to the Company's depository bank for the sole purpose of satisfying the Company's obligations to deliver ordinary shares in connection with the Fourth Amended and Restated 2018 Employee Share Purchase Plan ("2018 ESPP"). As of December 31, 2025, 905,996 shares are held in custody of the Company's depositary bank and are available for potential future issuances under the 2018 ESPP.

5 Other information

5.1 Full-time equivalent employees

The annual average number of full-time equivalent employees for the reporting period did not exceed 10.

5.2 Shares or options on shares for members of the Board of Directors

According to the compensation policy, independent Board members receive equity compensation in the form of share options and restricted share units (RSUs). Each director is granted equity awards with a total value of USD 400,000 at the time of their initial appointment (prorated to the first AGM cycle) and an additional USD 400,000 annually at each Annual General Meeting. 50 percent of the equity award is delivered as share options and 50 percent as RSUs. Both options and RSUs vest in full after one year (or earlier upon the next AGM). A director may elect to defer RSU settlement until six months after leaving the Board. Equity awards and cash compensation are capped at USD 1,000,000 per calendar year per director (except in the first year of service).

In 2025 the Board members received their compensation prior to the redomiciliation, consequently no allocation of shares and options is disclosed for the period May 27, 2025 to December 31, 2025.

5.3 Significant subsequent events

There have been no subsequent events requiring a change in the value of assets and liabilities or additional disclosure in the notes.

5.4 Guarantees

As part of daily operations, certain affiliates of the BeOne Group enter into various credit arrangements. In its role as ultimate holding company, the Company has provided guarantees in respect of certain of these credit arrangements. As of December 31, 2025, the aggregate maximum amount guaranteed by the Company is USD 4.41 million (equivalent to approximately CHF 3.49 million).

The Company has also provided a guarantee covering the lease payment obligations of an affiliate under agreements entered into with third parties amounting up to USD 12.36 millions (equivalent to approximately CHF 9.79 million).

As at December 31, 2025, the Company does not anticipate having to perform under these guarantees.

PROPOSED APPROPRIATION OF ACCUMULATED LOSSES

	USD in 000'	CHF in 000'
Losses brought forward	(7,585,270)	(6,009,810)
Losses for the period	(113,896)	(90,240)
Total available to the Annual General Meeting of Shareholders	**(7,699,166)**	**(6,100,050)**
Proposal of the Board of Directors for the appropriation of accumulated losses:		
Balance to be carried forward	(7,699,166)	(6,100,050)

CORPORATE OFFICERS

John V. Oyler
Co-Founder, Chairman and Chief Executive Officer

Aaron Rosenberg
Chief Financial Officer

Xiaobin Wu
President and Chief Operating Officer

Lai Wang
President, Global Head of Research and Development

Chan Lee
Senior Vice President, General Counsel and Corporate Secretary

BOARD OF DIRECTORS

John V. Oyler
Co-Founder, Chairman and Chief Executive Officer

Olivier Brandicourt
Blackstone Life Sciences

Margaret Dugan
Whitehawk Therapeutics, 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 Pharmaceuticals Inc.

Xiaodong Wang
Co-Founder and Chairman of the Scientific Advisory Board

Qingqing Yi
Hillhouse Capital Management, Ltd.

SHAREHOLDER MEETING

June 11, 2026
3:30 p.m. CEST
Homburger AG
Prime Tower
Hardstrasse 201
CH-8005 Zürich, Switzerland

EMPLOYEES

nearly 12,000
(as of December 31, 2025)

STOCK CODES

Nasdaq: ONC
HKEx: 06160
SSE: 688235

INVESTOR RELATIONS

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BeOne