BeyondSpring Inc.

Project Type: 10-K

EDGAR Submission Proof

Created At: 3/25/2026 10:01:44 AM EDT

Submission Information

Submission Type	10-K
Return Copy?	off
Contact Name	GLOBENEWSWIRE INC.
Contact Phone	310-642-6930
Exchange(s)	NASD
Confirmation of Paper Copy?	off
Filer CIK	0001677940
Filer CCC	********
Emerging Growth Company	False
ex Transition Period	False
Reporting Period	12/31/2025
Well Known Seasoned Issuer?	False
Voluntary Filer?	False
Smaller Reporting Company?	True
Accelerated Filer Status	Non-Accelerated Filer
Shell Company?	False

Documents

10-K	FORM 10-K
EX-4.2	Exhibit 4.2
EX-10.14	Exhibit 10.14
EX-10.17	Exhibit 10.17
EX-21.1	Exhibit 21.1
EX-23.1	Exhibit 23.1
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EX-31.1	Exhibit 31.1
EX-32.1	Exhibit 32.1
GRAPHIC	primout.jpg
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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
To
Commission File No. 001-38024

BeyondSpring Inc.
(Exact name of registrant as specified in its charter)

Cayman Islands	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
100 Campus Drive, West Side, 4th Floor, Suite 410 Florham Park, New Jersey	
(Address of Principal Executive Offices)	**07932 (Zip Code)**

(646) 305-6387
(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**
Ordinary Shares, par value $0.0001 per share	**BYSI**	**The Nasdaq Stock Market LLC**

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

None

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 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 Registrant's ordinary shares held by non-affiliates of the Registrant was approximately $69.7 million, based upon the closing price of such shares on the Nasdaq Capital Market on June 30, 2025.

As of February 27, 2026, 41,119,820 of the Registrant's ordinary shares, par value $0.0001 per share, were outstanding.

BEYONDSPRING INC.
FORM 10-K FOR THE YEAR ENDED DECEMBER 31, 2024
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FORWARD-LOOKING STATEMENTS

This annual report on Form 10-K contains forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements stated in or implied by these forward-looking statements.

All statements other than statements of historical facts are forward-looking statements. These forward-looking statements are made under the "safe harbor" provision under Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and as defined in the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. You should refer to "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K for specific risks that could cause actual results to be significantly different from those stated in or implied by these forward-looking statements. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Annual Report on Form 10-K and the documents that we reference in this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from any future results stated in or implied by these forward-looking statements.

Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the initiation, timing, progress and results of our studies in animals and clinical trials, and our research and development programs;
- our ability to advance our product candidates into, and successfully complete, clinical trials;
- our reliance on the success of our clinical-stage product candidates;
- the timing or likelihood of regulatory filings and approvals;
- our ability to address the concerns identified in the Complete Response Letter issued by the Food and Drug Administration, or FDA, in November 2021 regarding the New Drug Application, or NDA, seeking approval of Plinabulin in combination with granulocyte colony-stimulating factor, or G-CSF, for the prevention of chemotherapy-induced neutropenia, or CIN;
- our ability to file the NDA submission for the non-small cell lung cancer, or NSCLC indication with the National Medical Products Administration, or NMPA, in China;
- the commercialization of our product candidates, if approved;
- our ability to develop sales and marketing capabilities;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- costs associated with defending intellectual property infringement, product liability and other claims;

- regulatory development in the United States, China and other jurisdictions;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- our ability to maintain and establish collaborations or obtain additional grant funding;
- the rate and degree of market acceptance of our product candidates;
- developments relating to our competitors and our industry, including competing therapies;
- our ability to effectively manage our anticipated growth;
- our ability to attract and retain qualified employees and key personnel;
- our future revenue, hiring plans, expenses, capital expenditures, capital requirements and share performance;
- the future trading price of our ordinary shares and impact of securities analysts' reports on these prices;
- our ability to meet Nasdaq's continued listing requirements;
- the impact of widespread health developments, and the responses thereto, which could materially and adversely affect, among other things, enrollment of patients in our clinical trials, timing and completion of regulatory or other required inspections, our expected timeline for data readouts of our clinical trials and certain regulatory filings for our product candidates, and the review and approval timeline of regulatory authorities; and
- other risks and uncertainties, including those listed under "Item 1A. Risk Factors."

The items in "Item 1A. Risk Factors" of this Annual Report on Form 10-K reference the principal contingencies and uncertainties to which we believe we are subject, which should be considered in evaluating any forward-looking statements contained in this Annual Report on Form 10-K.

The forward-looking statements in this Annual Report on Form 10-K speak only to our views as of the date of this Annual Report on Form 10-K and we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report on Form 10-K.

This Annual Report on Form 10-K contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we believe the market position, market opportunity and market size information included in this Annual Report on Form 10-K is generally reliable, such information is inherently imprecise.

PART I.

Except as the context otherwise may require, all references to "us," "our," "BeyondSpring," "we," the "Company" and similar designations refer to Dalian Wanchun Biotechnology Co., Ltd., or Wanchun Biotech, the former holding company of our U.S. subsidiary, and its consolidated subsidiaries, as a whole, prior to the completion of our internal corporate reorganization, and BeyondSpring Inc. and its consolidated subsidiaries, after the completion of our internal corporate reorganization on July 20, 2015. All references in this Annual Report on Form 10-K to "$," "U.S. dollars" and "dollars" mean U.S. dollars, all references to "RMB" mean Renminbi, the legal currency of China, unless otherwise noted. All references to "PRC" or "China" in this Annual Report on Form 10-K refer to the People's Republic of China.

Item 1. Business.

Overview

We are a clinical stage global biopharmaceutical company focused on developing innovative therapies to improve clinical outcomes for patients with high unmet medical needs. Our first-in-class lead asset, Plinabulin is a novel brain-penetrant microtubule modulator with dendritic cell maturation and vasculature modulation mechanism, which has the potential to help mitigate "acquired resistance" from prior immune checkpoint inhibitors (ICI) treatment in cancer patients. Plinabulin has been administered to over 700 cancer patients with generally good tolerability and is being developed as a potential "pipeline in a drug" in various cancer indications as a direct anti-cancer agent with safety benefit of reducing chemotherapy-induced neutropenia (CIN). After a successful phase 3 study (DUBLIN-3) in NSCLC, Plinabulin regimen is in a confirmatory global phase 3 study in second- and third-line NSCLC with epidermal growth factor receptor (EGFR) wild type after progression on prior immune checkpoint inhibitors, a severe unmet medical need. We are also developing three small molecule immune agents, which are currently in pre-clinical stages. In addition, we founded and continue to own an equity stake in SEED Therapeutics Inc., or SEED. See "—SEED's relationship with BeyondSpring" for additional information. SEED is utilizing a proprietary Targeted Protein Degradation (TPD) drug discovery platform, or "molecular glue" technology, to develop innovative therapeutic agents from internal research and development efforts and with our collaborators on currently undruggable protein targets. SEED has advanced its wholly owned lead oncology asset, a novel RBM39 degrader into phase 1 clinical studies in January 2026. SEED is partnering with Eli Lilly and Co., or Eli Lilly, and Eisai Co., Ltd., or Eisai, to discover and develop new chemical entities through this proprietary TPD platform which could produce therapeutic benefits to patients suffering from oncology and central nervous system (CNS) disease, among others.

Through our 15-year research and development efforts to progress our lead asset Plinabulin, we discovered that Plinabulin has novel mechanisms of action. Plinabulin is a differentiated microtubule modulator with different binding and kinetics from other microtubule stabilizing or depolymerizing agents. By depolymerizing microtubule, it activates the immune defense protein GEF-H1, which leads to induction of innate and adaptive immunity via dendritic cell (DC) maturation. In June 2025, we published in Cell Press "Med" Plinabulin's DC maturation benefit to responding patients in eight cancers, based on our multi-year collaboration with The University of Texas MD Anderson Cancer Center, or MD Anderson. In January 2026, our research collaborator Dr. Steinmetz group published in "Cell" on the structural basis of microtubule-mediated signal transduction, which suggests the important role of microtubule as signal sensors to regulate cellular function, further supporting Plinabulin's unique biological function. With this unique immune mechanism, Plinabulin is being studied as an anti-cancer agent in a number of company-sponsored studies and investigator-initiated studies in late-line and first-line cancer treatments, including targeting patients progressed on checkpoint inhibitors in NSCLC with EGFR wild type, which we believe presents a severe unmet medical need.

The current standard of care for first-line EGFR wild type NSCLC is PD-1/PD-L1 antibodies with or without platinum doublet. However, over 60% patients progress on these therapies, defined as "acquired resistance" due to "T cell exhaustion" and/or "antigen presenting cell (APC) pathway mutation" (Memon et al., Cancer Cell 2024). Once patients progress on these regimens, docetaxel, a drug approved over 25 years ago, is recommended in the second- and third-line, but it has modest clinical benefit and high severe neutropenia. Recently, 11 phase 3 studies, with agents including PD-1/PD-L1 antibodies combinations or Antibody Drug Conjugate (ADC) have failed to surpass docetaxel in overall survival (OS) in this population. We believe that Plinabulin's mechanism of DC maturation could help mitigate ICI acquired resistance, as DC is the most potent APC and it can prime T cells.

To address the significant unmet need in this population, we have been conducting multiple studies on Plinabulin combinations. First, we completed a randomized global Phase 3 study of Plinabulin in combination with docetaxel compared with docetaxel alone for second- and third-line treatment of NSCLC, with EGFR wild type (DUBLIN-3 Phase 3 registration study). The DUBLIN-3 study enrolled 559 patients at 58 clinical sites globally and the final results from the study showed that the Plinabulin and docetaxel combination had statistically significant and clinically meaningful overall survival benefit compared to standard of care (SOC) docetaxel alone with doubling 2-year and 3-year OS rate. It has more pronounced overall survival benefit in plinabulin-mechanism targeted non-squamous patients (OS HR 0.72 after additional 2-year follow-up, p=0.0078). Key secondary endpoints were also achieved with additional clinically significant benefits in progression free survival (PFS) and objective response rate (ORR), coupled with a significant reduction in grade 4 neutropenia, with over 80% reduction from over 33% to 5% ($p<0.0001$). The finding was published in LANCET Respiratory Medicine journal in September 2024, and at the same time we made an oral presentation at the International Association for the Study of Lung Cancer (IASLC) conference. We plan to use our best efforts to file an NDA with the NMPA as soon as possible. Because DUBLIN-3 study had over 80% patients from Asia, we plan to initiate a confirmatory global phase 3 study in second- and third-line non-squamous NSCLC with epidermal growth factor receptor (EGFR) wild type after progression on prior immune checkpoint inhibitors, based on productive discussion with US regulatory agency.

In addition, we are conducting a number of investigator-initiated study (IIT) on Plinabulin in ICI progressed cancers, including NSCLC, head-and-neck cancer and Hodgkin's Lymphoma, and first line ES-SCLC. We provide financial support for these various investigator-initiated clinical trials as well as the drug supply of Plinabulin. First, our collaborators at Peking Union Medical College Hospital in China are conducting an investigator-initiated Phase 2 study (Study 303) with the completion of all 47 patients enrolled: Plinabulin in combination with Keytruda® (pembrolizumab), a PD-1 antibody, and docetaxel for the treatment of NSCLC patients who progressed from PD-1/PD-L1 antibodies. We presented clinically meaningful data of high disease control rate of 80% and prolonged PFS from this study at European Society for Medical Oncology (ESMO) 2024, Society for Immunotherapy of Cancer (SITC) 2024, and American Society of Clinical Oncology (ASCO) 2025. Second, our collaborators at MD Anderson Cancer Center have completed a phase 1 IIT study in Plinabulin combination with PD-1 or PD-L1 antibodies and radiation for the treatment of patients in eight cancers who progressed from PD-1/PD-L1 antibodies, with disease control rate of 54%. This paper was published in Cell Press "Med" in June 2025. Plinabulin's rapid DC maturation biomarker analysis was observed in responding patients. Third, Plinabulin is being studied in a Phase 2 IIT study (Study 302) in combination with Keytruda®, etoposide and platinum for the first-line treatment of extensive-stage small cell lung cancer, or ES-SCLC, patients at Wuhan Union Hospital in China, where the current standard of care has limited median PFS. Additional completed investigator initiated studies with Plinabulin include: 1) in combination with nivolumab, a PD-1 antibody, for the treatment of NSCLC at the University of California San Diego, or UCSD, and the University of Washington (Phase 1 completed); 2) in combination with nivolumab and ipilimumab, a CTLA-4 antibody, for the treatment of second line ES-SCLC at the Rutgers University and other U.S. clinical centers (both Phase 1 and Phase 2 completed).

Our principal executive offices are located in New Jersey, and we also have offices in Beijing, China and Dalian, China. In addition, SEED has offices in Pennsylvania. We are incorporated in the Cayman Islands. Our management team has deep experience and capabilities in biology, chemistry, drug discovery, manufacturing, clinical development, regulatory and capital markets.

Plinabulin, Our Lead Drug Candidate

Plinabulin is a first-in-class, novel small molecule derived from a natural compound found in marine microorganisms. It is a Selective Immunomodulating Microtubule-Binding Agent (SIMBA), which may provide multiple therapeutic opportunities. As a low molecular weight small molecule, Plinabulin is relatively simple to manufacture. An advantage of natural products and their derivatives, such as Plinabulin, is that it may be difficult for others to discover structurally distinct molecules possessing a similar array of activities.

By binding to a distinct pocket and depolymerizing tubulin, Plinabulin triggers the release of the immune defense protein, GEF-H1, which activates RhoA/ROCK (Rho-associated protein kinases) pathway and leads to two distinct effects: 1) a durable anti-cancer benefit due to the maturation of dendritic cells resulting in activation of tumor antigen-specific T-cells to target cancer cells and 2) early-onset action in CIN prevention after chemotherapy by boosting the number of hematopoietic stem/progenitor cells, or HSPCs. Effects on HSPCs could explain the potential for Plinabulin not only to prevent CIN but also to increase circulating CD34+ cells in patients. As a potential "pipeline in a drug," Plinabulin is being broadly studied in combination with chemotherapy, radiation, or various immuno-oncology agents that could boost the effects of the PD-1/PD-L1 antibodies and potentially allow patients who progressed on PD-1/PD-L1 antibodies to respond to Plinabulin regimen. The elucidation of Plinabulin's unique mechanism was a multi-year collaborative effort among us, University of Basel, Massachusetts General Hospital, and MD Anderson.

In aggregate, as of the date of this Annual Report on Form 10-K, Plinabulin has been administered to over 700 patients with advanced cancer and thus far is generally well-tolerated. We believe the data from completed and ongoing clinical trials suggest there is a path forward for Plinabulin in the treatment of advanced and metastatic NSCLC with added safety benefit of CIN reduction.

Plinabulin for the Treatment of Advanced and Metastatic NSCLC

NSCLC disease overview

According to the National Cancer Institute, approximately 230,000 patients are diagnosed with lung cancer in the U.S. per year. The prognosis for patients with lung cancer is poor with five-year survival rate of only 18.6%. Lung cancer is the leading cause of cancer death in the U.S. and a global health problem with approximately 1.8 million cases diagnosed per year. Approximately one-third of lung cancer patients worldwide are in China, with approximately 700,000 cases of lung cancer diagnosed in China in 2015. These lung cancers are typically divided into two groups based upon the histologic appearance of the tumor cells—NSCLC and small cell lung cancer (SCLC), which are treated with distinct chemotherapeutic approaches. NSCLC accounts for approximately 87% of lung cancer cases. The global NSCLC market is increasing at a rate of 10% per year, with estimated sales of $26.7 billion and $44.6 billion in 2021 and 2026, respectively. In China, between 2015 and 2019, the number of new cases of NSCLC increased from 669,000 to 761,000, and the number of new cases is expected to reach over 1 million by 2030. According to Frost & Sullivan, in China, NSCLC targeted drug sales reached RMB 12.7 billion (approximately $2.0 billion) in 2018, RMB 20.8 billion (approximately $3.3 billion) in 2019, and RMB 29.1 billion (approximately $4.6 billion) in 2020.

Lung cancer is typically diagnosed relatively late in its clinical course after it has metastasized to other tissues in the body. In these advanced cases, treatment is not curative, and patients with EGFR wild type (around 85% western patients and 50-70% Asian patients) are generally treated with first-line therapies including platinum doublet with or without PD-1/PD-L1 inhibitors. However, over 60% patients could progress on these therapies and with docetaxel as the SOC after progression. Recently 11 phase 3 trials failed to show OS benefit of new agents compared to docetaxel in patients with advanced and metastatic NSCLC after progression on ICI-based therapy. These studies evaluated PD-(L)1 inhibitor combination with tyrosine kinase inhibitor (LEAP-008, SAPPHIRE, CONTACT-01), PD-L1 inhibitor with ATR inhibitor (LATIFY), PD-L1 inhibitor with VEGFR-2 antibody (PRAGMATICA-LUNG) , PD-1 inhibitor combined with Docetaxel with or without TIM3 inhibitor (COSTAR Lung), or novel bispecific antibodies (PD-L1x4-1BB, ABBIL1TY), or antibody-drug conjugates (TROPION-Lung01, EVOKE-1, CARMEN-LC03. Therefore, docetaxel, a drug approved 25 years ago, with limited survival benefit of around 9 months and high severe neutropenia rate of over 40%, remains the standard of care, highlighting a significant unmet medical need.

Plinabulin in advanced and metastatic NSCLC

Plinabulin is a Selective Immunomodulating Microtubule-Binding Agent (SIMBA), which activates immune defense protein GEF-H1, and leads to dendritic cell maturation and T-cell activation (La Sala 2019; Kashyap 2019) for anti-cancer benefit. High GEF-H1 immune signature patients in anti-cancer studies live much longer than the ones who have lower GEF-H1 immune signature (Kashyap 2019). In addition, Plinabulin has the benefit in tumor vasculature modulation (Clinical Cancer Research 2010).

Phase 1/2 in advanced and metastatic NSCLC (Study 101)

The primary purpose of the Phase 2 portion of the Phase 1/2 trial was to evaluate the potential anti-cancer effect of Plinabulin in combination with docetaxel compared to docetaxel monotherapy in advanced second- and third-line NSCLC patients. The trial enrolled 163 advanced NSCLC patients in the U.S., Australia, Argentina, Chile, Brazil and India. Patients enrolled in the trial had unresectable, locally advanced or metastatic cancers, meaning that in some patients the disease had spread to adjacent lymph nodes if not throughout the body. In such patients there may not be measurable lesions in the lungs.

For intent to treat, or ITT, population with no targeted patient selection, the trial did not meet the primary endpoint of a statistically significant improvement in overall survival for Plinabulin in combination with docetaxel compared to docetaxel monotherapy, with only modest 1.2 months survival benefit in the combination vs. docetaxel alone. However, we identified a subset of patients with measurable lung lesions (Plinabulin mechanism targeted patients) in which the addition of Plinabulin to docetaxel may increase anti-tumor activity compared to docetaxel monotherapy with survival benefit of 4.6 months. In this mechanism-based subset analysis, patients in the Plinabulin plus docetaxel arm had a median OS of 11.3 months, while those treated with docetaxel alone had a median OS of 6.7 months. Additionally, the Plinabulin plus docetaxel cohort had an objective response rate, or ORR, of 18.4% compared to 10.5% for the docetaxel monotherapy arm. This subset included only 38 patients from each arm and did not reach statistical significance on the OS (p=0.29). The patients who received Plinabulin plus docetaxel also had a duration of response, the initial response until documented tumor progression, of 12.7 months compared to only one month for the patients who received docetaxel monotherapy (p=0.049). This subset analysis was presented as an oral presentation at 2017 ASCO-SITC conference and was selected as one of five highlights of the meeting.

Phase 3 in advanced and metastatic NSCLC (Study 103 or DUBLIN-3)

In June 2016, we initiated a Phase 3 trial (DUBLIN-3), a randomized, active-controlled, single blind to patients, global trial that enrolled 559 patients in second- and third-line NSCLC, EGFR wild type, with a measurable lung lesion. Patients were treated on a 21-day cycle with infusion of docetaxel (D, 75 mg/m2 on Day 1) and Plinabulin (P, 30 mg/m2 on days 1 and 8) or with docetaxel alone (D, 75 mg/m2 on Day 1). The study was conducted in the U.S., China and Australia.

The primary endpoint is overall survival in patients given a combination of Plinabulin and docetaxel compared to patients given docetaxel alone. Secondary endpoints include the frequency of grade 4 neutropenia, ORR, PFS percentage of patients at or longer than two years of survival and at or longer than three years of survival, duration of response, cycles of chemo treatment, and quality of life.

The primary endpoint of OS was met in the ITT population (Combination (DP): n = 278 [male 199, female 79]; docetaxel (D): n = 281[male 207, female 74]). The following table summarizes the final results, which was published in Lancet Respiratory Medicine 12 (10): page 775-786 (2024).

	Docetaxel + placebo (n=281)	Docetaxel + plinabulin (n=278)	Difference (95% CI)	HR (95% CI)	p value
Primary outcome					
Median OS, months	9·4	10·5	..	0·82 (0·68 to 0·99)	0·0399
RMST, months (95% CI)	12·77 (11·45 to 14·10)	15·08 (13·42 to 16·74)	2·31 (0·18 to 4·44)	..	0·0332
Secondary outcomes					
ORR (CR+PR)*	24 (9%)	39 (14%)	5·49% (0·26 to 10·72)	..	0·0404
PFS*					
Median PFS, months	2·8	3·3	..	0·79 (0·66 to 0·96)	0·0174
RMST, months (95% CI)	3·99 (3·49 to 4·49)	4·92 (4·28 to 5·56)	0·93 (0·12 to 1·74)	..	0·0250
Grade 4 neutropenia on cycle 1 day 8	67/241 (28%)	12/228 (5%)	−22·54 (−28·89 to −16·18)	..	<0·0001
24-month OS rate, %	13%	22%	..	..	0·0072
36-month OS rate, %	5%	12%	..	..	0·0393
Median DoR*, months	6·1	8·3	..	..	0·0606†
Median DoR* (including stable disease), months	3·8	5·1	..	..	0·0122

Key findings of DUBLIN-3 study are summarized below:

- **Favorable benefit/risk ratio:** Significant improvement in OS (Hazard ratio or HR=0.82; same HR in the Western vs. Asian patients), PFS (HR=0.79) and ORR (nearly doubled). Durable anti-cancer benefits in doubling 24-months and 36-months OS rates. And 82% relative reduction in grade 4 neutropenia in Cycle 1 Day 8 ($p<0.0001$).

- **Consistent OS benefit in 24-month follow-up after the database lock:** OS HR=0.81 in the ITT population, with better OS benefit in the non-squamous subset (OS HR=0.72, p=0.0078). For the Plinabulin mechanism targeted non-squamous subset patients, median OS (mOS) in Plinabulin/docetaxel arm was 11.4 months vs. 8.8 months in the docetaxel arm, with mOS benefit of 2.6 months (OS HR 0.72, p=0.0078): mOS 11.2 months in DP (n=154) vs. mOS 8.8 months in D (n=178).

- **Improved OS benefit with more cycles of treatment** (≥ 4, 6, 8, 10, or 12 cycles): for patients who used at least 4 cycles of treatment, OS HR=0.64, p=0.0027, with mOS benefit of 4.8 months (Plinabulin/docetaxel arm n=133; docetaxel arm n=127).

- **Plinabulin/docetaxel combination is well-tolerated:** Treatment-emergent adverse-events occurred in 273/274 (99·6%) of patients in the Plinabulin group and 276/278 (99·3%) in the control group. Higher incidences of grade 3/4 gastrointestinal disorders (46 patients [16·8%] vs. 8 [2·9%]) and transient grade 3 hypertension (50 patients [18·2%] vs. 8 [2·9%]) occurred in the Plinabulin vs. control group.

Plinabulin in Combination with Immuno-oncology Agents in Anti-Cancer Indications

Preclinical studies have identified some novel and intriguing activities of Plinabulin associated with stimulation of the immune system, consistent with Plinabulin's ability to enhance the activity of immuno-oncology agents. We have observed in these studies that Plinabulin works at multiple early steps in the process of immune activation against cancer, in particular, to activate and mobilize tumor antigen-specific T-cells to the tumor. The potential role of Plinabulin in stimulating the activity of other immuno-oncology agents has been explored in several investigator-initiated Phase 1/2 trials described below.

Overview of immuno-oncology

The immune system is capable of recognizing and eliminating tumor cells; however, tumors are sometimes able to evade the immune response through alteration of regulatory checkpoint pathways. One of these pathways is driven by PD-1, a receptor that is expressed on immune T-cells. Between 35% and 100% of some tumors such as melanoma, hepatocellular carcinoma, colorectal cancer and NSCLC overexpress PD-L1, a compound naturally bound by PD-1. Binding of PD-L1 to PD-1 suppresses immune activation, allowing the tumor to evade destruction by the immune system. Immune checkpoint cancer therapies that target PD-1 such as nivolumab (Opdivo) have been approved for the treatment of around 20 types of cancers, including melanoma, NSCLC, renal cell carcinoma, classic Hodgkin's lymphoma, head and neck squamous cell carcinoma, urothelial carcinoma, colorectal carcinoma and hepatocellular carcinoma. While PD-1/PD-L1 inhibitors are highly effective in a subset of tumors, there are multiple pathways that tumors rely upon to evade the immune system allowing many tumors to continue to proliferate.

The global market size of PD-1 and PD-L1 inhibitors/ immune checkpoint inhibitors was around $60 billion in 2025 and is projected to reach $135.55 billion by 2031 at a compound annual growth rate (CAGR) of 13.88% (Mordor Intelligence 2025). Around 60% of the cancer patients who receive such treatment progressed from PD-1/PD-L1 antibodies, including in NSCLC (Cancer Cell 2024).

As with the treatment of most cancers, combination treatments are often required to increase efficacy. In 2020, the combination of nivolumab, a PD-1 antibody, and ipilimumab, a CTLA-4 antibody, was approved in melanoma based on increased efficacy. However, this combination resulted in increases in grades 3 and 4 adverse events, which occurred in 55% of the combination patients compared to 16.3% in patients treated with nivolumab alone and 27.3% of patients treated with ipilimumab alone. We believe that the addition of Plinabulin to an immune checkpoint inhibitor such as PD-1 or PD-L1 antibodies has the potential to increase activity without increasing the rate of serious adverse events, or potentially decrease immune-related side effects. In addition, cancer patients who progressed from PD-1/PD-L1 antibodies could potentially benefit from Plinabulin and PD-1/PD-L1 combination and chemotherapy/radiation. Current investigator-initiated studies on these Plinabulin combinations aim to help design an optimum registrational study for these indications for patients who progressed on PD-1/PD-L1 inhibitors, especially in NSCLC.

Preclinical study data supporting Plinabulin in immuno-oncology

Checkpoint inhibitors (PD-1/PD-L1 inhibitors) alleviate immune system blocks at a relatively late stage in the overall immune process—at the point when T-cells recognize cancer cells. Recent “Tamon et al Cancer Cell 2024” paper studied the mechanism of “acquired resistance” of PD-1/PD-L1 inhibitors, including T-cell exhaustion and antigen presentation pathway mutation, which we believe Plinabulin has the potential to revert. Preclinical studies indicate that Plinabulin activates the immune system multiple steps earlier in the process of immune activation, and thus has the potential to complement the activity of checkpoint inhibitors. Both published and unpublished preclinical study data have suggested that Plinabulin can stimulate an immune response to cancer cells by increasing the “presentation of cancer antigens” by dendritic cells, stimulating dendritic cell proliferation, increasing levels of helper T-cells and by decreasing the levels of immunosuppressive regulatory T-cells.

One example of this is in a colon cancer model (MC38) in immune competent mice. The combination of Plinabulin and a PD-1 antibody resulted in tumors that were approximately 25% smaller than those from control animals, similar to the levels seen with the combination of a PD-1 antibody and a CTLA-4 antibody. The triple combination of Plinabulin, a PD-1 antibody and a CTLA-4 antibody resulted in tumors that were smaller than those in animals treated with any of the other studied agents or the studied combinations thereof and approximately 40% smaller than the vehicle control.

Another example is in a PD-1 non-responsive tumor model which was conducted at Dr. Steven Lin’s lab at MD Anderson. The results of this preclinical study were highlighted in a poster presentation titled “Plinabulin, a microtubule destabilizing agent, improves tumor control by enhancing dendritic cell maturation and CD8 T-cell infiltration in combination immuno-radiotherapy,” at American Association for Cancer Research Virtual Annual Meeting in June 2020. Data highlights include:

- **Preclinical effectiveness:**
  The triple immuno-oncology combination of Plinabulin, anti-PD-1 and radiation (triple combination) achieved a 100% complete response in a breast cancer model that is not responsive to PD-1 antibody alone.

- **Sequential benefit:**
  Plinabulin's effects on dendritic cell maturation are greater when administered after each dose of fractionated radiotherapy, compared to administration before radiation, or administration only once after the first dose of radiotherapy.

- **Abscopal effect:**
  The Plinabulin triple combination anti-cancer effects in both irradiated and non-irradiated tumors in the same mice indicate the activation of a systemic anti-cancer immune response. Notably, CD8 cell levels in the non-irradiated tumors were almost double in the triple combination group compared to anti-PD-1 and radiation alone.

- **Dendritic cell major histocompatibility complex class II, or MHC-II, up-regulation and T-cell tumor infiltration:**
  Plinabulin triple combination significantly increased dendritic cell MHC-II expression and T-cell infiltration in the tumor.

We believe that the maturation of dendritic cells is a key to unlocking the next boost to the efficacy of immuno-oncology agents. Matured dendritic cells, which are the most potent antigen presenting cells, present foreign tumor antigens to T-cells to induce cancer-directed immune attacks. Thus, adding this critical step of dendritic cell activation in the immune cascade to the established effects of immune checkpoint inhibition therapies is expected to increase overall anti-cancer efficacy in the clinic and has the potential to re-sensitize patients who progress on prior immunotherapies. Even with the current PD-1 and PD-L1 antibody annual sales at around $60 billion, with most sales coming from lung cancer, around 60% of lung cancer patients could develop acquired resistance to PD-1 and PD-L1 antibody, and these patients currently have limited treatment options (Tamon et al Cancer Cell 2024). Our anti-cancer strategy is Plinabulin combination regimen. We believe the data strongly indicates that this combination has potential to help patients who failed or have progressed on anti-PD-1/PD-L1 targeted therapy, which represents a high unmet medical need.

Investigator-initiated studies in Plinabulin in immuno-oncology

We have explored and plan to continue to explore the role of Plinabulin in stimulating the activity of other immuno-oncology agents in clinical programs:

Plinabulin + Pembrolizumab + Docetaxel in 2L NSCLC who progressed on PD-1/PD-L1 inhibitors (Study 303)

Docetaxel remains the standard of care for second-line and third-line treatments of patients with EHFR wild type NSCLC who progress on immune checkpoint inhibitors with and without standard chemotherapy. In the recent TROPION Lung-01 Phase 3 studies, a similar patient population had an overall response rate (ORR) of 12.8% and median PFS (mPFS) of 3.7 months with docetaxel.

This investigator-initiated, single-arm, open-label, Phase 2 study (KeyPelms-004 or Study 303) evaluates the efficacy and safety of a triple combination regimen of pembrolizumab plus Plinabulin/docetaxel (NCT05599789) in metastatic EGFR wild type NSCLC who progressed on prior PD-1/L1 inhibitor in combination with or without platinum doublet. The study has completed enrollment of all 47 patients and is funded by Merck's Investigator Studies Program with provision of study drug and financial support. The study is ongoing at Peking Union Medical College Hospital, Beijing, China with the principal investigator Dr. Mengzhao Wang, Chief of the Department of Respiratory and Critical Care Medicine.

In March 2023, the first patient was enrolled. The data of 47 patients was presented at SITC 2025. Median follow-up was 14.3 months at the data cut-off date of Sep 30, 2025. Median age was 67 (44-83) with 80.9% male and 19.1% female. 72.3% were current or former smokers. Histology included 63.8% with non-squamous cell carcinoma, 36.2% with squamous cell carcinoma. In 42 patients who completed blood sampling on C1D0 and C3D0, the proportions of CD4+ and CD8+ T cells remained stable ($p>0.05$) while Ki67+CD8+ T cells were significantly increased ($p=0.004$). The frequencies of CD38+HLA-DR+CD4+T cells and CD38+HLA-DR+CD8+T cells were dramatically elevated ($p<0.0001$).

The combination was generally well tolerated. 53.2% of patients experienced grade 3 or higher treatment-related adverse effects, or TEAEs. Most common grade 3 or higher TEAE is myelosuppression (17.0%), gastrointestinal side effect (14.9%), and transient hypertension (17.0%). There were no treatment-related deaths.

Table below is the summary of the efficacy study of 47 patients presented at SITC conference in November 2025.

Primary Endpoint	Plinabulin + Pembrolizumab + Docetaxel (n=47)
Confirmed ORR (RECIST 1.1)	18.2%
Secondary Endpoints	
Median PFS (RECIST 1.1)	**7.0 M**
Median OS (Overall Survival)	Not reached
Disease Control Rate	**85.1%**
12 months OS Rate	**79.3%**
24 months OS Rate	**65.9%**

Note: partial response: tumor(s) size reduction more than 30% since initial baseline measurement and there are no new tumors; stable disease: the tumor(s) have not increased in size by more than 20% or decreased in size by more than 30% since the initial baseline measurement and there are no new tumors.

Plinabulin + Pembrolizumab + Etoposide / Platinum in 1L ES-SCLC (Study 302)

Current treatment for first-line ES-SCLC includes Etoposide and Platinum (EP) and EP plus PD-L1 antibodies. Although the objective response rate (ORR) is high (around 60-70%), median progression free survival (PFS) remains low, even for PD-L1 and EP at around 5 months, with median overall survival at 10-13 months. Therefore, first-line treatment of ES-SCLC remains a serious unmet medical need.

In an open-label, single-arm Phase 2 investigator-initiated trial, Pembrolizumab, Plinabulin plus EP in first-line ES-SCLC will be evaluated for the efficacy and safety in Wuhan Union Hospital in China, with Dr. Xiaorong Dong, Deputy Director of the Oncology Research Department and Director of the Thoracic Oncology Department, as the principal investigator. The study intends to enroll 45 patients and is funded by Merck's Investigator Studies Program with provision of study drug and financial support. The primary endpoint is the 12-month PFS rate. In March 2024, the first patient was enrolled. The study is ongoing.

Plinabulin + PD-1/PD-L1 antibody + Radiation in multiple cancers of PD-1/PD-L1 failed patients in Multiple Cancer Types

In July 2018, we entered into a sponsored research agreement with MD Anderson to evaluate the benefits of adding Plinabulin to radiation therapy plus immune checkpoint antibodies. The pre-clinical study has demonstrated that the triple combination approach (Plinabulin+radiation+PD-1 antibody) has dramatic benefits in tumor reduction (100% tumor shrinkage), increasing tumor dendritic cell maturation and increasing tumor T-cell infiltration in animal models.

In June 2021, the first patient was dosed in this Phase 1/2 study at MD Anderson, for the treatment of patients after progression on PD-1 or PD-L1 antibody therapies in seven different cancer types with Plinabulin+PD-1/PD-L1 antibodies and radiation. The cancer types include bladder cancer, melanoma, Merkle cell cancer, microsatellite instability-high cancers (of any histology), NSCLC, renal cell cancer, and hogkins lymphoma. The protocol was updated in 2022 to include patients that have any tumor type with checkpoint inhibitor approval that may or may not have progressed on previous PD-1/PD-L1 antibodies or anti-CTLA-4. Enrollment of the Phase 1 study has been completed in March 2023. Topline clinical data with corresponding biomarker analysis was presented at the SITC 38th Annual Meeting in November 2023. Durable response was observed in heavily pre-treated patients, including two Hodgkin's lymphoma patients who progressed after 12 or 16 prior lines of therapy respectively, including progression on PD-1 antibody and stem cell transplant therapies. In addition, DC maturation was observed in patients with the clinical benefit of partial response and stable disease.

Phase 1 portion of this study has been completed. The study was published in Med 2025.

Plinabulin + PD-1 antibody in 2/3L NSCLC

In September 2016, UCSD enrolled the first patient in an investigator-initiated Phase 1/2 trial of Plinabulin in combination with nivolumab in patients with metastatic NSCLC. UCSD has completed the enrollment of 18 patients. The study had achieved its Phase 1 endpoint of safety evaluation and dose selection and the study has been completed. In addition, Fred Hutchison Cancer Center, together with the University of Washington, launched an investigator-initiated Phase 1/2 trial of Plinabulin in combination with nivolumab in patients with advanced NSCLC who have failed up to two previous therapies. The University of Washington study achieved the dose regimen endpoint and therefore the study site has been closed.

Preliminary safety data from these two trials were presented at the ASCO-SITC meeting in January 2018. In the 10 patients evaluated, the combination therapy was well-tolerated, with no immune related serious adverse events. Only two patients presented with immune related adverse events, one with a grade 1 event and the other with a grade 2 event. While these studies showed limited efficacy in Plinabulin and PD-1 antibody in patients who failed PD-1/PD-L1 inhibitors in prior lines, they provide important tolerability data for Plinabulin in combination with PD-1 antibody.

Plinabulin + PD-1 + CTLA-4 antibodies in 2/3L ES-SCLC

In October 2018, we announced the opening of an investigator-initiated Phase 1 clinical trial with a triple combination therapy, consisting of Plinabulin, nivolumab (one type of PD-1 antibody), and ipilimumab (one type of CTLA-4 antibody), for the treatment of second- and third-line ES-SCLC. The trial, conducted through the Big Ten Cancer Research Consortium, enrolled 16 patients at Rutgers Cancer Institute of New Jersey and other clinical centers in the U.S. in the Phase 1 portion of this Phase 1/2 combined study. This study investigated whether the addition of Plinabulin results in a reduction of immune-related side effects of PD-1 and CTLA-4 antibodies and if it provides efficacy synergy. In ASCO meeting in June 2021, we presented positive Phase 1 data from this study on 13 evaluable patients with immunotherapy naïve or resistant tumors in second-line and beyond in ES-SCLC, Plinabulin in combination with nivolumab and ipilimumab showed a 46% ORR. Additionally, the data demonstrated that the Plinabulin combination was able to re-sensitize tumors to immune-oncology therapy, that had previously progressed on prior immunotherapies, with a 43% ORR.

In October 2021, the first patient was enrolled in the Phase 2 portion of this investigator-initiated study. Patients with histological or cytological confirmed ES-SCLC who progressed after at least one platinum-based chemotherapy regimen and checkpoint inhibitors received the triple combination of Plinabulin + nivolumab + ipilimumab. Patients in the Phase 2 study continued treatment until disease progression, development of unacceptable toxicity, or one of the protocol-defined reasons for treatment discontinuation occurs. Enrollment of the Phase 2 study has been completed in February 2023. Between September 2018 and February 2023, 39 patients were enrolled, and 36 patients received study treatment (16 in Phase 1; 20 in Phase 2). The data was published in 2024, with one patient using 90 cycles of treatment. Both Phase 1 and Phase 2 studies have been completed. We believe these studies were important to provide tolerability data for Plinabulin in combination with PD-1 and CTLA-4 inhibitors.

Plinabulin in Prevention of CIN

CIN overview

Neutropenia is an abnormally low blood concentration of neutrophils, a type of white blood cell, which may result from an abnormal rate of destruction or a low rate of synthesis of white blood cells in bone marrow. Neutropenia is graded according to its severity, which generally depends on neutrophil count. An absolute neutrophil count below 500 cells/mm3 (0.5 x 10^9 /L) is categorized as grade 4 neutropenia and a neutrophil count between 500 and 1,000 cells/mm3 (0.5-1.0 x 10^9 /L) is categorized as grade 3 neutropenia. Patients with low neutrophil counts are more susceptible to bacterial infections and sepsis, which are a significant cause of morbidity and mortality in cancer patients.

Chemotherapy is still the standard of care for cancer patients with or without combination with PD-1/PD-L1 antibodies in a number of cancer indications, including NSCLC, SCLC, Triple negative breast cancer, gastric cancer, esophageal cancer, head and neck cancer, cervical cancer, endometrial cancer, bladder cancer, and biliary tract cancer. Neutropenia represents a key limitation associated with most chemotherapies. Even with the current revolution of immunotherapies for anti-cancer treatment, PD-1/PD-L1 antibodies have been approved in combination with chemotherapy with improved anti-cancer efficacy, so chemotherapy is "here to stay". The current standard of care for neutropenia is biologic drugs based on G-CSF, a human growth factor that stimulates the proliferation, differentiation and maturation of neutrophils. Treatment or prevention of CIN with G-CSF has been the standard of care since Neupogen (filgrastim) was approved in 1991. G-CSF includes filgrastim and pegfilgrastim, which is long-lasting filgrastim. While monotherapy G-CSF reduces duration of severe neutropenia, or DSN, over 80% of patients still experience grade 4 neutropenia, which is the most common reason for reducing the relative dose intensity of chemotherapy, downgrading the chemotherapy regimen, delaying chemotherapy schedule and discontinuing chemotherapy, all of which will negatively impact patients' long-term survival outcome. Furthermore, G-CSF cannot be given on the same day as chemotherapy and the expansion of bone marrow generated by monotherapy G-CSF causes bone pain. According to post-marketing patient surveys, between 59% and 71% of patients report having experienced bone pain and, of those patients, about one-quarter describe the pain as severe.

The main benefit of G-CSF treatment, however, is in week 2 after chemotherapy and with side effect of bone pain. Week 1 after chemotherapy is considered the "Neutropenia Vulnerability Gap" where over 75% of CIN-related clinical complications occur, including febrile neutropenia, infection, hospitalization and death. Plinabulin has the potential to fill this "Neutropenia Vulnerability Gap" by working in week 1 to prevent the onset and progression of CIN. Therefore, we believe combining Plinabulin with G-CSF may maximize the protection of patients for the full cycle of chemotherapy, as demonstrated in the PROTECTIVE-2 Phase 3 registration study.

PROTECTIVE-2 Phase 3 study was the registration study to support the NDA submission for the use of Plinabulin in combination with G-CSF for the prevention of CIN. The NDA submission was based on positive data from this study, which shows that Plinabulin in combination with pegfilgrastim demonstrated superior CIN prevention benefit, compared to pegfilgrastim alone. The study met the primary endpoint, with a statistically significant improvement in the rate of prevention of grade 4 neutropenia (improved from 13.6% to 31.5%, p=0.0015) and met all key secondary endpoints, including DSN and absolute neutrophil count, or ANC nadir. In addition, the combination reduced clinical complications such as incidence and severity of febrile neutropenia, and incidence and duration of hospitalization for febrile neutropenia patients. The combination is well-tolerated, with over 20% reduction of grade 4 Treatment Emergent Adverse Events in the combination compared to that of pegfilgrastim. The NDA submissions included five supportive trials that show consistent CIN prevention in various chemotherapy regimens and cancers in over 1,200 patients.

Based on the meta-analysis data over 7,000 patients in 36 clinical studies which was published in Cancer Investigation 2023, grade 4 neutropenia rate (primary endpoint of PROTECTIVE-2 Phase 3) is linked to adverse clinical consequences, such as febrile neutropenia and hospitalization.

Plinabulin's effect in preventing CIN has been demonstrated in six clinical trials so far, namely Study 101, DUBLIN-3, PROTECTIVE-1 (Phase 2 and Phase 3), and PROTECTIVE-2 (Phase 2 and Phase 3), with consistent data for CIN prevention early onset benefit in week 1 after chemotherapy.

- In the Phase 2 portion of Study 101, the addition of Plinabulin to a standard regimen of docetaxel resulted in a statistically significant reduction (p=0.002) in the incidence of grade 3 and 4 neutropenia adverse events from 26% of patients in the docetaxel monotherapy arm to 7% in the Plinabulin plus docetaxel arm based upon a retrospective analysis of the data.

- In DUBLIN-3, a Phase 3 study for NSCLC, we evaluated 559 patients on a secondary endpoint of grade 4 neutropenia reduction in Cycle 1 Day 8 and demonstrated Plinabulin's ability to reduce docetaxel induced grade 4 neutropenia in NSCLC patients by 80% ($p<0.0001$).

- In our registration program for CIN, Plinabulin has been studied in two Phase 2/3 clinical trials, the first in Plinabulin monotherapy compared to pegfilgrastim for the prevention of CIN caused by intermediate-risk chemotherapy with high risk factors, composed solely of Taxotere (docetaxel), in various cancer including NSCLC, breast cancer and prostate cancer patients (PROTECTIVE-1), and the second in the Plinabulin and pegfilgrastim combination compared to pegfilgrastim alone for the prevention of CIN caused by high-risk chemotherapy, a myelosuppressive chemotherapeutic regimen composed of three agents, Taxotere (docetaxel), Adriamycin (doxorubicin) and Cytoxan (cyclophosphamide), in breast cancer patients (PROTECTIVE-2). TAC is an example of high febrile neutropenia risk chemotherapy and is the regimen used in all G-CSF biosimilar registration studies.

PROTECTIVE-1 (Plinabulin monotherapy vs. Pegfilgrastim monotherapy)

Based on the clinical profile observed in Study 101 and the results of the discussions between us and the FDA, we refined our design of our two Phase 2/3 trials in CIN. The first trial, PROTECTIVE-1, was a Phase 2/3 trial of Plinabulin monotherapy compared to pegfilgrastim monotherapy in 160 patients in both Phase 2 and Phase 3 studies in various cancers, including advanced breast cancer, hormone refractory prostate cancer and advanced NSCLC patients, treated with docetaxel (intermediate febrile neutropenia risk chemotherapy with high risk factors) in the U.S., China, Russia and Ukraine.

The primary endpoint of this trial was non-inferiority in DSN in the first cycle of chemotherapy, compared to the standard of care, Neulasta (one type of pegfilgrastim, a long-lasting G-CSF). DSN represents the days the patient has grade 4 neutropenia. A clinically meaningful DSN is less than one day.

In the Phase 2 portion of PROTECTIVE-1, published at JAMA Oncology in September 2020, 55 NSCLC patients treated with one dose of Plinabulin at 20 mg/m2 on Day 1 (same day as chemotherapy) had the same incidence or rate of severe neutropenia (grade 4) as patients treated with one dose of Neulasta (6 mg) in the first 21-day cycle. Grade 4 neutropenia occurred in 14% of patients treated with either Plinabulin or Neulasta. This result established the recommended dose of 40 mg (equivalent to 20 mg/m2) for the Phase 3 portion of the trial based on a clear dose response in grade 4 neutropenia incidence and the DSN seen in the Phase 2 portion. Additionally, in the Phase 2 portion of PROTECTIVE-1, Plinabulin was shown to reduce thrombocytopenia and demonstrated a superior immune profile compared to Neulasta based on promyelocytes and immature neutrophil data.

One of the secondary endpoints evaluated in PROTECTIVE-1 was the reduction of bone pain. Bone pain is a significant issue for this patient population and results in many patients discontinuing therapy. In the Phase 2 portion of PROTECTIVE-1, bone pain occurred in fewer patients treated with Plinabulin at 20 mg/m2 (11%, or 0% from Day 3) compared to patients treated with Neulasta (35%).

In the Phase 2 portion of PROTECTIVE-1, nearly half (45%) of patients who received Neulasta experienced thrombocytopenia (any grade) in Cycle 1, compared to 0% of patients who received 20 mg/m2 of Plinabulin. Plinabulin's platelet-protective effect also carried through all four cycles in a statistically significant manner. Clinically significant thrombocytopenia, which is defined as a decrease in platelet counts of more than 30%, occurred less frequently in patients who received docetaxel with Plinabulin, compared to patients who received docetaxel and Neulasta over all four cycles ($p=0.019$).

In addition, our data further demonstrated that Plinabulin mobilizes CD34+ progenitor cells into the peripheral blood through a mechanism of action different from G-CSF or Plerixafor, potentially presenting a new option for hematopoietic cell transplantation. We evaluated CD34+ cell counts in the blood by measuring CD34+ levels pre-dose and at multiple time points through Day 8 of treatment with docetaxel, both with and without Plinabulin. CD34+ measurements were obtained in at least nine patients on both Day 0 and Day 8 for each Plinabulin dose. Patients treated with Plinabulin had statistically significant increases in CD34+ levels at Day 8 in a dose-dependent manner ($p<0.0004$).

In the Phase 3 portion of PROTECTIVE-1 (double-blind, active-controlled), 105 NSCLC, breast cancer and prostate cancer patients were enrolled to compare Plinabulin with Neulasta in CIN prevention benefit, with DSN in cycle 1 as the primary endpoint. The Phase 3 portion of PROTECTIVE-1 had met its primary endpoint of non-inferiority versus Neulasta for DSN in the first cycle, with statistical significance in a pre-specified interim analysis at 105-patient enrollment in December 2018. This conclusion was confirmed at the Data and Safety Monitoring Board meeting in January 2019, chaired by Dr. Crawford, founding member and former Chairman of the National Comprehensive Cancer Network guidelines for Neutropenia Management in the U.S. This finding was published in JAMA Network Open in January 2022.

PROTECTIVE-2 (Plinabulin + Pegfilgrastim combination vs. Pegfilgrastim monotherapy)

The second trial, PROTECTIVE-2, was a Phase 2/3 trial of Plinabulin in combination with a myelosuppressive chemotherapeutic regimen composed of three agents, Taxotere (docetaxel), Adriamycin (doxorubicin) and Cytoxan (cyclophosphamide) in 336 patients with solid tumors (breast cancer) in China and Ukraine. This trial compared Plinabulin in combination with Neulasta (6 mg) (the Plinabulin/Neulasta Combo) to measure superiority in efficacy as compared to Neulasta monotherapy, with rate of prevention of grade 4 neutropenia as the primary endpoint per protocol.

We enrolled 115 patients in the Phase 2 portion of PROTECTIVE-2. In October 2018, we announced Phase 2 data that demonstrated that the Plinabulin/Neulasta Combo led to a clinically meaningful reduction of the duration of grade 3 and 4 neutropenia, a statistically significant increase in the percentage of patients with no severe neutropenia (grade 3 and 4 neutropenia) in the first cycle of chemotherapy, a statistically significant reduction of bone pain, and less immune suppression compared with Neulasta monotherapy in the first cycle. Additionally, the Plinabulin/Neulasta Combo presented good tolerability and no cardio-safety issues. Our data suggested that combining Plinabulin with Neulasta reverses the immune-suppressive profile of Neulasta by lowering the percentage of patients with a neutrophil-to-lymphocyte ratio of less than 5 ($p<0.007$) or with a lymphocyte-to-monocyte ratio of greater than 3.2 ($p<0.07$) versus Neulasta alone. The data further suggested that Plinabulin can also activate the body's innate immune response by increasing plasma levels of both neutrophil count and the immune-modulatory protein haptoglobin.

In the Phase 3 portion of PROTECTIVE-2 (double-blind, active-controlled, registration superiority study), 221 patients were enrolled to evaluate the CIN prevention effect of the Plinabulin and pegfilgrastim combination compared with pegfilgrastim alone. It was designed as a superiority study to compare the safety and efficacy of Plinabulin (40 mg, Day 1 dose) in combination with pegfilgrastim (6 mg, Day 2 dose) versus a single dose of pegfilgrastim (6 mg, Day 2 dose) in patients with breast cancer, treated with TAC. The primary endpoint was the rate of prevention of grade 4 neutropenia, which correlates with high rates of infection, bacteremia, infection, fever and mortality. According to literature, patients treated with TAC and pegfilgrastim still have an incidence of grade 4 neutropenia of approximately 83-93%, or 7-17% of patients with rate of prevention of grade 4 neutropenia. Secondary endpoints include DSN cycle 1, which is the legacy primary endpoints for all biosimilar G-CSF approval studies. In addition, the incidence and duration of profound neutropenia were evaluated. According to literature, profound neutropenia leads to 80% patient death in first week of infection, 48% febrile neutropenia, and 50% infection.

PROTECTIVE-2 Phase 3 registration study demonstrated CIN prevention superiority in the Plinabulin and pegfilgrastim combination compared to pegfilgrastim alone, which met all primary and key secondary endpoints. Results of comparison of CIN prevention benefit between combo arm (Plinabulin+pegfilgrastim, n=111) and peg arm (pegfilgrastim alone, n=110) are detailed below.

	Plinabulin + Pegfilgrastim (n=111)	Pegfilgrastim (n=110)	p value
Primary Endpoint:			
Rate of prevention of grade 4 neutropenia	31.5%	13.6%	p=0.0015
Key Secondary Endpoints:			
Mean ANC Nadir	0.538 x 10^9 cells/L	0.538 x 10^9 cells/L	p=0.0002
Rate of prevention of grade 3 neutropenia	20.7%	4.6%	p=0.003

We had previously submitted an NDA to each of the FDA and the NMPA based on positive results in our PROTECTIVE-2 Study, supported by five additional clinical studies as described above, for the use of Plinabulin in combination with G-CSF for the prevention of CIN. In November 2021, the FDA issued a Complete Response Letter for Plinabulin in combination with G-CSF for the prevention of CIN. In March 2023, we withdrew the NDA submission for the indication of Plinabulin in combination of pegfilgrastim agents to treat CIN in adult non-myeloid cancer from the NMPA.

All of these well-controlled clinical studies demonstrated Plinabulin's benefit in the prevention of CIN with differentiated profile from G-CSF in week 1 benefit after chemotherapy, limited bone pain and limited thrombocytopenia. We are currently focusing on the anti-cancer benefit of Plinabulin, with CIN prevention as a safety benefit in anti-cancer studies of Plinabulin in combination with chemotherapy with or without PD-1/PD-L1 inhibitors.

Investigator-initiated study in multiple myeloma (Plinabulin + Pegfilgrastim combination)

Plinabulin in combination with pegfilgrastim was studied in a Phase 1, open label, investigator-initiated trial for the reduction of neutropenia burden in multiple myeloma patients who have undergone autologous hematopoietic cell transplantation, or AHCT, at Memorial Sloan Kettering Cancer Center. In this pilot study, patients with multiple myeloma were treated with a single high dose of melphalan and undergo AHCT. Patients received a Plinabulin 40 mg fixed dose intravenous infusion, and on day +1, pegfilgrastim 6 mg was administered per standard of care. The objectives of this study were to evaluate neutropenia burden, safety, tolerability, neutrophil and platelet engraftment rate, disease response, progression free survival, overall survival and patient reported outcome (PRO) assessment of symptom burden. In January 2022, the first patient was dosed in this study. Preliminary data was presented in August 2022 at the 19th International Myeloma Society Annual Meeting, showing that Plinabulin is well tolerated and only one out of the 10 patients enrolled (10%) had non-engraftment related neutropenic fevers or febrile neutropenia (FN) with Plinabulin and pegfilgrastim, compared to a historical number of 60% of FN with standard of care.

Enrollment of this Phase 1 study was completed in March 2023. The study was completed and the topline data was presented at the ASCO in June 2023.

Other Programs

In addition to exploring Plinabulin's therapeutic potential in combination with immuno-oncology agents, we have a pipeline of immuno-oncology product candidates and have utilized our research collaborators to advance these programs.

BPI-002 program

Our BPI-002 program is based on an oral small molecule agent that increases T-cell co-stimulation. Due to its short pharmacokinetics half-life, it has the potential of managing immune-related adverse events better than biological long half-life agents like CTLA-4 inhibitors in combination with PD-1/PD-L1 inhibitors. In preclinical cancer models, BPI-002 has significant anti-cancer effects as a monotherapy and in combination with checkpoint inhibitors. Investigational New Drug, or IND, enabling studies and efforts related to manufacturing and safety testing have been initiated.

BPI-003 program

Our IKK program, BPI-003, is based on a novel small molecule inhibitor of IKK, a protein kinase. IKK is involved in survival of some tumor cells as well as in the production of a number of cytokines and growth factors that serve as survival factors for various tumors. Our IKK inhibitor has shown promising activity in multiple animal models of pancreatic cancer.

BPI-004 program

Our BPI-004 program is focused on a small molecule that induces the production of neo-antigens by tumor cells, allowing tumors containing no immune cells to be infiltrated by the immune system. A large proportion of human cancers do not produce antigens that are recognized by the immune system. As a result, these tumors do not respond to treatments that work through interaction with the patient's immune response. For example, these tumors will not respond to treatment with PD-1 inhibitors. A treatment that induces the tumor cells to produce antigens has the potential to make these cancers responsive to PD-1 inhibitors.

SEED's Targeted Protein Degradation (TPD) Platform and Pipeline

SEED's TPD platform

SEED is investigating an alternative approach to disease treatment in which disease-causing proteins are marked for early degradation. This approach uses a protein called a ubiquitin E3 ligase to target and promote the destruction of disease-causing proteins. To trigger degradation, the target protein is labeled with poly-ubiquitin by a specific ubiquitin ligase enzyme. Poly-ubiquitin acts as an indicating tag to cellular proteasome machinery that the target protein should be destroyed. SEED's approach to tagging the target protein is using its proprietary "molecular glue" technology to bind the ubiquitin ligase to the target protein.

SEED uses its proprietary TPD technology platform on harnessing and engineering "molecular glue" to attack previously believed undruggable targets. Backed by a comprehensive intellectual property portfolio, SEED's mission is to positively impact human health by creating novel protein degradation therapeutics to treat various severe diseases that currently have limited options for patients and their families. SEED was co-founded with Nobel Prize winner in TPD field, Dr. Avram Hershko. SEED is establishing a growing pipeline of novel drug candidates for internal development and in R&D collaboration with Eli Lilly and Eisai on a path to potential clinical and commercial success. SEED's wholly owned lead oncology asset, a novel RBM39 degrader (ST-01156), has entered clinical study with first patient dose in January 2026 in the US. RBM39 degrader has the potential to target mechanism-based indications, including Ewing Sarcoma, Neuroblastoma, liver cancer, and colon cancer. ST-01156 has received Orphan Drug and Rare Pediatric Disease designations from the FDA for Ewing sarcoma.

We believe SEED is an established leader in overcoming the significant scientific challenges to discovering "molecular glue", which enables the development of a new class of drugs with the potential to treat many previously untreatable medical conditions through the targeting of disease-causing proteins that are resistant to inhibition with traditional drug discovery methods. SEED stands out from its competitors through the discovery and use of its proprietary technology platforms for "molecular glue" discovery, focused on platforms addressing the most challenging aspect of this effort, which is to select the novel E3 ligase to glue to the disease-causing protein to mark it for degradation. SEED was featured as one of leading TPD companies in two Nature Review articles in March 2024 and in October 2024.

SEED's relationship with BeyondSpring

Before founding SEED in June 2019, BeyondSpring has incubated the TPD technology internally through collaboration with Dr. Ning Zheng, a Howard Hughes Medical Institute Investigator at The University of Washington on a unique "molecular glue" used to selectively tag certain oncogene proteins with E3 ligase, one of the ubiquitin ligase enzymes. Dr. Huang and Dr. Zheng were the first to discover the crystal structure of the only two classes of E3 ligases. This work forms the structural basis for the selection of small molecules to be studied as a potential "molecular glue."

In November 2020, SEED completed its Series A-1/A-2 financing where SEED issued and sold an aggregate of 1,194,030 of its Series A-1 Preferred Shares to BeyondSpring and SEED Technology Limited, a majority-owned indirect subsidiary of the Company, or, collectively, the BYSI Entities, for an aggregate purchase price of $3.0 million, and 1,990,000 of its Series A-2 Preferred Shares to Eli Lilly for an aggregate purchase price of $5.0 million, each at a cash purchase price of $2.5125 per share. In June 2022, upon the achievement of certain milestones as described in the share purchase agreement, the BYSI Entities collectively purchased an additional 1,194,028 Series A-1 Preferred Shares for an aggregate purchase price of $3.0 million and Eli Lilly purchased an additional 1,990,000 Series A-2 Preferred Shares for an aggregate purchase price of $5.0 million, each at a cash purchase price of $2.5125 per share. In August 2024, SEED completed the first close of its Series A-3 financing, where SEED sold an aggregate of 5,647,059 of its Series A-3 Preferred Shares to Eisai and certain other third-party investors, for an aggregate purchase price of $24.0 million, each at a cash purchase price of $4.25 per share. In September 2025, SEED completed the second close of its Series A-3 financing, where SEED sold an aggregate of 1,411,761 of its Series A-3 Preferred Shares to a related party and certain third-party investors, for an aggregate purchase price of $6.0 million, each at a cash purchase price of $4.25 per share. See "Item 13. Item 13. Certain Relationships and Related Transactions, and Director Independence— Purchase of SEED's Preferred Shares."

In January 2025, we entered into definitive agreements to sell a portion of our Series A-1 Preferred Shares of SEED for $35.4 million, or $4.25 per share, to certain third-party investors in three installments. The first closing of approximately $7.35 million occurred in February 2025. The second closing of approximately $13.19 million is expected to be completed in 2026. Under the terms of the definitive agreements, the third closing of approximately $14.88 million is scheduled to occur no later than December 15, 2026. Each agreement contains specified termination rights for us and each purchaser, including a mutual termination right in the event a closing shall not have occurred by such specified date as set forth in each agreement. As of the date of this Annual Report on Form 10-K, the BYSI Entities own approximately 38.03% of the outstanding equity interest in SEED, and are expected to own approximately 26.56% and 13.62% of the outstanding equity interest in SEED after the second and third closings, respectively, in each case calculated on an as-converted basis (excluding any shares that may be reserved under an employee stock ownership plan, or similar arrangement), and assuming there is no other change to SEED's share capital prior to such closings. As a result, SEED's operations met the criteria under ASC 205-20 as discontinued operations for financial reporting purposes. See Note 3 (Discontinued operations) to our consolidated financial statements for additional information.

SEED's research collaborations with Eli Lilly and Eisai

Eli Lilly

In November 2020, SEED entered into a research collaboration and license agreement, or the Collaboration Agreement, with Eli Lilly, to discover and develop new chemical entities that could produce therapeutic benefit through TPD.

Under the terms of the Collaboration Agreement, SEED received a $10 million upfront cash payment. SEED will also be eligible to receive up to approximately $780 million in potential pre-clinical and clinical development, regulatory and commercial milestones, as well as tiered royalties on net sales of products that result from the collaboration. As of the date of this Annual Report, SEED has received $3 million of these milestone payments for pre-clinical development. With the proceeds of these payments, SEED has invested in developing additional breakthrough and proprietary methods for "molecular glue" discovery, in order to enhance its advantage in growing "molecular glue" drug discovery and development efforts.

Eisai

In August 2024, SEED entered into strategic research collaboration with Eisai to discover and develop novel molecular glue degraders for neurodegeneration and oncology indications. Under the terms of the research collaboration, SEED will lead preclinical discovery activities for the selected targets, including E3 ligase selection and identification of the appropriate molecular glue degraders. Eisai will have exclusive rights to develop and commercialize compounds derived from this collaboration. SEED will be eligible to receive upfront payments and potential preclinical, clinical, regulatory and sales milestone payments of up to $1.5 billion, plus tiered royalties on net sales of products that result from the collaboration upon Eisai's exercise of their exclusive rights under the strategic research collaboration.

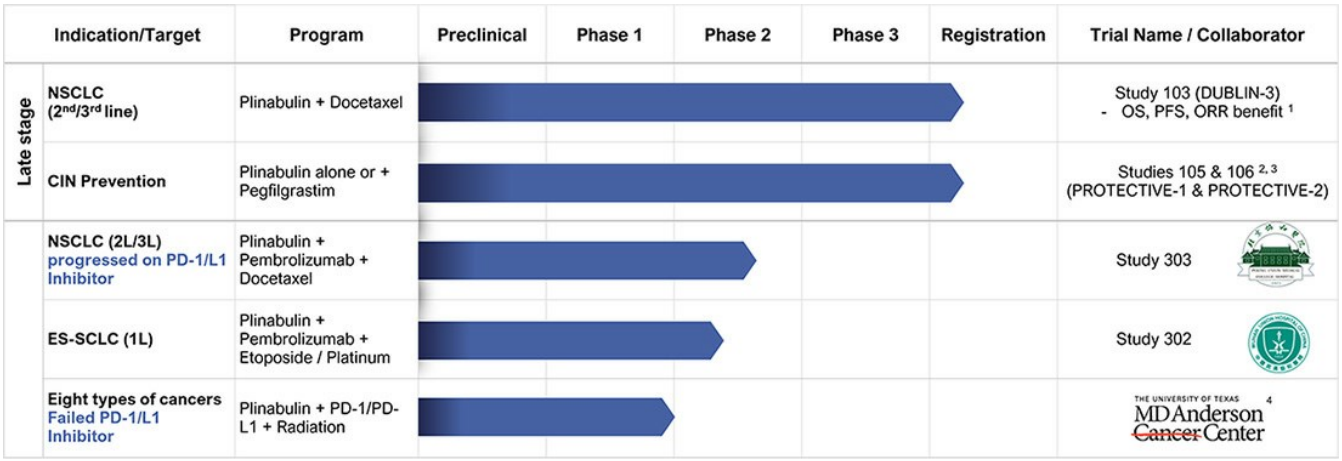
SEED's development pipeline

SEED's development pipeline includes six internal projects, as well as three joint development programs with Eli Lilly and Eisai. These nine programs involve multiple novel E3s and target oncology, neurodegeneration, immunology, and antiviral indications. Additional programs are in development for anti-aging applications.

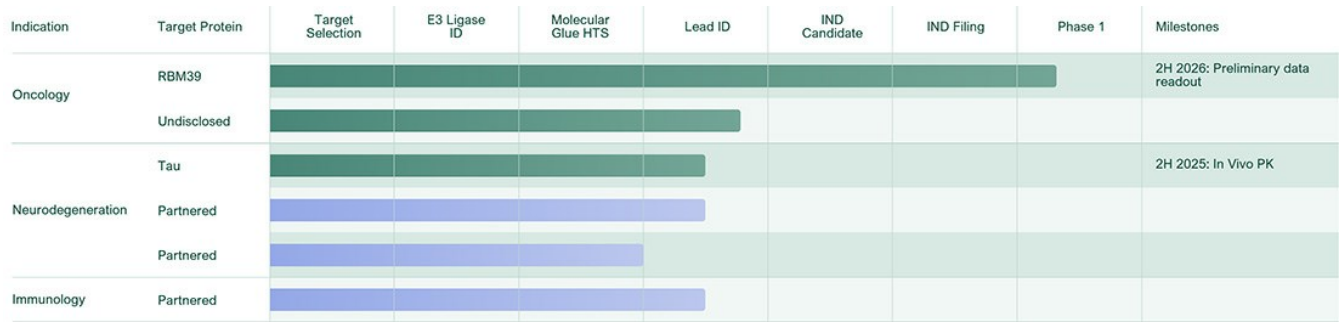
SEED's lead candidate, ST-01156, is a brain-penetrant RBM39 degrader entering clinical development for Ewing sarcoma and other RBM39-dependent cancers. In July 2024, ST-01156 received Orphan Drug and Rare Pediatric Disease designations from the FDA for Ewing sarcoma. The IND application was cleared by the FDA and the NMPA in August 2025 and November 2025, respectively. In January 2026, the first patient was dosed in the Phase 1a dose-escalation study of ST-01156.

Pipelines

The following table summarizes the current status of Plinabulin's and our other immuno-oncology product candidates' indication in development.



The following table summarizes the current status of SEED's pipeline.



Our Strategy

- **Develop Plinabulin as a potential "pipeline in a drug" in multiple solid tumor cancer indications.** We are exploring the potential of Plinabulin in combination with immuno-oncology agents and other synergistic standards of care to target severe unmet medical needs in oncology. Plinabulin is a first-in-class small molecule, which is a unique microtubule modulator and GEF-H1 agonist with mechanism to induce dendritic cell maturation and T-cell activation, and tumor vasculature modulation. We believe that its unique mechanism supports the improved anti-cancer efficacy potential in combination with tumor antigen generators, including chemotherapy or radiation, with or without checkpoint inhibitors. We have multiple ongoing investigator-initiated studies with PD-1 antibodies provided by Merck and BMS, and these studies were conducted at leading institutions including MD Anderson, Rutgers University, and Peking Union Medical College Hospital in Beijing, China. The goal of these studies is to advance Plinabulin in clinical trials to investigate its therapeutic potential immuno-oncology agent in multiple cancers, especially in PD-1/PD-L1 antibody progressed patients, which we believe represent high unmet medical needs.

- **Advance Plinabulin through global clinical trials and obtain regulatory approvals in select geographies in second- and third-line non-squamous EGFR wild type NSCLC.** We have treated over 700 cancer patients with Plinabulin with good tolerability. We have completed our Phase 3 clinical trial (DUBLIN-3 study) for second- and third-line NSCLC with EGFR wild type and have reported positive clinical data in publication "Lancet Respiratory Medicine" in September 2024. The study demonstrated that the combination of Plinabulin and docetaxel had significant improvement in overall survival, progression free survival, and objective response rate, and significant reduction in grade 4 neutropenia compared to docetaxel; this regimen represents a potential positive benefit/risk ratio for these very sick patient population. In plinabulin-mechanism based non-squamous population, the overall survival benefit is more pronounced in plinabulin and docetaxel combination. We plan to use our best efforts to file an NDA with the NMPA as soon as possible. We are also evaluating the feasibilities of filing NDAs with regulatory agencies of other jurisdictions. All of our clinical trials have been conducted globally by working with leading global contract research organizations, or CROs, such as ICON and Covance (now Labcorp) to assure the quality of the data. In addition, we plan to initiate a confirmatory global phase 3 study for Plinabulin+docetaxel vs. docetaxel alone in second- and third-line NSCLC with epidermal growth factor receptor (EGFR) wild type after progression on prior immune checkpoint inhibitors, a severe unmet medical need. We believe that our global development strategy has provided significant advantages, including the ability to conduct trials in China with timely and cost-effective enrollment. In addition, as China is the second largest pharmaceutical market in the world, we believe obtaining potential approvals in China could lead to significant commercial opportunity for Plinabulin.

- **Partner with one or more global pharmaceutical companies to further develop and commercialize Plinabulin in the U.S. and the rest of world.** We believe Plinabulin, if approved, could have significant commercial potential in the U.S. and globally as an anti-cancer agent across several substantial solid tumor patient populations, such as NSCLC, head and neck cancer, and ES-SCLC, among others. Additionally, our early clinical results in immune-oncology indicate that Plinabulin may play an important role in triple combination immunotherapy with chemotherapy to improve or expand effectiveness of current immune-oncology therapeutic regimens and reduce chemotherapy induced neutropenia. The opportunities created by Plinabulin's unique mechanism of action likely surpass our resources, and we plan to seek partners to accelerate and broaden Plinabulin's reach.

- **Maximize the value of SEED's targeted protein degradation (TPD) technology platform.** Through ongoing collaborations with world-leading pioneer experts in the ubiquitin proteasome and "molecular glue" discovery field, including Nobel Prize winner Dr. Avram Hershko, SEED is developing a breakthrough TPD technology platform for "molecular glue" discovery focused on protein of interest. We believe the investments and collaborations with Eli Lilly and Eisai serve to validate this TPD platform and its enormous future potential. Further, SEED has since reached three R&D milestones under the Collaboration Agreement with Eli Lilly, which we believe demonstrates the team's execution capabilities. Furthermore, SEED currently has a robust pipeline with nine programs (six internal and three with Eli Lilly and Eisai) in diverse indications including oncology, neurodegeneration, immunology and anti-viral, with a lead clinical candidate, ST-01156, a brain-penetrant RBM39 degrader. With over 600 E3 ligases in the cell, TPD has the potential to develop drugs for over 70% of undruggable targets with novel discovery agents in multiple disease areas. SEED will seek to form additional partnerships to expand its TPD platform into several therapeutic areas, while advancing its proprietary product pipeline.

The strategies around Plinabulin described above are dependent upon our ability to obtain additional funding. We continue to explore strategic options in the United States and globally to support the execution of our business plan and to maximize shareholder value. These options may include licensing and partnership arrangements, a sale of the Company or its assets, equity or debt financing, or a combination of the above.

Commercialization

In August 2021, Dalian Wanchunbulin Pharmaceuticals Ltd., or Wanchunbulin, our partially owned Chinese subsidiary, entered into an exclusive commercialization and co-development agreement with Jiangsu Hengrui Pharmaceuticals Co., Ltd., or Hengrui, to further develop and commercialize Plinabulin in Greater China. Under the terms of the agreement, Wanchunbulin granted Hengrui exclusive rights to commercialize and co-develop Plinabulin in the Greater China markets, including mainland China, Hong Kong, Macau and Taiwan. Wanchunbulin retains the manufacturing rights of Plinabulin in the Greater China markets and will receive all Plinabulin net sales proceeds in such markets. Hengrui will receive a pre-determined percentage of the net sales in each quarter. Wanchunbulin received an upfront payment of RMB 200 million (approximately $28.6 million), and will receive regulatory and sales milestones of up to RMB 1.1 billion (approximately $157.3 million). Hengrui will be responsible for all costs associated with commercialization of Plinabulin in the Greater China markets. Pursuant to the terms of the agreement, Wanchunbulin will be responsible for 100% of the clinical and regulatory costs for the first two indications for Plinabulin: prevention of CIN and second/third- line treatment of NSCLC (EGFR wild type). Hengrui will fund 50% of the clinical development costs for additional indications for Plinabulin in the Greater China markets, with a Joint Steering Committee overseeing the clinical strategy and priorities.

In the U.S. and for the rest of the world, we currently plan to seek a co-development and commercialization partner to maximize Plinabulin's potential in multiple cancer indications, if approved.

Intellectual Property

The proprietary nature of, and protection for, our product 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 obtained U.S. patents and filed patent applications in the U.S. and other countries relating to certain of our product candidates, and are pursuing additional patent protection for them and for other of our product candidates and technologies.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for our product candidates and other commercially important products, technologies, inventions and know-how, as well as on our ability to defend and enforce our patents including any patent that we have or may issue from our patent applications, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of other parties.

As of December 31, 2025, we owned or co-owned 183 patents, in 35 jurisdictions, including 26 issued U.S. patents. We also owned 13 pending U.S. non-provisional patent applications as well as corresponding patent applications pending in other jurisdictions and two pending U.S. provisional patent applications. In addition, we owned three pending international patent applications related to Plinabulin filed under the Patent Cooperation Treaty, or PCT, which we plan to file nationally in the U.S. and in other jurisdictions directed to combination therapies using plinabulin.

Our patent portfolio as of December 31, 2025 included 19 issued U.S. patents directed to polymorphic forms of Plinabulin, Plinabulin compositions, Plinabulin analogs, and Plinabulin use in the treatment of various disorders including docetaxel-induced neutropenia and certain other CIN, RAS mutant tumors, and brain tumors, and use of Plinabulin in combination with gemcitabine to reduce thrombocytopenia, and in combination with a PD-1 or PD-L1 inhibitor to treat cancer resistant to or progressed after prior treatment with one or more immune checkpoint inhibitor. These U.S. patents were scheduled to expire between 2033 and 2042, excluding any potential patent term restorations. The patent portfolio also contained patents granted in 34 foreign jurisdictions including Japan, South Korea, China, European countries, and other countries.

The term of individual patents may vary based on the countries in which they are obtained. In most countries in which we file including the U.S., the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the U.S., the term of a patent may be lengthened in some cases by a patent term adjustment, which extends the term of a patent to account for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in excess of a patent applicant's own delays during the prosecution process, or may be shortened if a patent is terminally disclaimed over a commonly owned patent having an earlier expiration date. In addition, in certain instances, the term of one patent for a given drug product can be restored (extended) to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. However, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. We plan to seek such an extension of one of our U.S. patents directed to Plinabulin or its use when appropriate.

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. In particular, up to a five-year extension may be available in the EU and Japan. We plan to seek such extensions as appropriate.

Furthermore, the patent positions of biotechnology and pharmaceutical products and processes like those we intend to develop and commercialize are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in such patents has emerged to date in the U.S. The scope of patent protection outside the U.S. is even more uncertain. Changes in the patent laws or in interpretations of patent laws in the U.S. and other countries have diminished, and may further diminish, our ability to protect our inventions and enforce our intellectual property rights and, more generally, could affect the value of intellectual property.

Additionally, while we have already secured a number of issued patents directed to our product candidates, we cannot predict the breadth of claims that may issue from our pending patent applications or may have or may be issued from patents and patent applications owned by others. Substantial scientific and commercial research has been conducted for many years in the areas in which we have focused our development efforts, which has resulted in other parties having a number of issued patents and pending patent applications relating to such areas. Patent applications in the U.S. and elsewhere are generally published only after 18 months from the priority date, and the publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Therefore, patents and patent applications relating to drugs similar to our current product candidates and any future drugs, discoveries or technologies we might develop may have already been issued or filed, which could prohibit us from commercializing our product candidates.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our product candidates and technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the pending patent applications that we currently own, may file or license from others will result in the issuance of any patents. The issued patents that we own or may receive in the future, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent.

We may rely, in some limited circumstances, on trade secrets and unpatented know-how to protect aspects of our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisors and contractors and invention assignment agreements with our employees. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our commercial success will also depend in part on not infringing the proprietary rights of other parties. The existence of any patent by others with claims covering or related to aspects of our product candidates would require us to alter our development of commercial strategies, redesign our product candidates or processes, obtain licenses or cease certain activities. Such licenses may not be available on reasonable commercial terms or at all, which could require us to cease development or commercialization of our product candidates. In addition, our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our product candidates would have a material adverse impact on us. If others have prepared and filed patent applications in the U.S. that also claim technology to which we have filed patent applications or otherwise wish to challenge our patents, we may have to participate in interferences, post-grant reviews, inter parties reviews, derivation or other proceedings in the USPTO and other patent offices to determine issues such as priority of claimed invention or validity of such patent applications as well as our own patent applications and issued patents.

For more information on these and other risks related to intellectual property, see "Item 1A. Risk Factors—Risks Related to Our Intellectual Property."

Competition

Our industry is highly competitive and subject to rapid and significant change. While we believe that our development and commercialization experience, commercial strategy, scientific knowledge and industry relationships provide us with competitive advantages, we face competition from pharmaceutical and biotechnology companies, including specialty pharmaceutical companies, and generic drug companies, academic institutions, government agencies and research institutions.

There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of cancer for which we are developing our product candidates. For treatment of NSCLC with EGFR wild type, with PD-1 and pemetrexed have moved into first-line therapy, only the ramucirumab/docetaxel combination and docetaxel are effectively approved for treatment of second/third-line NSCLC. Bristol-Myers Squibb Company and Merck & Co., Inc. currently market and sell Opdivo (nivolumab) and Keytruda (pembrolizumab) respectively, both of which are PD-1 inhibitors. Eli Lilly currently markets and sells Cyramza (ramucirumab). Even though a number of Phase 3 clinical trials as second- and third-line treatments of NSCLC had not shown success in overall survival compared with docetaxel, there might be other competitors in clinical studies if and when they receive regulatory approval.

Our strategy in developing Plinabulin as an anti-cancer agent is in its unique mechanism as a potent dendritic cell maturation agent, which leads to tumor antigen specific T-cell activation. Plinabulin effectively activates GEF-H1, an immune defense protein, which is shown to prolong patient survival in a number of cancers. The immune mechanism of Plinabulin can effectively add more T-cells, or "hit the gas" to kill cancer cells, while PD-1/PD-L1 antibodies are known to let T-cells "see" cancer cells, or "release the break." Thus, combining Plinabulin, and chemotherapy or radiation, with or without PD-1/PD-L1 antibodies have the potential to elevate the anti-cancer benefit and re-sensitize patients who progressed on immunotherapies.

While we are investigating an alternative approach to disease treatment by using molecular glue technology to tag dysfunctional proteins with ubiquitin ligase and destroy such proteins, there are a number of companies who are also working on using such technology to target and destroy dysfunctional proteins.

Many of our competitors have longer operating histories, better name recognition, stronger management capabilities, better supplier relationships, a larger technical staff and sales force and greater financial, technical or marketing resources 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. Our commercial opportunity could be reduced or eliminated if our competitors develop or market products or other novel therapies that are more effective, safer or less costly than our current product candidates, or any future product candidates we may develop, or obtain regulatory approval for their products more rapidly than we may obtain approval for our current product candidates or any such future product candidates. Our success will be based in part on our ability to identify, develop and manage a portfolio of product candidates that are safer and more effective than competing products.

Government Regulation

Government authorities in the U.S. at the federal, state and local level and in other countries extensively regulate, among other things, the research and clinical development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, pricing, export and import of drug products, such as those we are developing. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized to address the requirements of and in the format specific to each regulatory authority, submitted for review and approved by the regulatory authority. This process is very lengthy and expensive, and success is uncertain.

Drugs are also subject to other federal, state, local and foreign statutes and regulations. The regulation of pharmaceutical products by government authorities can be affected by a variety of factors, including government budget, funding and staffing levels, payment of user fees and reauthorization of user fee programs, ability to hire and retain key personnel, as well as statutory, regulatory and policy changes. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable legal and regulatory requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions or other actions. These could include, among other actions, the regulatory authority's refusal to approve pending applications, withdrawal of an approval, clinical holds, untitled or warning letters, voluntary product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, disbarment, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any such administrative or judicial enforcement or other action could have a material adverse effect on us.

U.S. Regulation

U.S. Government Regulation and Product Approval

Government authorities in the U.S. at the federal, state and local levels extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, export and import of drug products such as those we are developing. In the U.S., the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations and biologics under the FDCA and the Public Health Service Act and its implementing regulations.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates or any future product candidates we may develop. The FDA and other U.S. government agencies also have been or may be subject to reductions in funding and downsizing of agency staffing levels, which could materially impact our business and operations. It is impossible to predict whether further legislative or FDA regulation, policy, funding or staffing changes will be enacted or implemented and what the impact of such changes, if any, may be.

U.S. Drug Development Process

The process of obtaining regulatory approvals and maintaining compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions or other actions or lead to voluntary product recalls. Administrative or judicial actions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory tests, preclinical studies and formulation studies according to Good Laboratory Practices, or GLP, regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practice requirements, or GCPs, to establish the safety and efficacy of the proposed product for its intended use;
- preparation and submission to the FDA of an NDA, for a drug;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP;
- satisfactory completion of FDA inspection of selected clinical investigators, clinical trial sites and/or the clinical trial sponsor, to assure compliance with GCP requirements and the integrity of the clinical data;
- payment of user fees and
- FDA review and approval of the NDA.

The testing and approval process requires substantial time, effort and financial resources and we cannot be certain that any approvals for our product candidates, or any future product candidates we may develop, will be granted on a timely basis, if at all.

Once a drug product candidate is identified for development, it enters the nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies to assess potential safety and efficacy. Adherence to federal regulations, such as GLPs and the Animal Welfare Act enforced by the Department of Agriculture, is required during the conduct of these tests. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND prior to commencing any testing in humans. An IND sponsor must also include a protocol detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Some nonclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical trial and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA 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. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical trials of a certain duration or for a certain dose.

We are conducting our current clinical trials under two INDs. Investigator-led clinical trials are being conducted under separate INDs.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an IRB representing each institution participating in a clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB is responsible for protecting the rights of clinical trial subjects and considers, among other things, whether the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs, for approval. The Food and Drug Omnibus Reform Act, or FDORA, which was signed into law on December 29, 2022, made numerous amendments to the FDCA including provisions intended to, among other things, decentralize and modernize clinical trials and enhance diversity in clinical trial populations.

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.

- **Phase 2.** The drug is administered to 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.** The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate data to evaluate the efficacy and safety of the product for approval, to establish the overall benefit-risk profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and clinical investigators within 15 calendar days for serious and unexpected suspected adverse events, 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 drug candidate. Additionally, a sponsor must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction no later than 7 calendar days after the sponsor's receipt of the information. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate 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. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product has been associated with unexpected serious harm to subjects.

Concurrent with clinical trials, companies usually complete additional preclinical studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product drug and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product drug does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

Assuming successful completion of the required clinical testing, the results of product development, nonclinical studies and clinical trials, together with other detailed information regarding the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA requesting approval to market the new drug in the U.S. for one or more indications. Under the Prescription Drug User Fee Act, as amended, applicants are required to pay fees to the FDA for reviewing an NDA. These user fees, as well as the annual fees required for commercial manufacturing establishments and for approved products, can be substantial. The NDA review fee alone can currently exceed $4 million, and is likely to increase over time. The user fee requirement is subject to certain limited deferrals, waivers and reductions.

The FDA reviews all NDAs submitted within 60 days of submission to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA's established goal is to review 90% of NDA applications given "Priority" status – where there is evidence that the proposed product would be a significant improvement in the safety or effectiveness in the treatment, diagnosis, or prevention of a serious condition – within 6 months, and 90% of applications given "Standard" status within 10 months, whereupon a review decision is to be made. The FDA, however, may not approve a drug within these established goals, and its review goals are subject to change from time to time. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective 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, 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 are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA also may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts, including clinicians and other scientific experts, who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making decisions.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA 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 in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA 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, addressing all of the deficiencies identified in the letter, or 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. In addition, the FDA may require post-approval studies, including Phase 4 clinical trials, to further assess a product's safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA also may conclude that an NDA may only be approved with a Risk Evaluation Mitigation Strategy, or REMS, designed to mitigate risks through, for example, a medication guide, physician communication plan, or other elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these measures may materially affect the potential market and profitability of the product.

Failure to satisfy FDA post-marketing requirements can result in FDA enforcement action, up to and including withdrawal of NDA approval, and the FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

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

Manufacturers and other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory requirements, and test each product batch or lot prior to its release. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other regulatory requirements. We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates and any future product candidates we may develop. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution or may require substantial resources to correct.

The FDA may withdraw a product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, problems with manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on the product's marketing; mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; imposition of distribution or other restrictions under a REMS program may result in restrictions on the product's marketing or even complete withdrawal of the product from 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 consent decrees, or civil or criminal penalties, or may lead to voluntary product recalls.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our product candidates, or any future product candidates we may develop, 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 the 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 plus the time between the submission date of an NDA and the approval of that application, except that this review period is reduced by any time during which the applicant failed to exercise due diligence. 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 one of our currently owned 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; however, any such extension may not be granted to us.

Market 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 marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or 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, 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 marketing 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 by the FDA to be essential to the approval of the application, for example, 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. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Disclosure of Clinical Trial Information

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

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the U.S., sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. Third-party payors generally decide which products they will pay for and establish reimbursement levels for those products. In the United States, no uniform policy for coverage and reimbursement exists, and 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, or formulary, 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, particularly for new and innovative products and therapies, which may result in lower average selling prices. 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. Our product candidates, or any future product candidates we may develop, may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective 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 or enable it to realize an appropriate return on its investment in product development.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement, requirements for substitution of generic products for branded prescription drugs, and increased transparency around drug pricing practices. For example, the Affordable Care Act contains provisions that may reduce the profitability of drug products, including, for example, 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. There also has been increased public and governmental scrutiny of the cost of drugs and drug pricing strategies, including by the U.S. Senate and federal and state prosecutors. Although a number of proposed measures will require authorization through additional legislation to become effective, Congress and the current Trump administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. For example, the Inflation Reduction Act of 2022, or IRA, enacted on August 16, 2022, seeks to reduce prescription drug costs by, among other provisions, allowing Medicare to negotiate prices for certain high-cost prescription drugs in Medicare Parts B and D, imposing an excise tax on pharmaceutical manufacturers that refuse to negotiate pricing with Medicare, requiring inflation rebates to limit annual drug price increases in Medicare, and redesigning the Medicare Part D formula. Further, budget reconciliation legislation enacted in 2025 provided for significant spending reductions for Medicaid and other federal programs, which could impact our future business prospects. However, it is unclear if or how these or other measures may be effectuated or changed under the current administration or the degree of impact any of them may ultimately have upon our business. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals including our product candidates, if any achieve approval.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, the emphasis on cost containment measures in the U.S. has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates also may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

If we obtain regulatory approval of our products, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and education programs and our clinical research activities, and they may constrain the business or financial arrangements and relationships with healthcare providers and other parties through which we may market, sell and distribute any products for which we obtain marketing approval. In addition, we may be subject to patient privacy regulations by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order, or recommendation of, an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws, false statement laws, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or making a false statement or record material to payment of a false claim or avoiding, decreasing, or concealing an obligation to pay money to the federal government;

- Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes federal criminal and civil liability for executing a scheme to defraud any healthcare benefit program, including private third-party payors and making false statements relating to healthcare matters;

- the federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the Affordable Care Act, that requires applicable manufacturers of covered drugs to disclose payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and are not preempted by HIPAA, thus complicating compliance efforts.

The Affordable Care Act broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act or the civil monetary penalties statute. These and similar laws may be subject to further amendment or reinterpretation, and implementing regulations may be revised or reinterpreted, in ways that may significantly affect our business. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

Although we would not submit claims directly to payors, manufacturers can be held liable under the federal False Claims Act and other healthcare laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future 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, will be subject to scrutiny under the False Claims Act. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties, and the potential for exclusion from participation in federal healthcare programs. The applicable civil penalties are subject to an annual increase based on inflation; for 2025, the penalties were between $14,308 and $28,619 for each separate false claim. In addition, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. Further, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations were found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we could be subject to significant criminal, civil and administrative penalties including damages, fines, individual imprisonment, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our product candidates were sold in a foreign country, we could be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, implementation of corporate compliance programs, reporting of payments or transfers of value to healthcare professionals, and additional data privacy and security requirements.

Patient Protection and the Affordable Care Act

The Affordable Care Act, enacted in March 2010, includes measures that have or will significantly change the way health care is financed in the U.S. by both governmental and private insurers. Among the provisions of the Affordable Care Act of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. The Affordable Care Act increased pharmaceutical manufacturers' rebate liability on most branded prescription drugs from 15.1% of the average manufacturer price to 23.1% of the average manufacturer price, added a new rebate calculation for line extensions of solid oral dosage forms of branded products, and modified the statutory definition of average manufacturer price. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization and expanding the population potentially eligible for Medicaid drug benefits.

- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing.

- The Affordable Care Act imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications.

In addition to these provisions, the Affordable Care Act established a number of bodies whose work may have a future impact on the market for certain pharmaceutical products. These include the Patient-Centered Outcomes Research Institute, established to oversee, identify priorities in, and conduct comparative clinical effectiveness research and the Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services, to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

The Affordable Care Act has been subject to challenges, as well as numerous ongoing efforts by the U.S. Congress and the administrations of President Trump to repeal or amend the Affordable Care Act in whole or in part. For example, in March 2023, the U.S. District Court for the Northern District of Texas struck down the Affordable Care Act's requirement that private insurers cover certain preventative services. On appeal, in June 2024 the U.S. Court of Appeals for the Fifth Circuit held, among other things, that the Affordable Care Act's requirement that group health plans and health insurance issuers cover certain preventative services without cost-sharing is unconstitutional. The parties appealed the case to the U.S. Supreme Court, which granted certiorari in January 2025 and upheld the constitutionality of the requirement in June 2025. Although we cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, we believe that legislation or regulations that would reduce reimbursement for, or restrict coverage of, our products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our product candidates if we gain approval for any of them.

Chinese Regulation

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

General Regulations on China Food and Drug Administration

In China, the NMPA monitors and supervises the administration of pharmaceutical products, as well as medical devices and equipment. The NMPA's primary responsibility includes evaluating, registering and approving new drugs, generic drugs, imported drugs and traditional Chinese medicines; formulating administrative rules and policies concerning the supervision and administration of cosmetics, pharmaceuticals and medical equipment. The local provincial drug administrative authorities are responsible for supervision and administration of drugs within their respective administrative regions.

The PRC Drug Administration Law, promulgated by the Standing Committee of the National People's Congress in 1984, as amended in 2001, 2013, 2015 and 2019, respectively, and the Implementing Measures of the PRC Drug Administration Law promulgated by the State Council in 2002, as amended in 2016, 2019 , 2024 and 2026 respectively and the most recently revised version shall take effect on May 15, 2026, set forth the legal framework for the administration of pharmaceutical products, including the research, development and manufacturing of drugs.

The PRC Drug Administration Law was revised to strengthen the supervision and administration of pharmaceutical products and to ensure the quality and safety of those products for human use. The revised PRC Drug Administration Law applies to the development, production, trade, application, supervision and administration activities of pharmaceutical products. It regulates and prescribes a framework for the administration of pharmaceutical preparations of medical institutions and for the development, research, manufacturing, distribution, packaging, pricing and advertisement of pharmaceutical products. The most recently revised PRC Drug Administration Law incorporates the drug marketing authorization holder system, reiterates that several kinds of drugs may be approved conditionally or enjoy priority to the drug marketing examination and approval procedures, applies a so-called implied license system for clinical trial approval and cancels several certification requirements. The revised Implementing Measures of the PRC Drug Administration Law provide detailed implementing regulations for the revised PRC Drug Administration Law.

Under these regulations, we need to follow related regulations for nonclinical research, clinical trials and production of new drugs.

Good Laboratories Practice Certification for Nonclinical Research

To improve the quality of animal research, the China Food and Drug Administration, or CFDA, promulgated the Administrative Measures for Good Laboratories Practice of Nonclinical Laboratory in 2003, which was amended in July 2017, and began to conduct the certification program of the GLP. In April 2007, the CFDA issued the Circular on Measures for Certification of Good Laboratory Practice, or CFDA Circular 214, which was amended on January 19, 2023, providing that the NMPA is responsible for certification of nonclinical research institutions. Under CFDA Circular 214, the NMPA will approve and issue GLP certificates to the applicants that meet the GLP requirements, and the GLP certificates are valid for 5 years.

Approval for Clinical Trials and Production of New Drugs

According to the Provisions for Drug Registration promulgated by the State Administration for Market Regulation in 2020, Circular on Chemical Drug Registration Classification and Requirements on Application Materials by the NMPA in June 2020, Drug Administration Law promulgated in 1984 and amended by the Standing Committee of the National People's Congress in 2001, 2013, 2015 and 2019, Circular on Regulations for Special Approval on New Drug Registration issued by the CFDA in 2009, and Circular on Information Publish Platform for Pharmaceutical Clinical Trials issued by the CFDA in 2013, we must comply with the following procedures and obtain several approvals for clinical trials and production of new drugs.

Good Clinical Trial Practice

To improve the quality of clinical trials, the CFDA promulgated the Administration Rules of Quality of Drug Clinical Practice in August 2003. According to the Administration Rules of Quality of Drug Clinical Practice, clinical trial means systematical investigation of drugs conducted on human subjects (patients or healthy volunteers) to prove or reveal the function, adverse reactions and/or absorption, distribution, metabolism and excretion of the drug being investigated. The purpose of a clinical trial is to determine the therapeutic efficacy and safety of the drug.

In April 2020, the NMPA and the National Health Commission promulgated the revised Administration Rules of Quality of Drug Clinical Practice, which became effective in July 2020, in order to further ensure the quality of clinical trials and the safety of human subjects. The revised Administration Rules of Quality of Drug Clinical Practice provides comprehensive and substantive requirements on the design and conduct of clinical trials in China. In particular, the revised Administration Rules of Quality of Drug Clinical Practice enhances the protection for study subjects and tightens the control over bio-samples collected under clinical trials.

The revised Administration Rules of Quality of Drug Clinical Practice also set out the qualifications and requirements for the investigators and centers participating in clinical trial, including: (i) professional certification at a clinical trial center, professional knowledge, training experience and capability of clinical trial, and being able to provide the latest resume and relevant qualification documents per request; (ii) being familiar with the trial protocol, investigator's brochure and relevant information of the trial drug provided by the applicant; (iii) being familiar with and complying with the revised Administration Rules of Quality of Drug Clinical Practice and relevant laws and regulations relating to clinical trials; (iv) keeping a copy of the authorization form on work allocation signed by investigators; (v) investigators and clinical trial centers shall accept supervision and inspection organized by the applicant and inspection by the drug regulatory authorities; and (vi) in the case of investigators and clinical trial centers authorizing other individual or institution to undertake certain responsibilities and functions relating to clinical trial, they shall ensure such individual or institution are qualified and establish complete procedures to ensure the responsibilities and functions are fully performed and generate reliable data.

Clinical Trial Application

Upon completion of its nonclinical research, a research institution must apply for approval of a clinical trial application before conducting clinical trials.

On July 24, 2018, the NMPA issued the Announcement on Adjusting the Approval Process for Drug Clinical Trials, which provides that clinical trials shall be deemed to have been approved if the application is filed with the Center for Drug Evaluation, or CDE, and there is no negative or questionable comment received from the CDE in 60 working days from the date that the application is accepted and the application fee is paid.

On December 1, 2019, the newly revised PRC Drug Administration Law came into effect, which adopted the above-mentioned implied license system into state legislative level. It provides that the medical products administrative department under the State Council shall, within 60 working days from the date of acceptance of the application for clinical trial, decide whether to approve the application and notify the clinical trial applicant of the decision; if it fails to notify the clinical trial applicant within the aforesaid time limit, it shall be deemed that the application is approved.

On January 22, 2020, the revised Provisions for Drug Registration were issued by the State Administration for Market Regulation, or SAMR, which came into effect on July 1, 2020. The provisions provide that the CDE shall decide whether to approve an application for clinical trial within 60 working days upon acceptance. If the applicant is not notified within such time limit, it shall be deemed that the application is approved.

Special Examination and Approval for Domestic Category 1 Pharmaceutical Products

Domestic Category 1 New Drugs are Eligible for Preferred Procedures

According to Provisions for Drug Registration promulgated by the SAMR in 2020, drugs fall into one of three categories, namely chemical drugs, biological product or traditional Chinese medicine. And according to the Circular on the Chemical Drug Registration Classification and Requirements on Application Materials, which was promulgated by the NMPA on June 29, 2020 and came into effect on July 1, 2020, chemical drugs are classified into 5 categories. A Category 1 drug is a new drug that has never been marketed in any country.

Pursuant to the revised Provisions for Drug Registration, during the clinical trial for new drugs used for severe life-threatening diseases or diseases which seriously impact the quality of life and for which there is no other effective treatment approach or there is adequate evidence to prove that said new drugs have obvious clinical advantages over existing treatment approach(es), the applicant may request for application of breakthrough therapeutic drug procedure. The clinical trials under the breakthrough therapeutic drug procedure may enjoy the following priority: (i) the applicant may submit an application for communication to the CDE during the key phase of the clinical trial of drugs, and the CDE shall arrange for review officers to communicate with the applicant; (ii) the applicant may submit research materials in phases to the CDE, and the CDE shall, based on the available research materials, give opinions or recommendations pertaining to the next step of the research scheme and feedback to the applicant. On December 10, 2020, the CDE issued the revised Administration Measures for the Communication of Drug Development and Technical Review which stipulated detailed procedural rules of the communication.

Pursuant to the revised Provisions for Drug Registration, the following drugs with significant clinical value may enjoy a priority procedure for drug marketing authorization: (i) urgently needed clinical drugs and innovative drugs and improved new drugs developed for prevention and treatment of major infectious and orphan diseases; (ii) new varieties, dosage forms and specifications of children's medicines that conform to the physiological characteristics of children; (iii) urgently needed vaccines and innovative vaccines for disease prevention and control; (iv) pharmaceuticals under breakthrough therapeutic drug procedures; (v) drugs meeting the requirements of conditional approvals; and (vi) other circumstances as further specified by the NMPA. The drug registration applicant may submit an application for priority review and approval for their drug applications simultaneously with filing the drug marketing application upon confirmation with the CDE beforehand. The drug marketing review time limit is stipulated as 130 working days for the drug applications, which enjoy a priority procedure for drug marketing authorization. On July 8, 2020, the NMPA issued Protocol for the Review of Breakthrough Therapeutic Drugs (Trial), Protocol for Review and Approval of Conditional Approval of Drugs Marketing Applications (Trial) as well as Protocol for Prioritized Review and Approval of Drugs Marketing Certificates (Trial), which stipulated detailed procedural rules for the breakthrough therapeutic drug procedure and priority procedure, procedural rules for drugs that meet the conditions for conditional approval for marketing, and procedures and detailed conditions of the priority review and approval, respectively.

The Advantages of Category 1 New Drugs over Category 5 Drugs

Prior to the enactment of the Reform Plan for Registration Category of Chemical Medicine, or the Reform Plan, Category 3 drugs are drugs which have already been marketed abroad by multinational companies, but are not yet approved in China, and Category 3 drugs now are reclassified as Category 5 according to the Reform Plan. NMPA issued the Circular on Chemical Drug Registration Classification and Requirements on Application Materials in June 2020 (effective in July 2020), which reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan, and made minor adjustments to the subclassifications of Category 5. According to such rule, Category 5.1 are innovative chemical drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China. Compared with the application for Category 5 drugs, the application for Category 1 domestic new drugs has a more straight-forward registration pathway. According to the Administration Measures for the Communication of Drug Development and Technical Review issued by CDE on December 10, 2020, where breakthrough therapeutic drug procedure and priority procedure is granted, the application for clinical trial and marketing will be handled with priority and with enhanced communication with the CDE.

In comparison, according to Provisions for Drug Registration promulgated by the SAMR in 2020, the registration pathway for Category 5 drugs is complicated and evolving. Category 5 drug applications may only be submitted after a company obtains an NDA approval and receives the Certificate of Pharmaceutical Product, or CPP, granted by a major regulatory authority, such as the FDA or the European Medicines Agency, or EMA. Multinational companies may need to apply for conducting multi-regional clinical trials, which means that companies do not have the flexibility to design the clinical trials to fit the Chinese patients and standard-of-care. Moreover, a requirement to further conduct local clinical trials can potentially delay market access by several years from its international NDA approval. Further, according to Opinions on Reforming the Review and Approval Process for Drugs and Medical Devices issued by the State Council in August 2015, which is a guideline for future legislation and NMPA examination, the drugs which have already been marketed abroad may no longer be categorized as new drugs under Chinese law in the future, and therefore may not be able to enjoy any preferential treatment for new drugs. In order to implement this guideline, in March 2016, the CFDA issued the Reform Plan, which changed the registration category of chemical medicine stipulated in Provisions for Drug Registration. According to the Interpretation of Reform Plan issued by CFDA, a new drug refers to a drug that has never been marketed in China or abroad. And according to Provisions for Drug Registration promulgated by the SAMR in 2020 and the Circular on the Chemical Drug Registration Classification and Requirements on Application Materials which was promulgated by the NMPA on June 29, 2020 and came into effect on July 1, 2020, the interpretation on new drugs was also accepted.

Our product candidates are all new therapeutic agents and we expect that all of our current product candidates fall under the Category 1 application process. Although the regulatory framework previously required approval of separate clinical trial applications prior to initiating each phase of clinical development, in December 2015, the CFDA approved our clinical trial application including all phases of clinical trials for Plinabulin as a direct anti-cancer agent in NSCLC when combined with docetaxel and for the prevention of CIN.

Changes to the Review and Approval Process

In August 2015, the State Council issued Opinions on Reforming the Review and Approval Process for Drugs and Medical Devices, providing several potential policy changes that could benefit the pharmaceutical industry:

- A plan to accelerate innovative drug approval with a special review and approval process, with a focus on areas of high unmet medical needs, including innovative drugs for HIV, malignant tumors, serious infectious diseases, orphan diseases; drugs sponsored by national science and technology major projects and national major research and development plans; innovative drugs to be manufactured locally in China; children's drugs; drugs using advanced formulation technology, using innovative treatment methods, or having distinctive clinical benefits;

- A plan to adopt a policy which would allow institutions of drugs research and development to act as the marketing authorization holder;

- A plan to improve the review and approval of clinical trials, and to allow the new drugs which have not been marketed in abroad to conduct clinical trials in China at the same time as they are doing so in other countries and encourage domestic clinical trial institutions to participate in international multi-center clinical trials.

In November 2015, the CFDA released the Circular concerning Several Policies on Drug Registration Review and Approval, which further clarified the following policies potentially simplifying and accelerating the approval process of clinical trials:

- A one-time umbrella approval procedure allowing approval of all phases of a new drug's clinical trials at once, rather than the phase-by-phase approval procedure, will be adopted for new drugs' clinical trial applications;

- A fast-track drug registration or clinical trial approval pathway will be available for the following applications: (1) registration of innovative new drugs treating and preventing HIV, malignant tumors, serious infectious diseases and orphan diseases, etc.; (2) registration of pediatric drugs; (3) registration of geriatric drugs that treat China-prevalent geriatric diseases; (4) registration of drugs sponsored by national science and technology major projects and national major research and development plans ; (5) registration for drugs with urgent clinical need using advanced technology, using innovative treatment methods, or having distinctive clinical benefits; (6) registration of foreign innovative drugs to be manufactured locally in China; (7) concurrent applications for new drug clinical trials which are already approved in the U.S. or European Union, or concurrent drug registration applications for drugs which have applied for marketing authorization and passed onsite inspections in the U.S. or European Union and are manufactured with the same production line in China; and (8) clinical trial applications for drugs with urgent clinical need and patent expiry within three years, and marketing authorization applications for drugs with urgent clinical need and patent expiry within one year.

In December 2017, the CFDA released the Opinions on Encouraging Drug Innovations and Implying the Prioritized Review and Approval System, which further stipulated the scope of priority review and approval. The following drugs will be entitled to priority review and approval:

- Drugs with obvious clinical benefits if any of the following circumstances applies: (1) registration applications for innovative drugs that are not marketed in China or abroad; (2) registration applications for innovative drugs to be manufactured locally in China; (3) registration applications for drugs using advanced formulation technology, using innovative treatment methods, or having distinctive clinical benefits; (4) clinical trial applications for patented drugs with patent to be expired in three years and manufacturing applications for drugs with patent to be expired in one year; (5) concurrent applications for new drug clinical trials which are already approved in the U.S. or European Union, or concurrent drug registration applications for drugs which have applied for marketing authorization and passed onsite inspections in the U.S. or European Union and are manufactured using the same production line in China; (6) registration applications for traditional Chinese drugs (including ethnic drugs) with clear clinical directions in the prevention and treatment of severe diseases; (7) registration applications for new drugs sponsored by national science and technology major projects, national major research and development plans and of which clinical trials were conducted by national clinical medical research centers and recognized by the administration department of such centers.

- Drugs with obvious clinical benefits in the prevention and treatment of following diseases: (1) HIV; (2) pulmonary tuberculosis; (3) viral hepatitis; (4) orphan diseases; (5) malignant tumor; (6) pediatric drugs; (7) geriatric diseases.

On July 8, 2020, the NMPA issued Protocol for the Review of Breakthrough Therapeutic Drugs (Trial), Protocol for Review and Approval of Conditional Approval of Drugs Marketing Applications (Trial) as well as Protocol for Prioritized Review and Approval of Drugs Marketing Certificates (Trial), which replaced the Opinions on Encouraging Drug Innovations and Implying the Prioritized Review and Approval System.

In November 2015, the Standing Committee of the National People's Congress issued the Decision on Authorizing the State Council to Conduct the Pilot Program of the System of the Marketing Authorization Holder in Several Regions and the Relevant Issues, which authorized the State Council to conduct the pilot program of the system of the holders of drug marketing licenses in Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong and Sichuan, and authorized the State Council to conduct reforms of registration category for drugs. In May 2016, the General Office of the State Council issued Circular on the Pilot Program for the Drug Marketing Authorization Holder System, or Circular 41, which signals that the drug marketing authorization holder system is finally put into implementation. Circular 41 allows institutions of drugs research and development and research specialist staff in Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong and Sichuan, to act as the applicant of drugs registration and to submit applications for drug clinical trials and drug marketing. For those drugs newly registered after the effective date of Circular 41, applicants are allowed to submit applications for becoming a drug marketing authorization holder at the same time as they submit applications for drug clinical trials or drug marketing. In July 2016, the CFDA issued Circular on Conducting Works regarding the Pilot Program for the Drug Marketing Authorization Holder System, which provides further details on the application procedures stipulated in Circular 41. In August 2017, the CFDA issued the Circular on the Matters relating to Promotion of the Pilot Program for the Drug Marketing Authorization Holder System. This notice was issued, among other things, to advance implementation of a system pilot program for holders of drug marketing authorization, to delineate the rights and obligations of such holders, to enhance the quality control system for the drug manufacturing process and to improve the responsibility system over drug manufacturing and marketing supply chains. In October 2018, the Standing Committee of the National People's Congress issued the Decisions on Extending the Term of the Pilot Program for the Drug Marketing Authorization Holder System in Several Regions, which extended the expiration date of the pilot program from November 4, 2018 to November 4, 2019.

On December 1, 2019, the newly revised PRC Drug Administration Law came into effect, which formally adopts and signals the nationwide implementation of the drug marketing authorization holder system. In accordance with the PRC Drug Administration Law, an enterprise or a drug research and development institution is permitted to act as the marketing authorization holder and to engage pharmaceutical manufacturers to produce drug products. Moreover, it provides that the drug marketing authorization holder shall establish a drug quality assurance system and shall be responsible for the non-clinical research, the clinical trials, the drug production and operation, the post-marketing research and the adverse reaction monitoring of the drugs, etc.

Furthermore, the PRC Drug Administration Law provides that priority in the drug registration approval process shall be given to drugs in short clinical supply and new drugs developed for the prevention and treatment of major infectious diseases, orphan diseases and other diseases.

On January 22, 2020, the revised Provisions for Drug Registration were issued by the SAMR, which came into effect on July 1, 2020. Pursuant to the revised Provisions for Drug Registration, the following drugs with significant clinical value may enjoy a priority procedure for drug marketing authorization: (1) urgently needed clinical drugs and innovative drugs and improved new drugs developed for prevention and treatment of major infectious and orphan diseases; (2) new varieties, dosage forms and specifications of children's medicines that conform to the physiological characteristics of children; (3) urgently needed vaccines and innovative vaccines for disease prevention and control; (4) pharmaceuticals under breakthrough therapeutic drug procedures; (5) drugs meeting the requirements of conditional approvals; and (6) other circumstances as further specified by the NMPA. The drug registration applicant may submit an application for priority review and approval for their drug applications simultaneously with filing the drug marketing application upon confirmation with the CDE beforehand. The drug marketing review time limit is stipulated as 130 working days for the drug applications, which enjoy a priority procedure for drug marketing authorization. On July 8, 2020, the NMPA issued Protocol for Prioritized Review and Approval of Drugs Marketing Certificates (Trial), which stipulated procedures and detailed conditions of the priority review and approval, while replacing the Opinions on Encouraging Drug Innovations and Implying the Prioritized Review and Approval System by the CFDA.

On March 12, 2021, the National People's Congress released the Fourteenth Five-Year Plan of the National Economy and Social Development of the People's Republic of China, or the Fourteenth Five-Year Plan, which provides that the government will improve the accelerated review and approval mechanism for innovative drugs, vaccines and medical devices, enhance the review and approval of drugs and medical devices for the treatment of orphan diseases and diseases with urgent clinical needs, and promote the domestic marketing of new drugs and medical devices marketed abroad with urgent clinical needs.

On May 10, 2021, the General Office of the State Council issued the Implementing Opinions on Comprehensively Strengthening the Building of Drug Regulation Capability. It provides that the ability of the authorities on technical review shall be improved. Focusing on the strategic needs of coordinated regional development, existing regulatory resources shall be integrated, the establishment of inspection institutions for traditional Chinese medicine and biological products (vaccines) shall be optimized, and professional and technical abilities shall be strengthened. The coordinated working mechanism between research and review of drugs and medical devices which are innovative or with urgent clinical needs shall be improved and the application of new technologies and research and development of new products shall be encouraged. The authority shall give full play to the role of expert advisory committees in reviewing and making decisions, and disclose expert opinions, evaluation results and evaluation reports in accordance with the laws. Communication methods and channels shall be enhanced, communication frequency of innovative medicine and medical device conferences shall be increased, and technical guidance and services for applicants shall be strengthened. The system for importing overseas marketed drugs with urgent clinical needs shall also be improved.

Non-Inferiority Standard

In China, a drug may receive regulatory approval without showing superiority in its primary endpoint. Rather, a drug may be approved for use if it shows non-inferiority in its primary endpoint and superiority in one of its secondary endpoints.

Accelerated or Conditional Approval

In October 2017, the General Office of the Central Committee of the Communist Party of China and the State Council issued the Opinions on Deepening the Reform of the Review and Approval System and Inspiring Innovation of Drugs and Medical Devices. This opinion provides that, among other things:

- the review and approval process should be accelerated for drugs or medical devices that are urgently in need for clinical practice;
- for drugs or medical devices that are (i) for treatment of severe and life threatening diseases that cannot be cured in an effective manner, or (ii) urgently in need for public health, if early and mid-term indicators in clinical trials for the aforementioned drugs or medical devices show efficacy and potential clinical value, the marketing of these drugs and medical devices may be approved conditionally, and companies who desire to market such drugs or medical devices shall develop risk control plans and conduct research according to applicable requirements;
- extend the protection term for patents related to certain new drugs in trials, given that clinical trials and the review and approval process may cause delay in bringing new drugs to the market; and
- clinical trial data obtained from international multi-centers may be used to register drugs and medical devices in China if such data meet applicable requirements for the registration of drugs and medical devices in China.

On November 19, 2020, the Announcement on the Technical Guidance Principles for Conditional Approval of Drugs (Trial) was issued by the CDE and came into effect on the same day. This Announcement stipulates the definition of severe and life-threatening diseases and drugs in need in public health and requires applicants to discuss and reach consensus with the CDE on the research and other contents promised to be completed after the marketing, including without limitation, submitting post-marketing clinical research plans, the anticipated completion date thereof, the submission date of the clinical research report and the post-marketing risk control plans, etc.

On December 1, 2019, the newly revised PRC Drug Administration Law came into effect, which reiterates that drugs (i) for treatment of severe and life-threatening diseases that cannot be cured in an effective manner or (ii) urgently in need to improve public health, may be approved conditionally, provided that indicators in clinical trials for these drugs show efficacy and potential clinical value. With regard to a drug that has been approved conditionally, the market authorization holder of the drug shall take corresponding risk management measures and complete the relevant research as required within the prescribed time limit. If the research fails to be completed as required within the prescribed time limit or fails to prove that the benefits outweigh the risks, then, at the worst, the drug marketing license may be revoked.

On January 22, 2020, the revised Provisions for Drug Registration were issued by the SAMR, which came into effect on July 1, 2020. Such revised Provisions of Drug Registration adopt the aforesaid conditional approval mechanism and further provide that, in addition to the aforementioned two categories of drugs, vaccines urgently needed in response to major public health emergencies or other vaccines urgently needed as determined by the National Health Commission of the PRC, of which the benefits outweigh the risks upon assessment, may also be approved conditionally. After a drug has been approved conditionally, the market authorization holder shall take corresponding risk management measures, complete the clinical trial and other relevant studies as required within the prescribed time limit, and apply for the registration for the drug in the form of a supplementary application.

On October 17, 2020, the revised Patent Law of the PRC was issued by the Standing Committee of the National People's Congress, which came into effect on June 1, 2021. Such revised Patent Law of the PRC stipulates that in order to compensate for the time consumed in the examination and approval of new drugs for marketing, the patent administration department shall, at the request of the patentee, grant compensation for the term of the patent right for invention patents related to new drugs that have been approved for marketing in China.

On July 8, 2020, the NMPA issued Protocol for Review and Approval of Conditional Approval of Drugs Marketing Applications (Trial) which stipulated procedures and detailed conditions of the conditional approval. On August 24, 2023, the NMPA issued the revised draft Protocol for Review and Approval of Conditional Approval of Drugs Marketing Applications (Trial) and the policy interpretations for such protocol for public comments, and on July 7, 2025, the NMPA issued the revised draft Protocol for Review and Approval of Conditional Approval of Drugs Marketing Applications (Trial) and the policy interpretations for such protocol for public comments again. The draft protocol and its policy interpretations provide for strengthened post-marketing supervisions for conditionally approved drugs. The NMPA solicited comments until August 7, 2025, and as of the date of this Annual Report, there is no timeline for its enactment.

On March 12, 2021, the National People's Congress issued the Fourteenth Five-Year Plan, which provides that the accelerated evaluation and approval mechanism shall be improved for innovative drugs, vaccines, medical devices. The evaluation and approval of drugs and medical devices with urgent clinical needs or for orphan diseases shall be advanced. The import of overseas on market new drugs and medical devices with urgent clinical needs shall also be facilitated.

Four Phases of Clinical Trials

A clinical trial consists of Phases 1, 2, 3 and 4. Phase 1 refers to the initial clinical pharmacology and safety evaluation studies in humans. Phase 2 refers to the preliminary evaluation of a drug candidate's therapeutic effectiveness and safety for particular indication(s) in patients, which provides evidence and support for the design of Phase 3 clinical trial and settles the administrative dose regimen. Phase 3 refers to clinical trials undertaken to confirm the therapeutic effectiveness of a drug. Phase 3 is used to further verify the drug's therapeutic effectiveness and safety on patients with target indication(s), to evaluate overall benefit-risk relationships of the drug, and ultimately to provide sufficient evidence for the review of drug registration application. Phase 4 refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used, to evaluate overall benefit-risk relationships of the drug when used among general population or specific groups, and to adjust the administration dose, etc. On July 1, 2020, the revised Provisions for Drug Registration came into effect, which in the latest version removed the definitions of the four Phases.

Drug Clinical Practice Certification

To improve the quality of clinical trial, the CFDA promulgated the Administration Rules of Quality of Drug Clinical Practice in August 2003, which was further revised by the NMPA and the National Health Commission of the PRC, formerly known as the Ministry of Health or the National Health and Family Planning Commission, on April 23, 2020. The revised Administration Rules of Quality of Drug Clinical Practice came into effect on July 1, 2020.

In February 2004, the CFDA issued the Circular on Measures for Certification of Drug Clinical Practice Institutions (trial), providing that the NMPA is responsible for certification of clinical trial institutions, and that the National Health Commission of the PRC is responsible for relevant things in respect of certification of clinical trial institutions within its duties. Under the Circular on Measures for Certification of Drug Clinical Practice Institutions (trial), the NMPA and the National Health Commission of the PRC decide whether an institution is qualified for undertaking pharmaceutical clinical trial upon the evaluation of the institution's organizational administration, its research personnel, its equipment and facilities, its management system and its standard operational rules. If all requirements are met, a GCP Certification will be issued by the NMPA and the result will be published on the NMPA's website.

On December 1, 2019, the newly revised PRC Drug Administration Law came into effect, which provides that instead of the aforesaid certification, the drug clinical trial institutions are now subject to a record-filing system. In accordance therewith, the NMPA and the National Health Commission of the PRC jointly issued the Announcement on the Release of Regulations for Drug Clinical Trial Institutions on November 29, 2019, which changes the GCP certification system for drug clinical trial institutions to a filing system and overrides the Circular on Measures for Certification of Drug Clinical Practice Institutions (trial). A clinical trial institution shall, by itself or appoint third parties, to evaluate whether the institution is qualified for undertaking pharmaceutical clinical trial. If such evaluation determines that the institution is qualified then a filing is required to the newly established filing system run by the NMPA.

New Drug Application

When Phase 1, 2 and 3 of the clinical trials have been completed, the applicant must apply to the NMPA for approval of an NDA. The NMPA then determines whether to approve the application according to the comprehensive evaluation opinion provided by the CDE of the NMPA. We have obtained approval of our clinical trial application for Plinabulin as a direct anti-cancer agent in NSCLC when combined with docetaxel in China, and we initiated clinical trials in June 2016. We must obtain approval of an NDA before our drugs can be manufactured and sold in the Chinese market.

Good Manufacturing Practice

All facilities and techniques used in the manufacture of products for clinical use or for sale in China must be operated in conformity with cGMP guidelines as established by the NMPA. Failure to comply with applicable requirements could result in the termination of manufacturing and significant fines. The NMPA issued the Good Manufacturing Practice for Drugs Used in Clinical Trial (Exposure Draft for Public Comment) on July 2018, which provides the requirements on quality management, personnel, facilities and equipment, packaging and certain other issues relating to drugs used in clinical trials. As of the date of this Annual Report, there is no timetable as to the enactment of the exposure draft.

Animal Test Permits

According to Regulations for the Administration of Affairs concerning Experimental Animals approved by the State Council and promulgated by the State Science and Technology Commission in November 1988 and amended in January 2011, July 2013 and March 2017, and Administrative Measures on the Certificate for Animal Experimentation (Trial) promulgated by the Ministry of Science and Technology and other regulatory authorities in December 2001, performing experiments on animals requires a Certificate for Use of Laboratory Animals. Applicants must satisfy the following conditions:

- Laboratory animals must be qualified and sourced from institutions that have Certificates for Production of Laboratory Animals;
- The environment and facilities for the animals' living and propagating must meet state requirements;
- The animals' feed must meet state requirements;
- The animals' feeding and experimentation must be conducted by professionals, specialized and skilled workers, or other trained personnel;
- The management systems must be effective and efficient; and
- The applicable entity must follow other requirements as stipulated by Chinese laws and regulations.

International Multi-Center Clinical Trials Regulations

On January 30, 2015, the CFDA promulgated Notice on Issuing the International Multi-Center Clinical Trial Guidelines (Trial), or the Multi-Center Clinical Trial Guidelines, which took effect as of March 1, 2015, aiming to provide guidance for the regulation of application, implementation and administration of international multi-center clinical trials in China. Pursuant to the Multi-Center Clinical Trial Guidelines, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicant plans to make use of the data derived from the international multi-center clinical trials for application to NMPA for approval of an NDA, such international multi-center clinical trials shall satisfy, in addition to the requirements set forth in the PRC Drug Administration Law and its implementation regulations, Provisions for Drug Registration and relevant laws and regulations, the following requirements:

- The applicant shall first conduct an overall evaluation on the global clinical trial data and further make trend analysis of the Asian and Chinese clinical trial data. In the analysis of Chinese clinical trial data, the applicant shall consider the representativeness of the research subjects, i.e., the participating patients;

- The applicant shall analyze whether the amount of Chinese research subjects is sufficient to assess and adjudicate the safety and effectiveness of the drug under clinical trial, and satisfy the statistical and relevant legal requirements; and

- The onshore and offshore international multi-centers clinical trial research centers shall be subject to on-site inspections of competent PRC governmental agencies.

International multi-center clinical trials shall follow international prevailing GCP principles and ethics requirements. Applications shall ensure the truthfulness, reliability and trustworthiness of clinical trials results; the researchers shall have the qualification and capability to perform relevant clinical trials; ethics committee shall continuously review the trials and protect the subjects' interests, benefits and safety. Before the performance of the international multi-center clinical trial applicants shall obtain clinical trial approvals or complete filings pursuant to requirements under the local regulations where clinical trials are conducted, and register and disclose the information of all major researcher, clinical trial organizations on the NMPA drug clinical trial information platform.

When using international multi-center clinical trial data to support NDAs in China, applicants shall submit the completed global clinical trial report, statistical analysis report and database, along with relevant supporting data in accordance with ICH-CTD (International Conference on Harmonization-Common Technical Document) content and format requirements; subgroup research results summary and comparative analysis shall also be conducted concurrently.

In April 2020, the NMPA and the National Health Commission promulgated the revised Administration Rules of Quality of Drug Clinical Practice, which came into effect in July 2020. The revised Administration Rules of Quality of Drug Clinical Practice summarizes the requirements for initiating a multi-center clinical trial, that is, before initiating a multi-center clinical trial: (i) the applicant shall ensure that all the centers participating in the clinical trial comply with the trial protocol; (ii) the applicant shall provide each center with the same trial protocol, and each center shall comply with the same unified evaluation criterion for clinical trial and laboratory data and the same guidance for case report form; (iii) each center shall use the same case report form to record the data of each human subject obtained during the trial; (iv) before initiating a clinical trial, a written document is required to specify the responsibilities of the investigators of each center; and (v) the applicant shall ensure the communication among the investigators of each center.

Leveraging the clinical trial data derived from international multi-center clinical trials, we may avoid unnecessary repetitive clinical trials and thus further accelerate the NDA process in China.

Collecting and Using Patients' Human Genetic Resources and Derived Data

In June 1998, the Ministry of Science and Technology and the former Ministry of Health jointly established the Interim Measures for the Administration of Human Genetic Resources in China. In July 2015, the Ministry of Science and Technology issued the Service Guide for the Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, which provides that foreign entities that collect and use patients' human genetic resources in clinical trials shall be required to file for an advance approval with the Human Genetic Resources Administration Office, or the HGRAO through its online system.

In May 2019, the State Council issued the Human Genetic Resources Regulation, or the HGR Regulation and revised in March 2024, which stipulates the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to this new rule, a new filing system (as opposed to the advance approval approach originally in place) is put in place for international clinical trials using Chinese patients' biospecimens at clinical study sites without involving the export of such biospecimens outside of China. A notification filing that specifies the type, quantity and usage of the biospecimens, among others, with the HGRAO is required before conducting such clinical trials. The collection, use, and outbound transfer of Chinese patients' biospecimens in international collaboration for basic scientific research involving export are still subject to the advance approval of the HGRAO.

In October 2020, the Standing Committee of the National People's Congress of the PRC, or the SCNPC, promulgated the China Biosecurity Law, which became effective on April 15, 2021 and was amended on April 26, 2024. The China Biosecurity Law reaffirms the regulatory requirements stipulated by the HGR Regulation.

In May 2023, the Ministry of Science and Technology promulgated the Implementing Rules of the Regulation on the Administration of Human Genetic Resources, which became effective on July 1, 2023. The Implementing Rules of the Regulation on the Administration of Human Genetic Resources further provide specific requirements on the collection, preservation, utilization and external provision of China's human genetic resources.

Data Privacy and Data Protection

China continues to strengthen its regulation of network security, data protection, and personal information (including personal health information). For example, the PRC Civil Code, which was promulgated by the National People's Congress in May 2020 and became effective in January 2021, provides that the personal information of a natural person shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or make public personal information of others.

In November 2016, the SCNPC promulgated the Cyber Security Law, which became effective in June 2017 and was amended in October 2025. The Cyber Security Law requires network operators to perform certain functions related to cybersecurity protection and strengthen the network information management. For instance, under the Cyber Security Law, network operators of key information infrastructure generally shall, during their operations in the PRC, store the personal information and important data collected and produced within the territory of the PRC. When collecting and using personal information, in accordance with the Cyber Security Law, network operators shall abide by the "lawful, justifiable and necessary" principles. The network operator shall collect and use personal information by announcing rules for collection and use, expressly notify the purpose, methods and scope of such collection and use, and obtain the consent of the person whose personal information is to be collected. The network operator shall neither collect the personal information unrelated to the services they provide, nor collect or use personal information in violation of the provisions of laws and administrative regulations or the agreements with such persons, and shall process the personal information they store in accordance with the provisions of laws and administrative regulations and agreements reached with such persons. The network operator shall not disclose, tamper with or destroy personal information that it has collected, or disclose such information to others without prior consent of the person whose personal information has been collected, unless such information has been processed to prevent a specific person from being identified and such information from being restored. Each individual is entitled to require a network operator to delete his or her personal information if he or she finds that collection and use of such information by such operator violate the laws, administrative regulations or the agreement by and between such operator and such individual, and is entitled to require any network operator to make corrections if he or she finds errors in such information collected and stored by such operator. Such operator shall take measures to delete the information or correct the error. Any individual or organization may neither acquire personal information by stealing or through other illegal ways, nor illegally sell or provide personal information to others.

In July 2018, the National Health Commission promulgated the Measures on Standards, Security and Services of National Healthcare Big Data (for Trial Implementation), which set out the guidelines and principles for standards management, security management and services management of health and medical big data. Pursuant to the Measures on Health and Medical Big Data, the healthcare data produced by the PRC citizens in the PRC can be managed and used by the state for the purposes of the state strategic safety and the benefits of the life and health of the PRC citizens, provided that the state guarantees the PRC citizens their respective right of information, usage and personal privacy.

On December 28, 2021, the CAC, National Development and Reform Commission, or the NDRC, and several other administrations jointly promulgated the Cybersecurity Review Measures, which took effect on February 15, 2022 and replace the Measures for Cybersecurity Review promulgated in April 2020 and effective in June 2020. According to the Cybersecurity Review Measures, critical information infrastructure operators that intend to purchase internet products and services and internet platform operators engaging in data processing activities that affect or may affect national security must be subject to the cybersecurity review, and an internet platform operator possessing personal information of over one million users and intending to be listed on a foreign stock exchange must be subject to the cybersecurity review.

In June 2021, the SCNPC promulgated the Data Security Law, which became effective on September 1, 2021. The Data Security Law establishes a tiered system for data protection in terms of their importance. Data categorized as "important data", which will be determined by governmental authorities in the form of catalogs, shall be treated with higher levels of protection. Specifically, the Data Security Law provides that processors of important data shall appoint a "data security officer" and a "management department" to take charge of data security. In addition, such processor shall evaluate the risk of its data activities periodically and file assessment reports with relevant regulatory authorities. Since the Data Security Law is relatively new, uncertainties still exist in relation to its interpretation and implementation.

On July 7, 2022, the CAC promulgated the Security Assessment Measures for Outbound Data Transfer, effective from September 1, 2022, or the Security Assessment Measures, to regulate outbound data transfer activities, protect the information rights and interests of individuals, safeguard national security and social public interests, and promote the safe and free cross-border flow of data. Furthermore, the Security Assessment Measures provide that the security assessment for outbound data transfers shall follow principles of the combination of pre-assessment and continuous supervision and the combination of risk self-assessment and security assessment, so as to prevent the security risks arising from outbound data transfers and ensure the orderly and free flow of data according to the law. For outbound data transfers activities that have been carried out prior to the implementation of the Security Assessment Measures, and not in compliance with the Security Assessment Measures, rectification shall be completed within 6 months from the implementation of the Security Assessment Measures. The Security Assessment Measures further provide that a data processor intending to implement outbound data transfer under the following circumstances shall apply for security assessment to the CAC: (a) a data processor intending to provide critical data abroad; (b) a critical information infrastructure operator or a data processor processing the personal information of more than one million individuals intending to provide personal information abroad; (c) a data processor, who has cumulatively provided personal information of 100,000 individuals or sensitive personal information of 10,000 individuals abroad since January 1st of the previous year, intending to provide personal information abroad; and (d) other circumstances prescribed by the CAC for which application for security assessment for outbound data transfers is required. On March 22, 2024, the CAC promulgated the Provisions on Facilitating and Regulating Cross-border Data Flow, effective on the same date. The provisions require data processors to identify and declare important data in accordance with the regulations, and provide that unless the competent departments or areas so notify or publicly release certain data as important data, the data processors do not need to apply for security assessment for outbound important data transfer for such data.

The provisions set forth various circumstances exempted from application for security assessment for outbound data transfer, execution of a standard contract for personal information outbound transfer and passing of the certification for personal information protection. To the extent in compliance with the national data classification and hierarchical protection system framework, the provisions allow the pilot free trade zones to promulgate their own negative list of data requiring application for security assessment for outbound data transfer, execution of a standard contract for personal information outbound transfer or passing of the certification for personal information. The provisions further provide for, subject to exemptions set forth therein and negative lists of pilot free trade zones, circumstances requiring application for security assessment for outbound data transfer, execution of a standard contract for personal information outbound transfer or passing of the certification for personal information protection. A data processor intending to implement outbound data transfer under the following circumstances should apply for security assessment to the CAC: (a) a critical information infrastructure operator intending to provide personal information or important data abroad; or (b) a data processor that is not a critical information infrastructure operator intending to provide important data abroad, or has since January 1st of the current year cumulatively provided personal information (excluding sensitive personal information) of over one million individuals, or sensitive personal information of over 10,000 individuals, abroad. For any data processors other than critical information infrastructure operators who have since January 1st of the current year cumulatively provided personal information (excluding sensitive personal information) of over 100,000 and less than one million individuals, or sensitive personal information of less than 10,000 individuals abroad, should execute a standard contract for outbound transfer of personal information with the recipient abroad or pass the certification for personal information protection. The approval for security assessment for outbound data transfer is valid for three years and may be applied for extension if the data processors need to carry on its outbound data transfer activities and there occurs no circumstance requiring re-application for security assessment for outbound data transfer. To the extent that any provision set forth in the Security Assessment Measures is inconsistent with the provisions set forth in the provisions, the provisions prevail.

On September 24, 2024, the State Council published the Administrative Regulations on the Internet Data Security, effective from January 1, 2025, or the Data Security Measures. The Data Security Measures stipulates on personal information protection, the security of important data, the cross-border security management of network data, and the obligations of network platform service providers.

Since our subsidiaries are located in China, we are required to comply with the requirements of China's network and data protection regime. In addition, in the ordinary course of our business, we collect and store personal information, including personal information about our clinical trial subjects, customers, and employees in China. We may need to share such personal information with our subsidiaries, licensors, partners, or contractors located outside China. China's network and data protection regime is constantly evolving, and we continue to face uncertainties as to whether our efforts to comply with these requirements will be sufficient. Although we develop and maintain compliance protocols and controls designed to maintain compliance with these requirements, development and maintenance of these protocols and controls is costly. In addition, our CROs, licensees, and partners are also required to comply with these laws, and our agreements with them require them to comply with these requirements, but there is always a risk that they may not fully comply with them.

PRC Enterprise Income Tax Law and Its Implementation

The Enterprise Income Tax Law of the PRC, or the EIT Law, and its implementation rules permit certain high and new technologies enterprises, or HNTEs, to enjoy a preferential enterprise income tax rate subject to these HNTEs meeting certain qualification criteria.

On March 23, 2016, the Ministry of Finance and the State Administration of Taxation, or SAT, issued the Circular on Comprehensively Promoting the Pilot Program of the Collection of Value-added Tax in Lieu of Business Tax. Effective from May 1, 2016, the PRC tax authorities collect VAT in lieu of business tax in all regions and industries. In accordance with the Value-Added Tax Law of the PRC, promulgated by the SCNPC and effective as of January 1, 2026, entities and individuals (including individual industrial and commercial households) that sell goods, services, intangible assets, real estate, and import goods within the territory of China are regarded as value-added tax payers and shall pay value-added tax in accordance with said Law. The term "selling goods, services, intangible assets, and real estate" refers to the transfer of ownership of goods and real estate for consideration, the provision of services, and the transfer of ownership or the right to use intangible assets. The value-added tax rates are set at 13%, 9%, 6%, and 0%, depending on the nature of the transactions. The tax rate applicable under the simplified tax calculation method is 3%.

Regulations Relating to Intellectual Property Rights

Patent

General

Pursuant to the Patent Law of the PRC, most recently amended in October 2020, and its implementation rules, most recently amended in December 2023, patents in China fall into three categories, namely invention patent, utility model and design patent. Invention patent refers to a new technical solution proposed in respect of a product, method or its improvement; utility model refers to a new technical solution that is practicable for application and proposed in respect of the shape, structure or a combination of both of a product; and design patent refers to the new design of the whole or part of a certain product in shape, pattern or a combination of both and in color, shape and pattern combinations aesthetically suitable for industrial application. Under the Patent Law of the PRC, the term of patent protection starts from the date the patent was filed. Patents relating to utility-models are effective for ten years from the initial date the patent application was filed, patents relating to designs are effective for fifteen years from the initial date the patent application was filed, and patents relating to invention are effective for twenty years from the initial date the patent application was filed. The Patent Law of the PRC adopts the principle of "first to file," which means where more than one person files a patent application for the same invention, a patent will be granted to the person who first filed the application.

Moreover, in order to compensate for the time consumed in the examination and approval of new drugs for marketing, the patent administration department shall, at the request of the patent holder, grant compensation for the term of the patent right for invention patents related to new drugs that have been approved for marketing in China. The compensation period shall not exceed five years, and the total validity term of patent rights since the new drug approved to be marketed shall not exceed 14 years.

Existing patents can become invalid or unenforceable due to a number of factors, including lack of novelty, and/or lack of inventive step in technology, and deficiencies in patent application. In China, a patent must have novelty, inventive step and practical applicability. Under the Patent Law of the PRC, novelty means that an invention or a utility model does not fall under the prior art; and no organisation or individual has submitted an application to the patent administrative department under the State Council for an identical invention or utility model prior to the filing date, and record shall be made in the announced patent application documents or promulgated patent documents after the filing date. Inventive step means, compared with existing technology, an invention has prominent substantial features and represents notable progress, and a utility model has substantial features and represents any progress; practical applicability means an invention or utility model can be manufactured or used and may produce positive results. Patents in China are filed with the CNIPA. Normally, the CNIPA publishes an announcement for the invention patent 18 months after the application is filed, which may be shortened upon request by the applicant. The applicant must apply to the CNIPA for a substantive examination within three years from the date the application is filed.

Article 19 of the Patent Law of the PRC provides that, for an invention or utility model completed in China, any applicant (not just Chinese companies and individuals), before filing a patent application outside of China, must first submit it to the CNIPA for a confidential examination. Failure to comply with this requirement will result in the denial of any Chinese patent for the subject invention or utility model. This added requirement of confidential examination by the CNIPA has raised concerns by foreign companies who conduct research and development activities in China or outsource research and development activities to service providers in China. Currently we have 10 invention patents granted by CNIPA and 18 invention patents under the application process.

Patent Enforcement

Unauthorized use of patents without consent from owners of patents, forgery of the patents belonging to other persons, or engagement in other infringement acts against patent rights, will subject the infringers to tortious liabilities. Serious offences of forgery of the patents belonging to other persons may be subject to criminal penalties.

When a dispute arises as a result of infringement of the patent owner's patent right, Chinese law requires that the parties first attempt to settle the dispute through consultation between them. Where the parties concerned are not willing to negotiate or the negotiation is unsuccessful, the patent owner, or an interested party who believes the patent is being infringed, may either file a civil legal suit or file an administrative complaint with the relevant patent administration authority. A Chinese court may issue a preliminary injunction upon the patent owner's or an interested party's request before instituting any legal proceedings or during the proceedings. Damages for infringement are calculated as the loss suffered by the patent holder arising from the infringement or the benefit gained by the infringer from the infringement. If it is difficult to ascertain damages in this manner, damages may be determined by using a reasonable multiple of the license fee under a contractual license. For intentional infringement of patent rights, in certain cases, the compensation amount shall be one to five times the amount determined pursuant to the aforesaid method. Where it is difficult to ascertain the losses of the patent holder, the benefits gained by the infringer and the license fee of the patent, the people's court may, in light of such factors as patent right type as well as infringement nature and circumstances, determine a compensation amount ranging from RMB 30,000 to RMB 5,000,000. As in other jurisdictions, with one notable exception, the patent owner in China has the burden of proving that the patent is being infringed. However, if the owner of an invention patent for manufacturing process of a new product alleges infringement of its patent, the alleged infringer has the burden of proving that it has not infringed. To our knowledge, there are no disputes as to our infringement of any third party's patent.

Medical Patent Compulsory License

According to the Patent Law of the PRC, for the purpose of public health, the CNIPA may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which the PRC has acceded.

Exemptions for Unlicensed Manufacture, Use, Sell or Import of Patented Drugs

The Patent Law of the PRC provides five exceptions for unlicensed manufacture, use, sell or import of patented drugs. None of following circumstances are deemed an infringement of the patent rights, and any person may manufacture, use, sell or import patented drugs without authorization granted by patent owner as follows:

- Any person who uses, promises to sell, sells or imports any patented product or product directly obtained in accordance with the patented methods after such product is sold by the patent owner or by its licensed entity or individual;
- Any person who has manufactured an identical product, has used an identical method or has made necessary preparations for manufacture or use prior to the date of patent application continues to manufacture such product or use such method only within the original scope;
- Any foreign transportation facility that temporarily passes through the territory, territorial waters or territorial airspace of China uses the relevant patents in its devices and installations for its own needs in accordance with any agreement concluded between China and that country to which the foreign transportation facility belongs, or any international treaty to which both countries are party, or on the basis of the principle of reciprocity;
- Any person who uses the relevant patents solely for the purposes of scientific research and experimentation; or
- Any person who manufactures, uses or imports patented drugs or patented medical equipment for the purpose of providing information required for administrative approval, or manufactures or imports patented drugs or patented medical equipment for the abovementioned person.

However, even if patented drugs are utilized on the ground of exemptions for unlicensed manufacture, use, sell or import of patented drugs prescribed in Patent Law of the PRC, such patented drugs cannot be manufactured, used, sold or imported for any commercial purposes without authorization granted by the patent owner.

Trademarks

Trademarks are protected by the Trademark Law of the People's Republic of China, or the PRC Trademark Law, adopted on August 23, 1982 and subsequently amended on February 22, 1993, October 27, 2001, August 30, 2013 and April 23, 2019, respectively, as well as the Implementation Regulation of the PRC Trademark Law adopted by the State Council on August 3, 2002 and amended on April 29, 2014. The Trademark Office of the CNIPA handles trademark registrations and grants a term of ten years to registered trademarks and another ten years if requested upon expiry of the first or any renewed ten-year term. The PRC Trademark Law has adopted a "first-to-file" principle with respect to trademark registration.

Trade Secrets

According to the Law Against Unfair Competition of the PRC promulgated in September 1993 and amended in November 2017, April 2019 and June 2025, respectively, the term "trade secrets" refers to technical information, business operation information and other commercial information that are not known to the public and have commercial value and for which corresponding confidentiality measures have been taken by their rights holders.

Under this law, business persons are prohibited from employing the following methods to infringe trade secrets: (1) obtaining the trade secrets from the legal owners or holders by any unfair methods such as stealing, solicitation, coercion or electronic intrusion; (2) disclosing, using or permitting others to use the trade secrets obtained illegally under item (1) above; (3) disclosing, using or permitting others to use the trade secrets, in violation of any confidentiality obligations or any requirements of the legal owners or holders to keep such trade secrets in confidence; or (4) instigating, inducing or helping others to obtain, disclose, use or allow others to use the trade secrets of the rights holders in violation of any confidentiality obligations or any requirements of the legal owners or holders to keep such trade secrets in confidence. Natural persons, legal persons and other unincorporated organizations other than business persons, if violating the aforementioned provisions, shall be deemed to have infringed upon trade secrets. If a third party knows or should have known of the above-mentioned illegal conduct but nevertheless obtains, uses or discloses trade secrets of others, the third party may be deemed to have committed a misappropriation of the others' trade secrets. The parties whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties in the amount of RMB100,000 to RMB1,000,000, and where the infringement is material, the fine shall range from RMB500,000 to RMB5,000,000. Alternatively, persons whose trade secrets are being misappropriated may file lawsuits in a Chinese court for loss and damages caused by the misappropriation.

The measures to protect trade secrets include oral or written agreements or other reasonable measures to require the employees of, or persons in business contact with, legal owners or holders to keep trade secrets confidential. Once the legal owners or holders have asked others to keep trade secrets confidential and have adopted reasonable protection measures, the requested persons bear the responsibility for keeping the trade secrets confidential.

Regulations Relating to Foreign Exchange and Dividend Distribution

Foreign Exchange Regulation

The Foreign Exchange Administration Regulations, most recently amended in August 2008, are the principal regulations governing foreign currency exchange in China. Under Chinese foreign exchange regulations, payments of current account items, such as trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from State Administration of Foreign Exchange, or SAFE, by complying with certain procedural requirements. In contrast, approval from or registration with appropriate government authorities 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.

In November 2012, SAFE promulgated and revised in May 2015 the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment, which substantially amends and simplifies the foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds by foreign investors in China, and remittance of foreign exchange profits and dividends by a Foreign Investment Enterprise, or FIE, to its foreign shareholders no longer require the approval or verification of SAFE, and multiple capital accounts for the same entity may be opened in different provinces, which was not previously possible. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents in May 2013, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in China will be conducted by way of registration, and banks must process foreign exchange business relating to the direct investment in China based on the registration information provided by SAFE and its branches.

Under the Circular of the SAFE on Further Improving and Adjusting the Policies for Foreign Exchange Administration under Capital Accounts promulgated by SAFE on January 10, 2014 and last amended by the Circular on Further Deepening the Reform to Facilitate Cross-border Trade and Investment promulgated by SAFE on December 4, 2023, administration over the outflow of the profits by domestic institutions has been further simplified. In principle, a bank is no longer required to examine transaction documents when handling the outflow of profits of no more than the equivalent of US$50,000 by a domestic institution. When handling the outflow of profits exceeding the equivalent of US$50,000, the bank, in principle, is no longer required to examine the financial audit report and capital verification report of the domestic institution, provided that it must examine, according to the principle of transaction authenticity, the profit distribution resolution of the board of directors (or the profit distribution resolution of the partners) relating to this profit outflow and the original copy of its tax record-filing form. After each profit outflow, the bank must affix its seal to and endorsements on the original copy of the relevant tax record-filing form to indicate the actual amount of the profit outflow and the date of the outflow.

On March 30, 2015, SAFE promulgated the Circular on Reforming the Management Approach regarding the Settlement of Foreign Exchange Capital of Foreign-invested Enterprises, or SAFE Circular 19, which became effective on June 1, 2015. According to SAFE Circular 19, the foreign exchange capital of foreign-invested enterprises may be settled on a discretionary basis, meaning that the foreign exchange capital in the capital account of an FIE for which the rights and interests of monetary contribution has been confirmed by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operational needs of the FIE. The proportion of such discretionary settlement is temporarily determined as 100%. The RMB converted from the foreign exchange capital will be kept in a designated account, and if an FIE needs to make further payment from such account, it still must provide supporting documents for the use of funds from the previous foreign exchange settlement and go through the review process with the banks.

Furthermore, SAFE Circular 19 stipulates that the use of capital by FIEs must adhere to the principles of authenticity and self-use within the business scope of enterprises. The capital of an FIE and capital in RMB obtained by the FIE from foreign exchange settlement must not be used for the following purposes:

- directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations;
- directly or indirectly used for investment in securities, unless otherwise provided by relevant laws and regulations;
- directly or indirectly used for granting the entrusted loans in RMB, unless permitted by the scope of business, repaying the inter-enterprise borrowing (including advances by the third party), or repaying the bank loans in RMB that have been sub-lent to the third party; and/or
- paying the expenses related to the purchase of real estate that is not for self-use, except for the foreign-invested real estate enterprises.

On June 9, 2016, SAFE promulgated the Circular on Reforming and Regulation of Administrative Policy on Settlement of Foreign Exchange of Capital Account, or SAFE Circular 16, which was last amended by the Circular on Further Deepening the Reform to Facilitate Cross-border Trade and Investment promulgated by SAFE on December 4, 2023. According to SAFE Circular 16, the foreign exchange capital of FIEs, foreign debt and funds raised through offshore listing may be settled on a discretionary basis, and can be settled at the banks. The proportion of such discretionary settlement is temporarily determined as 100%. The RMB converted from relevant foreign exchange will be kept in a designated account, and if a domestic enterprise needs to make further payment from such account, it still must provide supporting documents for the use of funds from the previous foreign exchange settlement and go through the review process with the banks.

Furthermore, SAFE Circular 16 reiterates that the use of capital by domestic enterprises must adhere to the principles of authenticity and self-use within the business scope of enterprises. The foreign exchange income of capital account and RMB obtained by domestic enterprise from foreign exchange settlement must not be used for the following purposes:

- directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations;
- directly or indirectly used for investment in securities and investment in wealth management products except for wealth management products with a risk rating of level 2 or lower and structured deposits, unless otherwise provided by relevant laws and regulations;
- directly or indirectly used for extending the entrusted loans to non-affiliate enterprises, unless permitted by the scope of business; and/or
- used for purchase of real estate of residential nature that is not for self-use, except for the enterprises engaging in real estate development and operation business or real estate leasing and operation business.

On January 26, 2017, SAFE issued the Notice on Improving the Examination of Authenticity and Compliance to Further Promote Foreign Exchange Administration, or the SAFE Circular 3, which stipulates several capital control measures with respect to the outbound remittance of profit from domestic entities to offshore entities, including (i) under the principle of genuine transaction, banks shall check board resolutions regarding profit distribution, the original version of tax filing records and audited financial statements; and (ii) domestic entities shall hold income to account for previous years' losses before remitting the profits. Moreover, pursuant to SAFE Circular 3, domestic entities shall make detailed explanations of the sources of capital and utilization arrangements, and provide board resolutions, contracts and other proof when completing the registration procedures in connection with an outbound remittance.

On October 23, 2019, SAFE promulgated the Circular on Further Promoting the Facilitation of Cross-border Trade and Investment, or SAFE Circular 28, last amended by the Circular on Further Deepening the Reform to Facilitate Cross-border Trade and Investment promulgated by SAFE on December 4, 2023. On the basis of continuing to allow investment FIEs (including foreign investment companies, foreign-funded venture capital enterprises and foreign-funded equity investment enterprises) to use the registered capital for domestic equity investment in accordance with the laws and regulations, SAFE Circular 28 cancelled the restriction on the non-investment FIEs and allows the non-investment FIEs to use the registered capital for domestic equity investment under the premise of not violating the existing "negative list" and the authenticity and compliance of the domestic equity investment. SAFE Circular 28 further clarifies the two ways of using the foreign currency registered capital of non-investment FIEs for domestic equity investment, i.e., by way of transfer of the foreign currency registered capital in its original currency and by way of foreign exchange settlement of the foreign currency registered capital. On October 23, 2019, SAFE promulgated the Circular on Reducing Foreign Exchange Accounts, or SAFE Circular 29, which became effective on February 1, 2020. The Appendix B of SAFE Circular 29 provides operational guidance for SAFE Circular 28. SAFE Circular 29 further specifies that the domestic equity investment set forth in SAFE Circular 28 is not limited to direct investment in a domestic enterprise but also includes equity investment conducted in the form of "equity transfer."

Our Chinese subsidiaries' distributions to the offshore parent and carrying out cross-border foreign exchange activities shall comply with the various SAFE registration requirements described above.

Share Option Rules

Under the Administration Measures on Individual Foreign Exchange Control issued by the People's Bank of China on December 25, 2006, all foreign exchange matters involved in employee share ownership plans and share option plans in which Chinese citizens participate require approval from SAFE or its authorized branch. In addition, under the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly-Listed Companies, or Share Option Rules, issued by the SAFE on February 15, 2012, Chinese residents who are granted shares or share options by companies listed on overseas stock exchanges under share incentive plans are required to (1) register with the SAFE or its local branches; (2) retain a qualified Chinese agent, which may be a Chinese subsidiary of the overseas listed company or another qualified institution selected by the Chinese subsidiary, to conduct the SAFE registration and other procedures with respect to the share incentive plans on behalf of the participants; and (3) retain an overseas institution to handle matters in connection with their exercise of share options, purchase and sale of shares or interests and funds transfers.

SAFE Regulations on Offshore Special Purpose Companies Held by Chinese Residents or Citizens

SAFE promulgated SAFE Circular 37 on July 4, 2014. SAFE Circular 37 regulates foreign exchange matters in relation to the use of special purpose vehicles, or SPVs, by Chinese residents to seek overseas investment and financing and conduct round trip investment in China. Under SAFE Circular 37, an SPV refers to an offshore entity established or controlled, directly or indirectly, by Chinese residents or entities for the purpose of overseas investment and financing, with Chinese residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, while "round trip investment" refers to the direct investment in China by Chinese residents through SPVs, namely, establishing FIEs to obtain the ownership, control rights and management rights. Pursuant to SAFE Circular 37, before making contribution into an SPV, Chinese residents are required to complete foreign exchange registration with SAFE or its local branch. SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by PRC individuals, share transfer or exchange, merger, division or other material event. Failure to comply with the registration procedures set forth in SAFE Circular 37, or making misrepresentation on or failure to disclose controllers of an FIE that is established through round-trip investment, may result in restrictions on the foreign exchange activities of the relevant FIE, including payment of dividends and other distributions, such as proceeds from any reduction in capital, share transfer or liquidation, to its offshore parent or affiliate, and the capital inflow from the offshore parent, and may also subject relevant Chinese residents to penalties under PRC foreign exchange administration regulations.

Pursuant to SAFE Circular 37, PRC residents who participate in share incentive plans in overseas non-publicly-listed companies may submit applications to SAFE or its local branches for the foreign exchange registration with respect to offshore SPV. For more information on compliance with SAFE Circular 37, please see "Item 1A. Risk Factors—Risks Related to Our Doing Business in China—Chinese regulations relating to investments in offshore companies by Chinese residents may subject our future Chinese resident beneficial owners or our Chinese subsidiaries to liability or penalties, limit our ability to inject capital into our Chinese subsidiaries or limit our Chinese subsidiaries' ability to increase their registered capital or distribute profits."

We have completed the foreign exchange registration of PRC resident shareholders of Mr. Linqing Jia.

Regulation of Dividend Distribution

The principal laws, rules and regulations governing dividend distribution by FIEs in China are the Company Law of the PRC, which was most recently amended on December 29, 2023 and became effective on July 1, 2024, the Foreign Investment Law, which took effect on January 1, 2020, and its implementation regulations, which took effect on January 1, 2020. Under these laws and regulations, FIEs may pay dividends only out of their accumulated profit, if any, as determined in accordance with Chinese accounting standards and regulations. Both Chinese domestic companies and foreign-invested Chinese enterprises are required to allocate 10% of their respective accumulated after-tax profits each year, if any, to fund certain statutory common reserve funds until the aggregate amount of these reserve funds has reached 50% of the registered capital of the enterprises. At the discretion of the shareholders of an FIE, it may, after accruing the statutory common reserve funds, allocate a portion of its after-tax profits, based on PRC accounting standards, to discretionary common reserve funds. A Chinese 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 but the statutory common reserve funds and the discretionary common reserve funds are not allowed to be distributed as cash dividend.

Labor Laws and Social Insurance

Pursuant to the PRC Labor Law promulgated in July 1994 and amended in August 2009 and December 2018, and the PRC Labor Contract Law promulgated in June 2007 and amended in December 2012, employers must execute written labor contracts with full-time employees. All employers must comply with local minimum wage standards. Violations of the PRC Labor Contract Law and the PRC Labor Law may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

In addition, according to the PRC Social Insurance Law promulgated in October 2010, and amended on December 29, 2018, and Administrative Regulations on the Housing Provident Fund promulgated in April 1999 and amended in March 2002 and March 2019, respectively, employers like our Chinese subsidiaries in China must provide employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, medical insurance, and housing provident fund.

Foreign Investment Law

On March 15, 2019, the National People's Congress approved the Foreign Investment Law, which took effect on January 1, 2020 and replaced the trio of existing laws regulating foreign investment in China, namely, the Sino-foreign Equity Joint Venture Enterprise Law, the Sino-foreign Cooperative Joint Venture Enterprise Law and the Wholly Foreign-invested Enterprise Law, together with their implementation rules and ancillary regulations. On December 26, 2019, the State Council of the PRC passed the Regulation for Implementing the Foreign Investment Law of the PRC, which took effect on January 1, 2020. The Foreign Investment Law and its implementing regulations embody an expected PRC regulatory trend to rationalize its foreign investment regulatory regime in line with prevailing international practice and the legislative efforts to unify the corporate legal requirements for both foreign and domestic investments. According to the Foreign Investment Law, "foreign investment" refers to investment activities directly or indirectly conducted by one or more natural persons, business entities or other organizations of a foreign country in China.

On September 6, 2024, according to the Foreign Investment Law, the Ministry of Commerce of PRC, or the MOFCOM, and NDRC published the Special Administrative Measures (Negative List) for Foreign Investment Access (Edition 2024), or the "Negative List", which came into effect on November 1, 2024. The Negative List provides the scope of "restricted" or "prohibited" industries that have certain restrictions on foreign investment such as market entry clearance. Foreign investment in industries not included in the "negative list" are granted national treatment.

Regulations Relating to Overseas Listings

The relevant PRC government authorities issued Opinions on Strictly Cracking Down Illegal Securities Activities in accordance with the Law around July 2021. These opinions 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.

On February 17, 2023, the China Securities Regulatory Commissions, or the CSRC, promulgated Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies, or the Overseas Listing Trial Measures and relevant five guidelines, which became effective on March 31, 2023. The Overseas Listing Trial Measures comprehensively improves and reforms the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and regulates both direct and indirect overseas offering and listing of PRC domestic companies' securities by adopting a filing-based regulatory regime. According to the Overseas Listing Trial Measures, any of our offering and listing in an overseas market in future may be subject to the filing with the CSRC.

According to the Overseas Listing Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provides that an overseas listing or offering is explicitly prohibited, if any of the following: (i) such securities offering and listing is explicitly prohibited by provisions in laws, administrative regulations and relevant state rules; (ii) the intended securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with law; (iii) the domestic company intending to make the securities offering and listing, or its controlling shareholder(s) and the actual controller, have committed relevant crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to make the securities offering and listing is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company's controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

The Overseas Listing Trial Measures provides that if the issuer meets the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by PRC domestic companies: (i) 50% or more of any of the issuer's operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the main parts of the issuer's business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in mainland China. Where an issuer submits an application for initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted. The Overseas Listing Trial Measures also requires subsequent reports to be filed with the CSRC on material events, such as change of control or voluntary or forced delisting of the issuer(s) who have completed overseas offerings and listings. Subsequent securities offerings of an issuer in the same overseas market where it has previously offered and listed securities shall be filed with the CSRC within three working days after offerings are completed.

Furthermore, according to the Overseas Listing Trial Measures, if a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines.

On February 17, 2023, CSRC also issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies, which, among others, provided that (1) the domestic companies that have already been listed overseas on or before the effective date of the Overseas Listing Trial Measures (i.e. March 31, 2023) shall be deemed as existing issuers, or the Existing Issuers. Existing Issuers are not required to complete the filling procedures immediately, and they shall be required to file with the CSRC when subsequent matters such as refinancing are involved; (2) on or prior to the effective date of the Overseas Listing Trial Measures, domestic companies that have already submitted valid applications for overseas offering and listing but have not obtained approval from overseas regulatory authorities or stock exchanges may reasonably arrange the timing for submitting their filing applications with the CSRC, and must complete the filings before the completion of their overseas offering and listing; (3) a six-month transition period will be granted to domestic companies which, prior to the effective date of the Overseas Listing Trial Measures, have already obtained the approval from overseas regulatory authorities or stock exchanges (such as the completion of hearing in the market of Hong Kong or the completion of registration in the market of the United States), but have not completed the indirect overseas listing; if domestic companies fail to complete the overseas listing within such six-month transition period, they shall file with the CSRC according to the requirements.

On February 24, 2023, the CSRC, together with other authorities, jointly issued the Provisions on Strengthening the Confidentiality and Archives Administration Related to the Overseas Securities Offering and Listing by Domestic Enterprises, or the Confidentiality and Archives Administration Provisions, which came into effect on March 31, 2023. The Confidentiality and Archives Administration Provisions requires PRC domestic enterprises or its overseas listing vehicles, among others, seeking to offer or list its securities in overseas markets either directly or indirectly, to establish and improve their confidentiality and archives administration systems and take other necessary measures to prevent them from disclosing state secrets, secrets related to state authorities' affairs or undermining national or public interests. It further stipulates that it shall be subject to approval or filing procedures of competent authorities in accordance with relevant laws and regulations that PRC domestic enterprises or its overseas listing vehicles, among others, provide or publicly disclose documents or materials involving state secrets or secrets of state authorities or causing possible adverse effect on national security or public interests etc. to relevant securities companies, securities service institutions, overseas regulatory agencies and other entities and individuals.

Furthermore, according to the Negative List promulgated by the MOFCOM and the NDRC that became effective on March 2, 2022, domestic enterprises engaged in activities in any field prohibited from foreign investment under the Negative List shall be subject to review and approval by the relevant authorities of the PRC when listing and trading overseas. If it is determined that any approval, filing or other administrative procedure from the CSRC or other PRC governmental authorities is required for any future offering or listing, we cannot assure that we can obtain the required approval or accomplish the required filings or other regulatory procedures in a timely manner, or at all. If we fail to obtain the relevant approval or complete the filings and other relevant regulatory procedures, we may face sanctions by the CSRC or other PRC regulatory agencies, which may include fines and penalties on our operations in China, limitations on our operating privileges in China, restrictions on or prohibition of the payments or remittance of dividends by our subsidiaries in China, or other actions that could have a material and adverse effect on our business, financial condition, results of operations, reputation and prospects, as well as the trading price of our ordinary shares. The CSRC or other PRC regulatory authorities also may take actions requiring us, or making it advisable for us, to halt our offerings before settlement and delivery of the shares offered. Consequently, if investors engage in market trading or other activities in anticipation of and prior to settlement and delivery, they do so at the risk that settlement and delivery may not occur. In addition, if the CSRC or other regulatory authorities later promulgate new rules or explanations requiring that we obtain their approvals or accomplish the required filing or other regulatory procedures for our prior offshore offerings, we may be unable to obtain a waiver of such approval requirements, if and when procedures are established to obtain such a waiver. Any uncertainties or negative publicity regarding such approval requirement could materially and adversely affect our business, prospects, financial condition, reputation, and the trading price of our ordinary shares.

Rest of the World Regulation

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

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Manufacturing and Supply

We outsource the production of the active pharmaceutical ingredient of Plinabulin to external service providers, Johnson Matthey Pharma Services (JMPS) and Asymchem Laboratories (Asymchem), and the production of the final drug formulation to Pharmaceutics International Inc. (Pii) and for contingency planning purposes, we have also established relationships with other contract manufacturing organizations. We expect to continue our outsourcing relationships with contract manufacturers to meet the ongoing requirements for the development of Plinabulin. We have framework agreements with these external service providers, under which they provide services to us on a short-term, project-by-project basis. We also have a long-term commercial supply agreement in place with Pii to prepare for the commercial supply if approved.

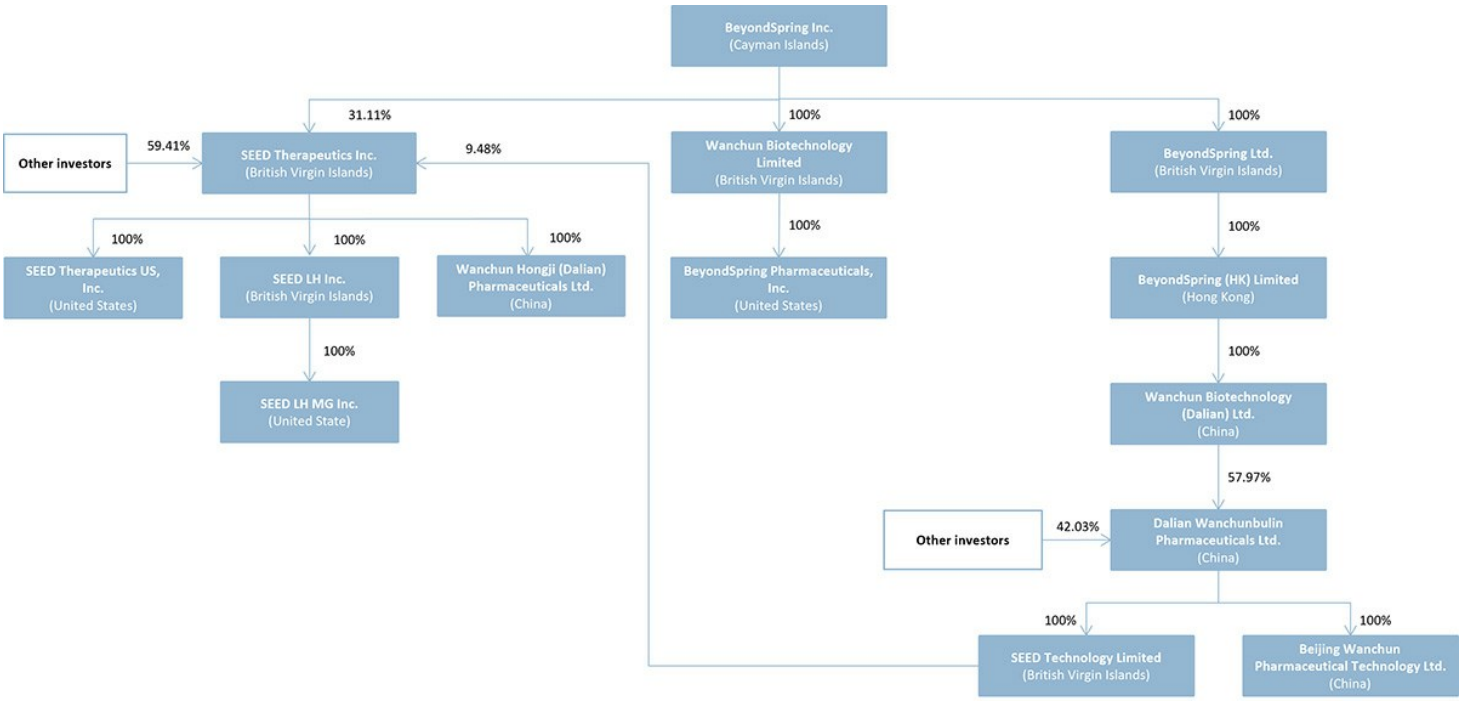
Currently, our contract manufacturers obtain materials for the manufacturing activities they perform for us from multiple suppliers who we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, a risk exists that an interruption supplies would materially harm our business. We typically order materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

We rely on BASF SE as the sole supplier of the stabilizing agent, Kolliphor HS15, used in Plinabulin's current formulation. If BASF SE becomes unable or unwilling to supply Kolliphor HS15, we will not be able to replace BASF SE and we would be required to reformulate Plinabulin. We will seek to find another formulation while continuing to use Kolliphor HS15, in accordance with our discussions with the FDA.

Manufacturing of pharmaceuticals is subject to extensive regulations that impose various procedural and documentation requirements governing record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. The contract manufacturing organizations we plan to use to manufacture our current product candidates, or any future product candidates we may develop, will be required to operate under cGMP conditions. These cGMP conditions are regulatory requirements for the production of pharmaceuticals that will be used in humans.

Organizational Structure

The diagram below depicts our current organizational structure.



Human Capital Resources

We are a research and development-focused biotechnology organization. Our research and development employees perform diverse responsibilities including managing clinical research studies, analyzing clinical trial data, preparing regulatory documents, and scaling up manufacturing processes. Our general and administrative employees focus on support functions such as finance, accounting and HR.

We place a premium on hiring employees with experience in both large, established pharmaceutical organizations and smaller emerging biotech companies. We offer employees a breadth of responsibilities and upper-level management positions that would not usually be afforded to them in larger organizations. We encourage a participatory culture built around our passion for working on breakthrough therapies in an agile, team-based organization. Our compensation and benefits offerings are designed to attract and retain top talent through the use of short-term (i.e., competitive base salaries and bonuses) and long-term incentives (i.e., stock-based compensation).

We offer employees 80% paid premium healthcare coverage benefits and up to 6% match for our 401(k) savings plan. We offer employees company paid major holidays as well as paid personal and sick time. We also have a mentorship program where employees may benefit from career guidance.

As of February 27, 2026, we had 44 full-time employees, including 34 employed by SEED. Of these, 25 were engaged in full-time research and development and laboratory operations and 19 were engaged in full-time general and administrative functions. As of February 27, 2026, 16 of our employees were located in China and 28 were located in the U.S. We have also engaged and may continue to engage independent contractors who are not full-time employees, to assist us with our operations. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have never experienced any employment related work stoppages, and we consider our relations with our employees to be good.

Corporate Information

BeyondSpring Inc. was incorporated as an exempted company under the laws of the Cayman Islands on November 21, 2014. In July 2015, we completed our internal restructuring.

Our principal executive offices are located at 100 Campus Drive, West Side, 4th Floor, Suite 410, Florham Park, New Jersey 07932 and our telephone number is +1 (646) 305-6387. Our registered office in the Cayman Islands is located at the offices of Harneys Fiduciary (Cayman) Limited, 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands. Our agent for service of process in the U.S. is CT Corporation System located at 28 Liberty Street, 42nd Floor, New York, New York 10005. Our website is www.beyondspringpharma.com. The information contained on, or that can be accessed through, our website does not constitute part of this Annual Report on Form 10-K and is not incorporated by reference herein.

Available Information

We make available free of charge 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 announce material information to the public about the Company, the progress and results of its clinical trials and research and development programs, and other matters through a variety of means, including filings with the SEC, press releases, public webcasts and presentations, the Company's website (www.beyondspringpharma.com), and/or social media, including its LinkedIn account (www.linkedin.com/company/beyondspring-pharmaceuticals/) and X account (@BeyondSpringInc), in order to achieve broad, non-exclusionary distribution of information to the public. We encourage investors and others to review the information we make public in these locations, as such information could be deemed to be material information. Please note that this list may be updated from time to time. Information that is contained in and can be accessed through our website, our LinkedIn posts and our X posts, are not incorporated into, and does not form a part of, this Annual Report.

Item 1A. Risk Factors.

An investment in our securities involves a high degree of risk. You should consider carefully all of the risks described below, together with the other information contained in this Annual Report, including our financial statements and related notes, before making a decision to invest in our securities. If any of the following events occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our securities could decline, and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business, financial condition and operating results.

Summary of Risk Factors

Risks Related to Our Financial Position and Need for Additional Capital

- We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.
- We have incurred net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future.
- We will need to obtain additional financing to fund our future operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our current or future product candidates.

Risks Related to Clinical Development of Our Product Candidates

- We depend substantially on the success of Plinabulin, which is being developed for multiple indications. Clinical trials of Plinabulin or any other product candidates we develop may not be successful. If we are unable to commercialize Plinabulin or any of our other product candidates, or experience significant delays in doing so, our business will be materially harmed.
- If the FDA does not approve our NDA for Plinabulin in combination with G-CSF for the prevention of CIN, or the FDA's review or approval of our NDA for Plinabulin in such indication is significantly delayed or prolonged, or the continued development of Plinabulin in such indication is significantly delayed or terminated, our business and results of operations could be significantly adversely affected.
- All of our current clinical trials involve Plinabulin for multiple indications and we may not be successful in our efforts to identify or discover additional product candidates. Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize the development of Plinabulin for multiple indications. If our current Plinabulin-based product candidates fail to become viable products, our business will be adversely affected.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Risks Related to Obtaining Regulatory Approval for Our Product Candidates

- The regulatory approval processes of the FDA, the NMPA, which is the successor to the CFDA, the EMA, and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our current product candidates or any future product candidates we may develop, our business will be substantially harmed.
- Regulatory approval may be substantially delayed or may not be obtained for one or all of our product candidates or target indications if regulatory authorities require additional time or studies to assess the safety or efficacy of our product candidates.

- Changes in funding or staffing for the FDA and other government agencies could hinder new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

- The results from our Phase 2/3 trials in CIN (PROTECTIVE-1 and PROTECTIVE-2) and our Phase 3 trial in advanced NSCLC (DUBLIN-3) may not be sufficiently robust to support the submission or approval of marketing applications for our product candidates. The FDA, NMPA, EMA or other regulatory authorities may require us to enroll additional subjects or conduct additional clinical trials.

Risks Related to Commercialization of Our Product Candidates

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

- Even if any of our product candidates receives regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

- Any commercialization efforts by us will require us to develop sales, marketing and distribution capabilities through arrangements with third parties or internally. If we are unable to enter into agreements with third parties to market and sell our product candidates or to establish marketing and sales capabilities, we may not be able to generate product sales revenue.

Risks Related to Our Intellectual Property

- A portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents and if our pending patent applications fail to issue, our business will be adversely affected. If we are unable to obtain and maintain patent protection for our technology and drugs, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

- We may not be able to protect our intellectual property rights throughout the world.

- We may become involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our product candidates could be found invalid or unenforceable if challenged in court or before the USPTO, or comparable non-U.S. authority.

Risks Related to Our Reliance on Third Parties

- We rely on third parties to conduct our studies in animals and clinical trials. If these third parties do not successfully comply with legal and regulatory requirements, carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

- We expect to rely on third parties to manufacture our product candidate supplies, and we intend to rely on third parties for the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

- We have formed, and may form or seek collaborations, strategic alliances or acquisitions or enter into licensing arrangements in the future, and we may not realize the benefits of these arrangements.

Risks Related to Our Industry, Business and Operation

- We may be limited in the promotional claims we can make and may not be able to use information about competing therapies to promote or market Plinabulin, if approved, without incurring significant legal, regulatory or enforcement risks.
- We have limited intellectual property rights to Plinabulin inside China. We have also granted to Hengrui exclusive rights to commercialize and co-develop Plinabulin in the Greater China markets, including mainland China, Hong Kong, Macau and Taiwan.
- Our future success depends on our ability to retain our Chief Executive Officer and other key executives and to attract, retain and motivate qualified personnel.

Risks Related to Our Doing Business in China

- The current tensions in international economic relations may negatively affect the process of our clinical trials, the cost of our operations and the growth of our business.
- It may be difficult for overseas regulators to conduct investigation or collect evidence within China.
- The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs.
- Changes in the political and economic policies of the Chinese government or in relations between China and the United States may materially and adversely affect our business, financial condition, results of operations and the market price of our ordinary shares.
- Changes in U.S. and Chinese regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our ordinary shares.

Risks Related to Our Ordinary Shares

- The trading prices of our ordinary shares are likely to be volatile, which could result in substantial losses to you.
- Sales or the availability for sales of substantial amounts of our ordinary shares in the public market could cause the price of our ordinary shares to decline significantly.
- Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ordinary shares for return on your investment.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

Wanchun Biotech, the former holding company of our U.S. subsidiary, was formed in 2010. Our operations to date have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, including protecting the rights to Plinabulin, and conducting studies in animals and clinical trials of Plinabulin. Our current pipeline consists of Plinabulin for multiple indications, including as a direct anticancer agent in NSCLC when combined with docetaxel, a pipeline of clinical and preclinical immuno-oncology product candidates, and the prevention of CIN. We have not yet demonstrated the ability to successfully complete large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale drug, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. We have not yet obtained regulatory approval for, or demonstrated an ability to commercialize, any of our product candidates. We have no products approved for commercial sale and have not generated any revenue from product sales. Consequently, it is difficult to evaluate our business and prospects for future performance.

We are focused on developing innovative cancer therapies to improve clinical outcomes for patients who have high unmet medical needs. Our limited operating history, particularly in light of the rapidly evolving cancer treatment field, may make it difficult to evaluate our current business and prospects for future performance. Our short history makes any assessment of our future performance or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in rapidly evolving fields as we seek to transition to a company capable of supporting commercial activities. In addition, as a new business, we may be more likely to encounter unforeseen expenses, difficulties, complications and delays due to limited experience. If we do not address these risks and difficulties successfully, our business will suffer.

We have incurred net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

Pharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or achieve commercial viability and acceptance by patients, doctors and payors. We have devoted most of our financial resources to research and development, including our studies in animals and clinical trials. We have not generated any revenue from product sales to date, and we continue to incur significant development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2010. For the years ended December 31, 2025 and 2024, we reported a consolidated net loss of $14.2 million, and $16.7 million, respectively, and had an accumulated deficit of $408.4 million and $407.4 million as of December 31, 2025 and 2024, respectively. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. We expect to continue to incur losses for the foreseeable future as we continue our development of, and seek regulatory approvals for, our product candidates, and begin to commercialize approved drugs, if any. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may increase our expenses and adversely affect our ability to generate revenue. The size of our future net losses will depend, in part, on our ability to manage these aspects of our business. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. For example, in November 2021, we received a Complete Response Letter from the FDA for the NDA seeking approval of Plinabulin in combination with G-CSF for the prevention of CIN. As a result, we will need to work closely with the FDA to consider the possible future clinical and regulatory pathway for the CIN prevention indication, and even if we do so, we may not be successful in obtaining approval from the FDA and as a result may incur substantial losses. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses and expected future losses have had, and will continue to have, an adverse effect on our shareholders' equity and working capital.

We expect our research and development expenses to continue to be significant in connection with our continued investment in our ongoing and planned clinical trials for our current product candidates and any future product candidates we may develop. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have a material adverse effect on our shareholders' equity, financial position, cash flows and working capital.

We will need to obtain additional financing to fund our future operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our current or future product candidates.

We have financed our operations with a combination of equity offerings, shareholder and third-party loans, including bank loans, collaboration arrangements, and sale of subsidiary interests. We have financed the operations of SEED through the issuance of ordinary and preferred shares and through collaboration payments from Eli Lilly. Through December 31, 2025, we have raised approximately $301.0 million in equity financing, $10.2 million of issuance of noncontrolling interests, $37.0 million from the sale of preferred shares of SEED in connection with its Series A-2/A-3 financings and $7.4 million from the sale of preferred shares of SEED by the Company to third-party investors, $2.1 million from bank loans, of which $0.6 million has been forgiven in July 2021 and $1.5 million has been repaid in March 2022, $2.5 million in third party loans, of which $1.0 million has since been converted into an equity investment and $1.5 million has been repaid, and $14.4 million in shareholder loans, of which $6.0 million has been repaid and $8.4 million was assumed by Wanchun Biotech, the former holding company of our U.S. subsidiary, on July 20, 2015 pursuant to our internal restructuring, $10.0 million upfront payment to SEED from Eli Lilly, and approximately $31.0 million upfront payment to our partially owned subsidiary, Wanchunbulin, from Hengrui. Our product candidates will require the completion of regulatory review, significant marketing efforts and substantial investment before they can provide us with any product sales revenue.

Our operations have consumed substantial amounts of cash since inception. The net cash used for operating activities was $19.8 million and $16.4 million for the years ended December 31, 2025 and 2024, respectively. We expect to continue to spend substantial amounts on discovering new product candidates and advancing the clinical development of our product candidates. We have partnered with Hengrui for the commercialization of Plinabulin in Greater China. In the U.S. and for the rest of the world, we currently plan to seek a co-development and commercialization partner to maximize Plinabulin's potential in multiple cancer indications, if approved.

We will need to obtain additional financing to fund our future operations. We will need to raise additional financing to conduct additional clinical trials that may be required by the FDA to meet any regulatory requirements for additional clinical trials to support a potential NDA filing for NSCLC and to support the NDA approval for prevention of CIN. We will also need to obtain additional financing to complete the development and commercialization of our future product candidates. Moreover, our operating expenses and other contractual commitments are substantial and are expected to increase in the future.

Our future funding requirements will depend on many factors, including, but not limited to:

- the costs of our current, planned and potential future clinical trials;
- the outcome, timing and cost of regulatory approvals by the FDA, NMPA, EMA, and comparable regulatory authorities, including any additional studies we may be required to perform;
- the cost of commercialization of our product candidates;
- the cost and timing of completion of commercial-scale outsourced manufacturing activities;
- the amount of profit we earn from product candidates that we succeed in commercializing, if any;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the expenses associated with any potential future collaborations, licensing or other arrangements that we may establish;
- cash requirements of any future acquisitions;
- the costs of operating as a public company;
- the time and cost necessary to respond to technological and market developments; and
- the number and characteristics of product candidates that we may develop and expenses associated with that development.

We may finance future cash needs through equity and debt financing, potential licensing and partnership arrangements, sale of subsidiary or investee interests, and sale of products after obtaining regulatory approvals. The issuances of additional equity securities by us may result in dilution in the equity interests of our current shareholders. Obtaining commercial loans, assuming those loans will be available, will increase our liabilities and future cash commitments. Sale of subsidiary or investee interests, such as the sale of our Series A-1 Preferred Shares of SEED as described under "Item 1. Business—SEED's Targeted Protein Degradation (TPD) Platform and Pipeline," will cause our controlling power over such subsidiary or investee to diminish and limit our ability to benefit from potential growth of its business. General market conditions and the Complete Response Letter received from the FDA have caused and may in the future continue to cause difficulties for us to seek financing from the capital markets. We may not be able to complete financing on reasonable terms or at all. If we are unable to obtain financing in the amounts and on terms deemed acceptable, the business and future success will be materially and adversely affected. 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 future 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 product candidates.

We may seek additional funding through a combination of equity and debt financing, potential licensing and partnership arrangements, and sale of products after obtaining regulatory approvals. Any issuance of equity or equity-linked securities could result in significant dilution to our shareholders. 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 ordinary shares to decline. In the event that we enter into collaborations or licensing arrangements 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 product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

We currently do not generate revenue from product sales and may never become profitable.

Our ability to generate revenue and become profitable depends upon our ability to successfully complete the development of, and obtain the necessary regulatory approvals for, our product candidates and any future product candidates we may develop, as we do not currently have any drugs that are available for commercial sale. We expect to continue to incur substantial and increasing losses through the commercialization of our product candidates and any future product candidates. None of our product candidates has been approved for marketing in China, the U.S., the European Union or any other jurisdiction and our product candidates may never receive such approval. Our ability to generate revenue and achieve profitability is dependent on our ability to complete the development of our product candidates and any future product candidates we develop, obtain necessary regulatory approvals, and have our drugs manufactured and successfully marketed.

Even if we receive regulatory approval and marketing authorization for one or more of our product candidates or one or more of any future product candidates for commercial sale, a potential product may not generate revenue at all unless we are successful in:

- developing a sustainable and scalable manufacturing process for our product candidates and any approved products, including establishing and maintaining commercially viable supply relationships with third parties;
- launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options; and
- addressing any competing technological and market developments.

In addition, our ability to achieve and maintain profitability depends on timing and amount of expenses we incur. Our expenses could increase materially if we are required by the FDA, the NMPA, the EMA or other comparable regulatory authorities to perform studies in addition to those that we currently anticipate. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with the commercial launch of these drugs.

Even if we are able to generate revenues from the sale of any products we may develop, we may not become profitable on a sustainable basis or at all. Our failure to become and remain profitable would decrease the value of our company and adversely affect the market price of our ordinary shares which could impair our ability to raise capital, expand our business or continue our operations and cause you to lose all or part of your investment.

Risks Related to Clinical Development of Our Product Candidates

We depend substantially on the success of Plinabulin, which is being developed for multiple indications. Clinical trials of Plinabulin or any other product candidates we develop may not be successful. If we are unable to commercialize Plinabulin or any of our other product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our business and the ability to generate revenue related to product sales, if ever, will depend on the successful development, regulatory approval and commercialization of Plinabulin and any other product candidates we may develop. We have invested a significant portion of our efforts and financial resources in the development of our current product candidates and expect to invest in other product candidates. The success of Plinabulin and any other potential product candidates will depend on many factors, including:

- successful enrollment in, and completion of, studies in animals and clinical trials;
- third parties' ability in conducting our clinical trials safely, efficiently and according to the agreed protocol;
- timely receipt of regulatory approvals from the FDA, NMPA, EMA and other comparable regulatory authorities for our product candidates;
- our ability to obtain regulatory approvals for the target indications;
- establishing commercial manufacturing capabilities by making arrangements with third-party manufacturers;
- launching commercial sales of our product candidates, if and when approved;
- ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property rights of third parties;
- obtaining acceptance of our product candidates by doctors and patients;
- obtaining reimbursement from third-party payors for our product candidates, if and when approved;
- our ability to compete against other product candidates and drugs;
- maintaining an acceptable safety profile for our product candidates following regulatory approval, if and when received; and
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity.

We may not achieve regulatory approval and commercialization in a timely manner or at all. Significant delays in our ability to obtain approval for and/or to successfully commercialize our product candidates would materially harm our business and we may not be able to generate sufficient revenues and cash flows to continue our operations.

If the FDA does not approve our NDA for Plinabulin in combination with G-CSF for the prevention of CIN, or the FDA's review or approval of our NDA for Plinabulin in such indication is significantly delayed or prolonged, or the continued development of Plinabulin in such indication is significantly delayed or terminated, our business and results of operations could be significantly adversely affected.

In November 2021, we received a Complete Response Letter from the FDA for Plinabulin in combination with G-CSF for the prevention of CIN. The FDA issues a complete response letter to indicate that the review cycle for an application is complete but the application cannot be approved in its current form. In the Complete Response Letter, the FDA indicated the results of the single registrational trial (PROTECTIVE-2 Phase 3) were not sufficiently robust to demonstrate benefit and that a second well-controlled trial would be required to satisfy the substantial evidence requirement to support the CIN indication. If the FDA does not approve our NDA for Plinabulin in combination with G-CSF for the prevention of CIN, or the FDA's review or approval of our NDA for Plinabulin in such indication is significantly delayed or prolonged, or the continued development of Plinabulin is significantly delayed or terminated, it would have a material adverse effect on our business, financial condition and results of operations.

All of our current clinical trials involve Plinabulin for multiple indications and we may not be successful in our efforts to identify or discover additional product candidates. Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize the development of Plinabulin for multiple indications. If our current Plinabulin-based product candidates fail to become viable products, our business will be adversely affected.

Although in the future we intend to explore other therapeutic opportunities in addition to Plinabulin, which we acquired from NPBSIPO Liquidating Trust, or Nereus, and did not develop on our own, currently we have only identified three product candidates and one drug development platform (currently under SEED) that do not include Plinabulin and clinical trials on those candidates have not begun. Development of product candidates requires substantial technical, financial and human resources whether or not we ultimately are successful. Our research programs and those of our collaborators may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs than we will possess, thereby limiting our ability to diversify and expand our drug portfolio.

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful. We also may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, we may never be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through either internal research programs, which could materially adversely affect our future growth and prospects, or our collaborations.

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 meet the trial criteria and remain in the trial until its conclusion. We may experience difficulties enrolling and retaining appropriate patients in our clinical trials for a variety of reasons, including:

- emergence of a pandemic or other widespread health emergencies or concerns over the possibility of such an emergency, including the COVID-19 pandemic, which, in particular, affected our enrollment of patients in Ukraine and China, and enrollment was shifted to other clinical sites. We experienced minor delays in enrollment of patients in our clinical trials in general, as well as minor delays in processing the clinical trial data. The COVID-19 pandemic also affected required regulatory clinical site inspections and regulatory review process, which have delayed regulatory review and approvals;
- the size, nature and geographical composition of the patient population;
- the patient eligibility criteria defined in the clinical protocol;
- the size of the study population required for statistical analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial and changes to the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics exist and will reduce the number and types of patients available to us;
- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- patients enrolled in clinical trials may not complete a clinical trial; and
- the availability of approved therapies that are similar to our product candidates.

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 prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

The ongoing hostilities between Russia and Ukraine and ancillary developments may have an adverse effect on our business.

A portion of our CIN clinical trials (PROTECTIVE-1 and PROTECTIVE-2) were conducted in Russia and Ukraine. Although we currently are not conducting and do not currently plan to conduct in the future any clinical trials in Russia or Ukraine, the ongoing hostilities between these two countries may require us to avoid conducting any future clinical trials in such jurisdictions due to difficulties in enrolling patients and supply chain disruptions.

Clinical drug development involves a lengthy and expensive process and can fail at any stage of the process. We have limited experience in conducting clinical trials and results of earlier studies and trials may not be reproduced in future clinical trials.

Clinical testing is expensive and can take many years to complete, and failure can occur at any time during the clinical trial process. The results of studies in animals and early clinical trials of our product candidates may not predict the results of later-stage clinical trials. We have conducted Phase 2/3 clinical trials in CIN prevention (PROTECTIVE-1 and PROTECTIVE-2) and a Phase 3 trial in advanced NSCLC (DUBLIN-3), investigator-initiated Phase 1 and Phase 2 clinical trials with a triple combination therapy for the treatment of ES-SCLC, NSCLC, and a basket Phase 1 study in a number of cancer indications; however, we did not conduct the Phase 1/2 clinical trial pertaining to the combination of Plinabulin and docetaxel, or Study 101. Study 101 was conducted by Nereus and we acquired Plinabulin from Nereus after such Phase 1/2 clinical trial had been substantially completed. Product candidates, including Plinabulin, evaluated in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through studies in animals and initial clinical trials. In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations (including genetic differences), patient adherence to the dosing regimen and the patient dropout rate. Results in later trials may also differ from earlier trials due to a larger number of clinical trial sites and additional countries and languages involved in such trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced and significant expense has been incurred.

A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of demonstrated efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. For example, the improvement in survival for all patients enrolled in the Plinabulin plus docetaxel arm of the Phase 2 portion of Study 101 was not statistically significant. We decided to proceed with a Phase 3 clinical trial of Plinabulin in combination with docetaxel for advanced NSCLC (DUBLIN-3 (previously referred to as Study 103)) based on a post hoc analysis of a certain subset of patients as amended based upon our discussions with the FDA. Based on this previous subset analysis, in DUBLIN-3, we enrolled advanced or metastatic NSCLC patients into this trial who failed at least one previous platinum-based chemotherapy and had measurable lesions. Designing the Phase 3 trial in this manner may increase the risk that the results of the trial may not be what we expect. While the results of DUBLIN-3 of Plinabulin in combination with docetaxel for advanced NSCLC demonstrated statistically significant efficacy, there is no assurance that we will be able to obtain approval of Plinabulin for such indication due to a variety of potential reasons, such as the applicability of the study for the U.S. patient population. In addition, our Phase 3 or any additional trial for the prevention of CIN caused by high-risk chemotherapy (PROTECTIVE-2 (previously referred to as Study 106)) or other trials we conduct might not support NMPA or FDA approval of Plinabulin in one or either of these indications. If this occurs, we would need to replace any of the failed trials with a new trial or trials, which would require significant additional expense, cause substantial delays in commercialization and materially adversely affect our business, financial condition, cash flows and results of operations.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA, NMPA, EMA or other comparable 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 product candidates.

Before applying for and obtaining regulatory approval for the sale of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and may fail. A failure of one or more of our clinical trials can occur at any stage of testing and successful interim results of a clinical trial do not necessarily predict successful final results. In the past, patients developed certain undesirable adverse events caused by Plinabulin, including nausea, vomiting, fatigue, fever, tumor pain and transient blood pressure elevation, and in the future patients may develop similar or different undesirable adverse events, that could delay or prevent regulatory approval. We and our CROs, are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, NMPA, EMA and other comparable regulatory authorities for all drugs in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites, among other measures. Compliance with GCPs can be costly and if we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, NMPA, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications.

We may experience numerous unexpected events during, or as a result of, clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including:

- regulators, IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate or patients may drop out at a higher rate than we anticipate;
- our third-party contractors and investigators may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a lack of clinical response or a determination that participants are being exposed to unacceptable health risks;
- regulators, IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; and
- our product candidates may cause adverse events or have undesirable side effects or other unexpected characteristics, causing us, our investigators, or regulators to suspend or terminate the trials.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product 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 product candidates;
- not obtain regulatory approval at all;
- obtain approval for indications that are not as broad as intended;
- have a drug removed from the market after obtaining regulatory approval;
- be subject to additional post-marketing testing requirements;
- be subject to restrictions on how a drug is distributed or used; or
- be unable to obtain reimbursement for use of a drug.

Delays in testing or approvals may result in increases in our drug development costs. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Clinical trials may produce negative or inconclusive results. Moreover, these trials may be delayed or proceed less quickly than intended. Delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues and we may not have sufficient funding to complete the testing and approval process. Any of these events may significantly harm our business, financial condition and prospects, lead to the denial of regulatory approval of our product candidates or allow our competitors to bring drugs to market before we do, impairing our ability to commercialize our drugs if and when approved.

Risks Related to Obtaining Regulatory Approval for Our Product Candidates

The regulatory approval processes of the FDA, NMPA, EMA and other comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our current product candidates or any future product candidates we may develop, our business will be substantially harmed.

We cannot commercialize product candidates without first obtaining regulatory approval to market each drug from the FDA, NMPA, EMA or comparable regulatory authorities in the applicable jurisdictions. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication in a particular jurisdiction, we must demonstrate in studies in animals and well-controlled clinical trials, and, to the satisfaction of the FDA with respect to approval in the U.S., that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate.

The time required to obtain approval by the FDA, NMPA, EMA and other comparable regulatory authorities is unpredictable but typically takes many years following the commencement of studies in animals and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval can differ among regulatory authorities and may change during the course of a product candidate's clinical development. We have not obtained regulatory approval for any product candidate. In November 2021, we received a Complete Response Letter from the FDA for the NDA seeking approval of Plinabulin in combination with G-CSF for the prevention of CIN. In March 2023, we withdrew the NDA submission for the indication of Plinabulin in combination of pegfilgrastim agents to treat CIN in adult non-myeloid cancer from the NMPA. It is possible that neither our existing product candidates nor any product candidates we may discover or acquire for development in the future will ever obtain regulatory approval. Even if we obtain regulatory approval in one jurisdiction, we may not obtain it in other jurisdictions or we may not obtain it for the same indications or under the same conditions.

Our product candidates could fail to receive regulatory approval from any of the FDA, NMPA, EMA or a comparable regulatory authority for many reasons, including:

- disagreement with regulators regarding the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective or safe, pure and potent for its proposed indication;
- failure of clinical trial results to meet the level of statistical significance required for approval. For example, the results of Study 101 were not statistically significant;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with regulators regarding our interpretation of data from studies in animals or clinical trials;
- insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of an NDA, or other submission or to obtain regulatory approval;
- the FDA, NMPA, EMA or a comparable regulatory authority's finding of deficiencies related to the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; and
- changes in approval policies or regulations that render our preclinical studies and clinical data insufficient for approval.

In addition, our late stage clinical trials for the treatment of NSCLC and prevention of CIN for Plinabulin include a majority of patients in China, which may create regulatory risks for our NDA filings in the U.S. Our NSCLC clinical trial (DUBLIN-3) was conducted in 559 patients with approximately 87% of the patients in China and 13% of the patients in the U.S. and Australia. Our CIN clinical trials (PROTECTIVE-1 and PROTECTIVE-2) were conducted in approximately 500 patients with approximately 50% of the patients in China and 50% of the patients in the U.S., Russia and Ukraine. If no benefit is shown in the U.S. population, if the results of our studies do not support the assessment that the Phase 3 study data may be pooled, or if the patient population enrolled does not reflect the U.S. standard of care, among other potential objections, the findings of the trials might not be considered to be applicable to U.S. patients and the FDA might not approve our NDA.

The FDA has expressed disapproval about the use of single country foreign data to support a U.S. marketing application. The FDA has declined to approve a marketing application for an immunotherapy product that had been studied through a clinical trial conducted exclusively in China. A briefing document for the FDA advisory committee meeting convened to assess the product's marketing application noted that the current trend of marketing applications submitted to the FDA based on foreign data from single country trials was a departure from the preferred method of multiregional clinical trials, and it stated that the data from the single country clinical trial in question was not applicable to the U.S. population and U.S. medical practice. If the FDA determines that our clinical trials are affected by similar concerns, it could require additional clinical trials, which would be costly and lead to delays in receiving FDA marketing approval for Plinabulin, or it could decline to approve our NDA for Plinabulin, which would have a material adverse effect on our business, financial condition and results of operations.

Any of the FDA, NMPA, EMA or a comparable regulatory authority may require more information, including additional preclinical studies or clinical data, to support approval for a target indication, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. For example, in the Complete Response Letter we received in November 2021, the FDA indicated that the results of the single registrational trial (PROTECTIVE-2 Phase 3) were not sufficiently robust to demonstrate benefit and that a second well-controlled trial would be required to satisfy the substantial evidence requirement to support the CIN indication.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022 with the passage of the Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans. If the FDA determines that the patient populations of any of our clinical trials are not sufficiently diverse, such as our advanced NSCLC study (DUBLIN-3), it could require additional clinical trials which would be costly and could lead to delays in receiving FDA marketing approval, or it could decline to provide marketing approval, for affected product candidates or indications, which would have a material adverse effect on our business, financial condition and results of operations. Due to general uncertainty with respect to the current U.S. legal, regulatory and policy environment, and specifically regarding positions that the Trump administration may take regarding clinical trial requirements, we are unable to predict the impact of any future legislative, regulatory or third-party actions with respect to these issues.

If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request. For example, because the FDA views squamous and non-squamous NSCLC as distinct diseases, we may only be able to obtain approval in one of those diseases. Regulatory authorities also may grant approval contingent on the performance of costly post-marketing clinical trials or other post-marketing requirements, or may approve a product candidate with a label that presents obstacles to the successful commercialization of that product candidate. In addition, if our product candidate produces undesirable side effects or involves safety issues, the FDA may require the establishment of a REMS, or the NMPA, EMA or a comparable regulatory authority may require the establishment of a similar strategy. Such a strategy may, for instance, restrict distribution of our product candidate, require patient or physician education or impose other burdensome implementation requirements on us.

Any of the foregoing or similar scenarios could materially harm the commercial prospects of our product candidates.

Regulatory approval may be substantially delayed or may not be obtained for one or all of our product candidates or target indications if regulatory authorities require additional time or studies to assess the safety or efficacy of our product candidates.

We may be unable to complete development of our product candidates, or initiate or complete development of any future product candidates we may develop, on schedule, if at all. We will need to raise additional financing to conduct any additional clinical trials required by the FDA to support the NDA approval for prevention of CIN and to meet any regulatory requirements for additional clinical trials to support a potential NDA filing for NSCLC. We may not have or in the future be able to obtain adequate funding to complete the necessary steps for approval for our product candidates or any future product candidate.

Studies in animals and clinical trials required to demonstrate the safety and efficacy of our product candidates are time consuming and expensive and take several years or more to complete. Delays in clinical trials, regulatory approvals or rejections of applications for regulatory approval in the U.S., China, Europe or other markets may result from many factors, including:

- our inability to obtain sufficient funds required to conduct or continue a clinical trial, including lack of funding due to unforeseen costs or business decisions;
- failure to reach agreement with, or inability to comply with conditions imposed by, the FDA, NMPA, EMA or other regulators regarding the scope or design of our clinical trials or other aspects of the regulatory approval process;
- clinical holds, other regulatory objections or conditions to commencing or continuing a clinical trial or the inability to obtain regulatory approval to commence a clinical trial in countries that require such approvals;
- our inability to reach agreements on acceptable terms with prospective CROs with the requisite experience and expertise, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain approval from IRBs or ethics committees to conduct clinical trials at their respective sites;
- our inability to enroll in a clinical trial a sufficient number of patients who meet the applicable inclusion and exclusion criteria of the clinical trial;
- our inability to retain a sufficient number of patients in a clinical trial;
- our inability to conduct a clinical trial in accordance with regulatory requirements or our clinical protocols;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, withdrawing from or dropping out of a trial, or becoming ineligible to participate in a trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;
- delay or failure in adding new clinical trial sites;
- failure of our CROs or third-party clinical trial managers to comply with legal and regulatory requirements, satisfy their contractual duties or meet expected deadlines;
- manufacturing issues, including delays or other problems with manufacturing, quality issues or timely obtaining from third parties sufficient quantities of a product candidate for use in a clinical trial;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- ambiguous or negative interim or final results, or results that are inconsistent with earlier results;
- unfavorable or inconclusive results of clinical trials or supportive studies in animals;
- regulatory requests for additional analyses, reports, data, or studies in animals or clinical trials, or regulatory questions regarding the interpretation of data, or regulatory requests for re-filing of NDAs;
- feedback from the FDA, NMPA, EMA, an IRB, data safety monitoring boards, or comparable entities, or results from earlier stage or concurrent studies in animals or clinical trials, regarding our product candidates or other drug products, including which might require modification of a trial protocol or suspension or termination of a clinical trial;

- unacceptable benefit-risk profile or unforeseen safety issues or adverse side effects in our product candidates or other drug products;
- a decision by the FDA, NMPA, EMA, an IRB, comparable entities, or us, or recommendation by a data safety monitoring board or comparable regulatory entity, to suspend or terminate clinical trials at any time for safety issues or for any other reason; and
- failure to demonstrate a benefit from using a drug.

Changes in regulatory requirements and guidance may also occur at any time, including after commencement of a clinical trial or subsequent to submitting an application for regulatory approval, and we may need to amend clinical trial protocols or other materials submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to IRBs or ethics committees for re-examination, which may increase the costs or time required to complete a clinical trial.

Changes in funding or staffing for the FDA and other government agencies could hinder new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

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, payment of user fees and reauthorization of user fee programs and ability to hire and retain key personnel, as well as statutory, regulatory and policy changes. In addition, funding of other government agencies that support research and development activities that pertain to FDA review, such as research to understand new technologies or establish new standards, is subject to the political process, which is inherently fluid and unpredictable. Such policy shifts, including, for example, the recent efforts to downsize the federal workforce by restructuring the U.S. Department of Health and Human Services (HHS) and eliminating positions at the FDA and other federal agencies, including senior and mid-level leaders as well as teams critical to the FDA's ability to conduct regular inspections, reviews and other regulatory activities, such as issuing regulations and guidance for industry, may affect the timelines, conclusions, completeness or duration of the FDA review process. In addition, HHS may change the user fee reauthorization process or fail to reauthorize user fee programs. As a result, average review times at the FDA may fluctuate, and the outcome of any such review process may be impacted. If political considerations or global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, 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.

The results from our Phase 2/3 trials in CIN (PROTECTIVE-1 and PROTECTIVE-2) and our Phase 3 trial in advanced NSCLC (DUBLIN-3) may not be sufficiently robust to support the submission or approval of marketing applications for our product candidates. The FDA, NMPA, EMA or other regulatory authorities may require us to enroll additional subjects or conduct additional clinical trials.

In November 2021, we received a Complete Response Letter from the FDA for Plinabulin in combination with G-CSF for the prevention of CIN. In the Complete Response Letter, the FDA indicated the results of the single registrational trial (PROTECTIVE-2 Phase 3) were not sufficiently robust to demonstrate benefit and that a second well-controlled trial would be required to satisfy the substantial evidence requirement to support the CIN indication. In March 2023, we withdrew the NDA submission for the indication of Plinabulin in combination of pegfilgrastim agents to treat CIN in adult non-myeloid cancer from the NMPA. It is possible that the NMPA, EMA or other regulatory authorities may not consider the results of our two Phase 2/3 trials in CIN to be sufficient for approval of such indication, similar to the FDA. It is also possible that the FDA, NMPA, EMA or other regulatory authorities may not consider the results of our one Phase 3 trial for NSCLC to be sufficient for approval of such indication. In particular, the FDA generally requires two pivotal clinical trials to approve a drug. In the area of oncology, however, the FDA has in some instances only required one Phase 3 clinical trial for approval of a drug in cases of severe unmet medical need.

The FDA typically does not consider a single clinical trial to be adequate to serve as a pivotal trial unless, among other things, it is well-controlled and demonstrates a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome, and a confirmatory study would be practically or ethically impossible. While we have been informed by the FDA that one Phase 2/3 trial with (i) results that are highly statistically significant, (ii) a clinically meaningful effect on survival that is consistent among relevant subgroups and (iii) an acceptable benefit-risk profile may be sufficient for approval of Plinabulin as an anticancer agent in advanced metastatic NSCLC, because the FDA generally requires two pivotal clinical trials, it may require that we conduct larger or additional clinical trials for NSCLC prior to the NDA submission or as a requirement for approval for such indication. It is also possible that, even if we achieve favorable results in the Phase 3 NSCLC trial, the FDA may require us to enroll additional subjects or conduct additional clinical trials, possibly involving a larger sample size or a different clinical study design, particularly if the FDA does not find the results from the Phase 3 NSCLC trial to be sufficiently persuasive to support the NDA submission.

If the FDA, NMPA, EMA, or other regulatory authorities require additional studies, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, it is possible that the FDA, NMPA, EMA, or other regulatory authorities may have divergent opinions on the elements necessary for a successful NDA or similar marketing application, which may cause us to alter our development, regulatory or commercialization strategies.

In October 2017, the General Office of the Central Committee of the Communist Party of China and the Chinese State Council, or the State Council, issued the Opinions on Deepening the Reform of the Review and Approval System and Inspiring Innovation of Drugs and Medical Devices. This opinion provides, among other things, that the review and approval process should be accelerated for drugs or medical devices that are urgently in need for clinical practice. For drugs or medical devices that are (i) for treatment of severe and life-threatening diseases that cannot be cured in an effective manner, or (ii) urgently in need for public health, if early and mid-term indicators in clinical trials for these drugs or medical devices show efficacy and potential clinical value, the marketing of these drugs and medical devices may be approved conditionally, and companies who desire to market such drugs or medical devices shall develop risk control plans and conduct research according to applicable requirements. On November 19, 2020, the Announcement on the Technical Guidance Principles for Conditional Approval of Drugs (Trial) was issued by the CDE, and came into effect on the same day. This announcement stipulates the definition of severe and life-threatening diseases and drugs in need in public health and requires applicants to discuss and reach consensus with the CDE on the research and other contents promised to be completed after the marketing, including without limitation, submitting post-marketing clinical research plans, the anticipated completion date thereof, the submission date of the clinical research report and the post-marketing risk control plans, etc. Furthermore, on December 1, 2019, the newly revised Drug Administration Law of the People's Republic of China, or the PRC Drug Administration Law, came into effect. The PRC Drug Administration Law reiterates that drugs (i) for treatment of severe and life-threatening diseases that cannot be cured in an effective manner or (ii) urgently in need for public health, may be approved conditionally, provided that indicators in clinical trials for these drugs show efficacy and potential clinical value. With regard to a drug that has been approved conditionally, the market authorization holder of the drug shall take corresponding risk management measures and complete the relevant research as required within the prescribed time limit. If the research fails to be completed as required within the prescribed time limit or fails to prove that the benefits outweigh the risks, then, at the worst, the drug marketing license may be revoked. The aforementioned conditional approval mechanism was further adopted by the newly revised Provisions for Drug Registration, which were issued by the State Administration for Market Regulation on January 22, 2020 and came into effect on July 1, 2020. The newly revised Provisions for Drug Registration reiterate the duties owed by the market authorization holder as stipulated in the PRC Drug Administration Law and further provide that the drug approved conditionally shall be declared in the form of a supplementary application after the relevant post-marketing clinical research is accomplished. On August 24, 2023, the NMPA issued the revised draft Protocol for Review and Approval of Conditional Approval of Drugs Marketing Applications (Trial) and the policy interpretations for such protocol for public comments, and on July 7, 2025, the NMPA issued the revised draft Protocol for Review and Approval of Conditional Approval of Drugs Marketing Applications (Trial) and the policy interpretations for such protocol for public comments again. The draft protocol and its policy interpretations provide for strengthened post-marketing supervisions for conditionally approved drugs. The NMPA solicited comments until August 7,2025, and as of the date of this Annual Report, there is no timeline for its enactment. Based on positive results in our two clinical trials, PROTECTIVE-1 and PROTECTIVE-2, we submitted an NDA for approval in China for the use of Plinabulin in combination with G-CSF for the prevention of CIN in March 2021. In March 2023, we withdrew this NDA submission from the NMPA.

Our product candidates may cause adverse events or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Adverse events caused by our product candidates or any future product candidates we may develop could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more limited indication, restrictive label or the delay or denial of regulatory approval by the FDA, NMPA, EMA or other comparable regulatory authority. Undesirable adverse events caused by Plinabulin may include, but are not limited to, nausea, vomiting, fatigue, fever, tumor pain and transient blood pressure elevation. Results of our trials at any stage of development could reveal a high and unacceptable severity or prevalence of adverse events. If that occurs, our trials could be suspended or terminated and the FDA, NMPA, EMA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications. Plinabulin is the active ingredient in all three of our current clinical product candidates and impacts all of our current clinical trials. As a result, any severe effect produced by Plinabulin will result in negative consequences for each of our current product candidates. Drug-related adverse events could also affect patient recruitment or the ability of enrolled subjects to complete the trial, could result in potential product liability claims and may harm our reputation, business, financial condition and business prospects significantly.

Additionally, if one or more of our current or future product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

- we may limit or suspend marketing of the drug;
- regulatory authorities may withdraw approvals of the drug;
- regulatory authorities may require additional warnings on the label;
- we may be required to develop a REMS for the drug 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 comparable regulatory authority;
- we may be required to conduct post-market studies;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

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

Further, combination therapy, such as our clinical trials of Plinabulin in combination with docetaxel and other chemotherapeutic agents, involves unique adverse events that could be exacerbated compared to adverse events from monotherapies. These types of adverse events could be caused by our product candidates and could also cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more limited indication or restrictive label or the delay or denial of regulatory approval by the FDA, NMPA, EMA or other comparable regulatory authority. Results of our trials could reveal a high and unacceptable severity or prevalence of adverse events.

Even if we receive regulatory approval for our product candidates, we 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 product candidates.

If our product candidates or any future product candidates we develop are approved, they will be subject to ongoing regulatory requirements, including for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the U.S. and requirements of comparable regulatory authorities in other jurisdictions.

Drug manufacturers and manufacturers' facilities are required to comply with extensive FDA, NMPA, EMA and comparable regulatory authority requirements, including, in the U.S., ensuring that quality control and manufacturing procedures conform to cGMP, regulations. As such, our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments including those made in any NDA, other marketing applications, and previous responses to 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.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing or other post-marketing requirements, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates or if new safety information emerges following approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA, NMPA, EMA or a comparable regulatory authority approves our product candidates, we will have to comply with requirements including, for example, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with GCPs and cGMPs, for any clinical trials that we conduct post-approval.

The FDA may impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after a drug reaches the market. Post-approval discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in consequences such as revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our drugs, 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 to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market in the U.S. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA, NMPA, EMA and other regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

The policies of the FDA, NMPA, EMA and of other regulatory authorities may change and 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. 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.

Risks Related to Commercialization of Our Product Candidates

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

We currently do not have any product candidates that have gained regulatory approval for sale in China, the U.S., the European Union or any other country, and we may never have marketable drugs. Our business is substantially dependent on our ability to complete the development of, obtain regulatory approval for and successfully commercialize product candidates in a timely manner. We cannot commercialize product candidates without first obtaining regulatory approval to market each drug from the FDA, NMPA, EMA and comparable regulatory authorities. Plinabulin is currently being developed in combination with standard of care (SOC) agents for multiple cancer indications. It has finished in two phase 3 clinical developmental programs. The first program is an anti-cancer therapy for second- and third- line NSCLC with EGFR wild type; we have completed the randomized global Phase 3 trial (DUBLIN-3) with the final data of significant benefit in OS and neutropenia reduction compared to SOC docetaxel, published in Lancet Respiratory Medicine in September 2024. We plan to use our best efforts to file an NDA with the NMPA and potentially other regulatory agencies as soon as possible. Aside from company-sponsored clinical trials, Plinabulin is being studied in multiple investigator-initiated studies (Phase 1/2 trials) as well as in preclinical models to investigate its therapeutic potential in combination with immuno-oncology agents in various cancer indications. The other program is prevention of CIN, for which we submitted an NDA filing in the U.S. and China in March 2021. We received a Complete Response Letter for the prevention of CIN from the FDA in November 2021 and withdrew the NDA submission of the indication of Plinabulin in combination of pegfilgrastim agents to treat CIN in adult non-myeloid cancer from the NMPA in March 2023. These trials and future trials may not be successful, and regulators may not agree with our conclusions regarding the studies in animals and clinical trials we have conducted to date.

Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate in studies in animals and well-controlled clinical trials, and to the satisfaction of the FDA with respect to approval in the U.S., that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate. For U.S. approval, an NDA must include extensive preclinical studies and clinical data and supporting information to establish the product candidate's safety and effectiveness for each target indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. The FDA also may decide not to accept our submission for filing.

Regulatory authorities outside of the U.S., such as the EMA or regulatory authorities in emerging markets, such as in China, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking non-U.S. regulatory approval could require additional studies in animals or clinical trials, which could be costly and time consuming. Non-U.S. regulatory approval processes may include risks similar to those associated with obtaining FDA approval as well as risks specific to the applicable jurisdiction. For all of these reasons, we may not obtain non-U.S. regulatory approvals on a timely basis or for each target indication, if at all.

Specifically, in China, the NMPA categorizes applications for innovative chemical drugs that have not been marketed in China or abroad as Category 1 and drug applications for drugs that have marketed abroad as Category 5. To date, most of local companies' domestically-manufactured drug applications are filed in Category 1 if the drug has not already been approved overseas. Most multinational pharmaceutical companies' drug registration applications are filed in what is now Category 5 according to the Reform Plan, issued by CFDA in March 2016. NMPA issued the Circular on Chemical Drug Registration Classification and Requirements on Application Materials in June 2020 (effective in July 2020), which reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan, and made minor adjustments to the subclassifications of Category 5. These two categories have distinct approval pathways. Companies are required to obtain clinical trial application approval before conducting clinical trials in China. This registration pathway has fast-tracked review and approval mechanisms if the product candidate meets certain criteria. Imported drug registration pathway, Category 5, is complicated and is evolving. China Category 5 registration applications may only be submitted after a drug has obtained an NDA approval and received the CPP, granted by a major drug regulatory authority, such as the FDA or EMA. We believe our lead asset Plinabulin will be considered a Category 1 drug in China according to the Reform Plan, the Provisions for Drug Registration amended in 2020 and the Circular on Chemical Drug Registration Classification and Requirements on Application Materials, because Plinabulin has never been marketed in China or abroad. However, a Category 1 designation by the NMPA may not be granted for all of our product candidates, may be revoked, or may not lead to faster development or regulatory review or approval process. A Category 1 designation also does not increase the likelihood that our product candidates will receive regulatory approval.

In March 2016, the CFDA released the Reform Plan, as mentioned above, outlining the re-classifications of chemical medicine applications. Under the new categorization, innovative drugs that have not been approved either in or outside China and are to be manufactured in China remain Category 1, while drugs approved outside China seeking marketing approval in China are Category 5. NMPA issued the Circular on Chemical Drug Registration Classification and Requirements on Application Materials in June 2020 (effective in July 2020), which reaffirmed the principles of the classification of chemical drugs set forth by the Reform Plan, and made minor adjustments to the subclassifications of Category 5. According to such rule, Category 5.1 are innovative chemical drugs and improved new chemical drugs while Category 5.2 are generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in China.

On December 1, 2019, the newly revised PRC Drug Administration Law came into effect, which formally adopts and signals the nationwide implementation of the drug marketing authorization holder system. In accordance with the PRC Drug Administration Law, an enterprise or a drug research and development institution is permitted to act as the marketing authorization holder and to engage pharmaceutical manufacturers to produce drug products. Moreover, it provides that the drug marketing authorization holder shall establish a drug quality assurance system and shall be responsible for the non-clinical research, the clinical trials, the drug production and operation, the post-marketing research and the adverse reaction monitoring, reporting and handling of the drugs, etc.

Furthermore, the PRC Drug Administration Law provides that priority in the drug registration approval process shall be given to urgently needed clinical drugs and new drugs developed for the prevention and treatment of major infectious diseases, orphan diseases and other diseases.

On January 22, 2020, the revised Provisions for Drug Registration were issued by the State Administration for Market Regulation, which came into effect on July 1, 2020. Pursuant to the newly revised Provisions for Drug Registration, the following drugs with significant clinical value may enjoy a priority procedure for drug marketing authorization: (1) urgently needed clinical drugs and innovative drugs and improved new drugs developed for prevention and treatment of major infectious and orphan diseases; (2) new varieties, dosage forms and specifications of children's medicines that conform to the physiological characteristics of children; (3) urgently needed vaccines and innovative vaccines for disease prevention and control; (4) pharmaceuticals under breakthrough therapeutic drug procedures; (5) drugs meeting the requirements of conditional approvals; and (6) other circumstances as further specified by the NMPA. The drug registration applicant may submit an application for priority review and approval for their drug applications simultaneously with filing the drug marketing application upon confirmation with the CDE beforehand. The drug marketing review time limit is stipulated as 130 working days for the drug applications, which enjoy a priority procedure for drug marketing authorization. On July 8, 2020, the NMPA issued Protocol for Prioritized Review and Approval of Drugs Marketing Certificates (Trial), which stipulated procedures and detailed conditions of the priority review and approval, while replacing the Opinions on Encouraging Drug Innovations and Implying the Prioritized Review and Approval System by the CFDA.

The NMPA may further issue detailed policies regarding fast-track clinical trial approval and drug registration pathway to facilitate the implementation of the PRC Drug Administration Law and the Provisions for Drug Registration, and we expect that the NMPA review and approval process will improve over time. Moreover, how this approval process will be implemented is still subject to further practice of the NMPA and is currently uncertain. It is not clear, therefore, whether Plinabulin will qualify for these programs and, if it does, what benefits they could ultimately offer.

The process to develop, obtain regulatory approval for and commercialize product candidates is long, complex and costly both inside and outside the U.S. and China, and approval may not be granted. Even if our product candidates were to successfully obtain approval from the regulatory authorities, any approval might significantly limit the approved indications for use, or require that precautions, contraindications or warnings be included on the product labeling, or require expensive and time-consuming post-approval clinical studies, surveillance or other measures as conditions of approval. Following any approval for commercial sale of our product candidates, certain changes to the drug, such as changes in manufacturing processes, labeling or product claims, may be subject to additional review and approval by the FDA, NMPA and EMA and comparable regulatory authorities. Also, regulatory approval for any of our product candidates may be withdrawn. If we are unable to obtain regulatory approval for our product candidates in one or more jurisdictions, or if any approval contains significant limitations or conditions, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue the development of our product candidates or any future product candidates we may develop.

Even if any of our product candidates receives regulatory approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates or any future product candidate we develop receives regulatory approval, it may nonetheless fail to gain 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 and current neutropenia treatments are well established in the medical community, and doctors may continue to rely on these treatments to the exclusion of our product candidates. In addition, physicians, patients and third-party payors may prefer other novel products to ours. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product sales revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, NMPA, EMA or other comparable regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA, NMPA, EMA or other comparable regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive drugs;
- the cost of treatment, including in relation to alternative treatments and their relative benefits;
- the amount of upfront costs or training required for physicians to administer our product candidates;
- the availability of adequate coverage, reimbursement and pricing by third-party payors and government authorities;

- the willingness of patients to pay out-of-pocket in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our drugs achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our drugs, receive more favorable reimbursement, are more cost effective or render our drugs obsolete.

Any commercialization efforts by us will require us to develop sales, marketing and distribution capabilities through arrangements with third parties or internally. If we are unable to enter into agreements with third parties to market and sell our product candidates or to establish marketing and sales capabilities, we may not be able to generate product sales revenue.

We currently do not have internal sales, marketing and distribution capabilities.

In China, we have entered into an exclusive commercialization and co-development agreement in Greater China with Hengrui to commercialize Plinabulin for the treatment of NSCLC and the prevention of CIN and any additional indications, if approved for sale. See "Item 1. Business—Commercialization." Plinabulin has achieved status as a 2017 National Science and Technology Major Project in China, or the 2017 Grant. As a result of the 2017 Grant, Plinabulin has been included in the National Drug Priority Review List in China. According to the Outline of the Thirteenth Five-Year Plan of the National Economy and Social Development of the People's Republic of China, the government encourages the research, development and production of new drugs, the new drugs with approval to be marketed shall enjoy priority to be included in the National Insurance System. Pending drug approval and successful pricing negotiations with the Chinese government, we believe that this status could help position Plinabulin for inclusion in the National Insurance System, which would allow for faster access to patients and reimbursement. According to the Outline of the Fourteenth Five-Year Plan, the government will improve the accelerated review and approval mechanism for innovative drugs, vaccines and medical devices, enhance the review and approval of drugs and medical devices for the treatment of orphan diseases and diseases with urgent clinical needs, and promote the domestic marketing of new drugs and medical devices marketed abroad with urgent clinical needs. However, even if Plinabulin is approved for sale in China, we may not be successful in transitioning to full commercialization or obtaining reimbursement under the National Insurance System. We have no experience negotiating pricing arrangements and may be unable to reach agreement on pricing.

In the U.S. and for the rest of the world, we currently plan to seek a co-development and commercialization partner to maximize Plinabulin's potential in multiple cancer indications, if approved.

We may not be able to establish or maintain collaborative arrangements with other pharmaceutical companies, and even if we are able to do so, such pharmaceutical companies may not have effective marketing capabilities or other capabilities which our business may require. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. In addition, depending on the nature of arrangements we are able to obtain with other pharmaceutical companies, we may have little or no control over their marketing and sales efforts, and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

Building our own commercial organization for marketing Plinabulin will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are not able to establish or maintain relationships with a third-party pharmaceutical company to successfully commercialize any product, or to develop in-house sales and commercial distribution capabilities, our ability to maximize product adoption and to meet forecasted revenue would be seriously impacted.

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

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies and specialty pharmaceutical and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell drugs or are pursuing the development of drugs for the treatment of cancer for which we are developing our product candidates. See "Item 1. Business—Competition." Some of these competitive drugs and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. 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. In addition, while we are investigating an alternative approach to cancer treatment by using molecular glue technology to tag oncogene proteins with ubiquitin ligase and destroy such proteins, there are a number of companies who are also working on using such technology to target and destroy oncogene proteins. See "Item 1. Business—SEED's Targeted Protein Degradation (TPD) Platform and Pipeline."

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are, or are perceived to be, safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain approval from the FDA, NMPA, EMA or other comparable regulatory authorities for their drugs 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 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, animal testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and recruiting patients for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our product candidates for which we intend to seek approval as drug products may face competition sooner than expected.

Drug products approved under an NDA (including those in China), such as our product candidates, if they were to be approved, could face generic competition earlier than expected. The enactment of the Generic Drug User Fee Amendments of 2012 and the Food and Drug Administration Safety and Innovation Act of 2012 established a user fee program that has generated hundreds of millions of dollars in funding for the FDA's generic drug review program. Funding from the user fee program, along with performance goals that the FDA negotiated with the generic drug industry, have contributed to decrease timeframes for FDA review and approval of generic drug applications.

In addition, legislative and regulatory proposals emerge from time to time in various jurisdiction to further encourage the early and rapid approval of generic drugs. For example, in 2017 the FDA announced the Drug Competition Action Plan, which consists of a series of proposals intended to increase competition in the prescription drug market and facilitate the entry of lower-cost generic alternatives. Any such proposal that is enacted into law or implemented through government regulations or other regulatory actions could increase competition for our product candidates in the event any of them gains approval. For example, the FDA has issued a series of guidance documents in connection with the Drug Competition Action Plan.

We must receive adequate reimbursement coverage for our product to successfully commercialize our product candidates or any future product candidate we may develop.

Should we receive the approvals necessary to market our product candidates or any future product candidate we may develop, we will still need to apply to government and other third-party payors for them to reimburse physicians and patients to administer and use our product. Newly-approved healthcare drugs face significant uncertainty regarding both whether they will be covered and their levels of reimbursement. Government and other healthcare payors, including Medicare, are increasingly attempting to contain healthcare costs by limiting both coverage and reimbursement levels. Even if our product candidates or future product candidates we may develop are approved by regulators, government or other third-party payors may decline to cover them or may offer reimbursement rates that are insufficient to cover our cost to supply the drugs or that otherwise fail to provide the revenue we expect to receive for the drugs. They may also set reimbursement rates for physicians who administer the drug that are insufficient to cover the physicians' costs or otherwise provide them with a disincentive to prescribe them. A decision by one third-party payor to provide reimbursement does not guarantee that other third-party payors will also provide reimbursement or provide reimbursement at the same levels. Further, once coverage and reimbursement rates are established, they may be changed or withdrawn in the future. The failure of government and other healthcare payors to cover or provide adequate reimbursement levels for our product candidates or any future product candidate we may develop, could reduce their market acceptance, limit our growth and cause our revenue and results of operations to suffer. Further, delays in establishing coverage and reimbursement would delay the commercialization of our product candidates, which would adversely affect our growth, operating results and financial position.

Prices in many countries, including China and many in Europe, are subject to local regulation. In these jurisdictions, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. As a result, we might obtain regulatory approval for a drug in a particular country, but be subject to price regulations that delay or prevent our commercial launch of the drug and negatively impact the revenue, if any, we are able to generate from the sale of the drug in that country. The existence of direct and indirect price controls and pressures over our product candidates could materially adversely affect our financial prospects and performance.

Recently enacted and future legislation and regulatory measures may increase the difficulty and cost for us to commercialize our product candidates and affect the prices we may obtain.

In China, the U.S., the European Union and some other jurisdictions, there have been a number of legislative regulatory, budgetary and staffing changes and proposed changes, as well as judicial challenges, regarding the healthcare system that could restrict or regulate post-approval activities and affect our ability to commercialize or profitably sell any product candidates for which we obtain regulatory approval. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by initiatives regarding pricing, transparency and other topics of reform.

Legislative and regulatory measures have been enacted or proposed to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, whether President Trump's administration will propose other initiatives, or whether FDA regulations, guidance or interpretations will be changed, and if so, what the impact of such changes on the regulatory approvals or commercialization of our product candidates, if any, may be. In addition, increased scrutiny of the FDA's approval process by the U.S. Congress or in connection with current or future litigation may significantly delay or prevent regulatory approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In March 2010, former President Obama signed into law the Patient Protection and Affordable Care Act, and the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act of importance to our potential product candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act pharmaceutical pricing program;
- requirements to report financial arrangements with physicians and teaching hospitals;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. For example, the U.S. Congress has made numerous efforts to repeal or amend the Affordable Care Act in whole or in part. The Tax Cuts and Jobs Act, which President Trump signed into law in December 2017, effectively eliminated the penalty for noncompliance with the Affordable Care Act's individual health insurance mandate, which is considered a key component of the Affordable Care Act. Further legislative and regulatory changes under the Affordable Care Act remain possible, although it is unknown what form such changes or any law would take, and how or whether it may affect the pharmaceutical industry as a whole or our business in the future.

In addition, other legislative changes and efforts to reform the healthcare market and delivery system that have been proposed and adopted in the U.S. since the Affordable Care Act was enacted could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates. We expect that the Affordable Care Act and other laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. As such, these and similar laws may result in additional reductions in Medicare and other third-party rates 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 of our product candidates could be prescribed or used. It is unclear how these or other healthcare reform measures will impact healthcare laws and regulations or our business.

In the U.S., there also has been particular and increased public and governmental scrutiny of the cost of drugs and drug pricing strategies, including by the U.S. Congress and federal and state prosecutors. To date, there have been several U.S. congressional inquiries, federal and state lawsuits, as well as proposed and enacted federal and state legislation and regulatory measures that may impact the prices that drug manufacturers are permitted to charge for their products or require increased transparency around drug pricing practices. For example, the Inflation Reduction Act of 2022, or IRA, enacted on August 16, 2022, seeks to reduce prescription drug costs by, among other provisions, allowing Medicare to negotiate prices for certain high-cost prescription drugs in Medicare Parts B and D, imposing an excise tax on pharmaceutical manufacturers that refuse to negotiate pricing with Medicare, requiring inflation rebates to limit annual drug price increases in Medicare, and redesigning the Medicare Part D formula. These provisions began taking effect progressively starting in fiscal year 2023, including the selection of certain drugs by HHS for Medicare drug price negotiation cycles which began in 2024; our revenues may be significantly impacted if one or more of our products are eventually selected for evaluation under this program. We are continuing to evaluate the IRA and its requirements, as well as any potential impact on our business. The IRA is currently subject to legal challenges and it is unclear how the IRA will be effectuated or changed under the Trump administration, but it is possible that the IRA could have a material adverse effect on our business, financial condition, results of operations and cash flows in the future.

The current U.S. administration is focused on lowering prescription drug costs. For example, on May 12, 2025, the current administration published an executive order that expressed support for equalizing the prices paid for drugs in the United States and other developed countries by employing a "most favored nations" (MFN) approach to drug pricing. The May 12 executive order directs the HHS Secretary to communicate MFN price targets to pharmaceutical manufacturers, which the Secretary announced on May 20, 2025. If significant progress towards MFN pricing targets is not delivered, the executive order directs the Secretary to propose a rulemaking plan to impose MFN pricing. On September 25, 2025 and October 2, 2025, the Centers for Medicare & Medicaid Services (CMS) submitted proposed rules for CMMI models, called the Global Benchmark for Efficient Drug Pricing (GLOBE) Model and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, to the White House for review. These models, if implemented, may allow CMS to pursue formalized approaches to MFN pricing for prescription drugs. In addition, on November 6, 2025, CMS published a request for applications for another CMMI model, the GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model. This is a voluntary model that tests the effect of supplemental rebate agreements between manufacturers and CMS, which align Medicaid prices with a defined MFN price. Likewise, the Trump administration has taken steps indicating that it will continue an initiative announced by the Biden administration to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. Further, budget reconciliation legislation enacted in 2025 provided for significant spending reductions for Medicaid and other federal programs, which could impact our future business prospects.

At the state level, individual states are becoming increasingly aggressive in passing legislation and implementing 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, as well as, in some cases, measures designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These and other drug pricing measures could cause significant operational and reimbursement changes for the pharmaceutical industry. We cannot know whether additional changes will be enacted and, if so, whether they would affect demand or impact the prices we would be able to charge for our product candidates, if they gain approval in the U.S.

We expect that additional U.S. healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal or state governments will pay for healthcare products and services, which could result in reduced demand for, or additional pricing pressures on, any of our current products or product candidates approved in the future. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the U.S. or any other jurisdiction. If we or any third parties we may rely on are slow or unable to adapt to changes in existing or new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, any current or future product candidates we develop may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any product approved in the future, which could have an adverse effect on demand for our products. Any reduction in reimbursement from Medicaid or other government programs may result in a similar reduction in payments from private payors. The adoption of cost containment measures or other healthcare reforms, and our associated compliance obligations, may prevent us from being able to generate revenue, attain profitability or commercialize any product candidates, if approved. The unavailability of, or a reduction in, the reimbursement of our products could have a material adverse effect on our business, financial condition, results of operations and cash flows.

We may be subject, directly or indirectly, to applicable U.S. federal and state 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 profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation and prescription of any products for which we obtain regulatory approval. If we obtain FDA approval for any of our product candidates and begin commercializing those drugs in the U.S., our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine and other disclosure laws and regulations. These laws may impact, among other things, our potential sales, marketing, patient assistance and education programs. In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, 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 in return for, either the referral of an individual, or the purchase, lease, order or recommendation 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;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which may be pursued through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, false or fraudulent claims for payment or approval from Medicare, Medicaid or other third-party payors or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- federal criminal statutes created through the HIPAA, which prohibit 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

- federal transparency requirements, including the Affordable Care Act provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

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

These and similar laws may be subject to amendment or reinterpretation, and implementing regulations may be revised or reinterpreted, in ways that may significantly affect our business. Additionally, we may be subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader or different in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. In addition, 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 the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state, and some states have passed their own data privacy and security measures. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties or other consequences.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, certain health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the Affordable Care Act provides that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Violations of fraud and abuse laws may be punishable by criminal or civil sanctions, including penalties, fines 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 False Claims Act as well as under the false claims laws of several states.

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 do 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, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the U.S. will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of the physicians or other providers or entities with whom we expect to do business with 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. This could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Intellectual Property

A portion of our intellectual property portfolio currently comprises pending patent applications that have not yet been issued as granted patents and if our pending patent applications fail to issue, our business will be adversely affected. If we are unable to obtain and maintain patent protection for our technology and drugs, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the U.S., China and other countries with respect to our proprietary technology and product candidates. As of December 31, 2025, we owned 19 issued U.S. patents directed to Plinabulin use in the treatment of various disorders, polymorphic forms of Plinabulin, Plinabulin compositions, and Plinabulin analogs. In addition, we had granted patents in 34 foreign jurisdictions, including Japan, South Korea, China, European countries, and other countries. The U.S. patents are scheduled to expire between 2033 and 2042, excluding any patent term restorations. We had 20 families of pending patent applications directed to use of Plinabulin in neutropenia reduction, use of Plinabulin for treating RAS mutant tumors and brain tumors, polymorphic forms of Plinabulin, use of Plinabulin in combination with checkpoint inhibitors, use of Plinabulin in reduction of immunotherapy related adverse events, use of Plinabulin in the treatment of thrombocytopenia, use of Plinabulin in combination with G-CSF therapy, use of Plinabulin for treating EGFR mutant tumors, use of Plinabulin in combination with an immune checkpoint inhibitor and a farnesyl pyrophosphate synthase inhibitor for treating cancer, use of Plinabulin in treating immune checkpoint inhibitor-resistant patients, Plinabulin impurities, use of Plinabulin as a monotherapy in treating certain cancers, kits and methods for providing and administering Plinabulin, use of Plinabulin in combination with a PARP inhibitor, Plinabulin micelle compositions, use of Plinabulin in combination with a cyclin-dependent kinase inhibitor, and use of biomarkers for Plinabulin therapy. If these applications were to issue, they would nominally expire between 2033 and 2044. We had three pending PCT patent applications directed to use of Plinabulin in combination with ADCs, use of Plinabulin in a combination therapy for treating small-cell lung cancer, and use of Plinabulin in a combination therapy for treating non-small cell lung cancer in patients who have failed first-line immune checkpoint inhibitor therapy. If applications claiming priority to these PCT applications were to issue, they would nominally expire in 2045.

With respect to issued patents in certain jurisdictions, for example, the U.S. and Europe, we may be entitled to obtain a patent term extension to extend the patent expiration date provided we meet the applicable requirements for obtaining such patent term extensions. We have sought to protect our proprietary position by filing patent applications in the U.S. and through the PCT related to novel technologies and product candidates that we consider to be important to our business. This process is time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

Our pending patent applications may not result in issued patents in the U.S. or non-U.S. jurisdictions in which such applications are pending. Even if patents do issue on any of these applications, a third party nevertheless may challenge their validity. Moreover, we may not obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our product candidates. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or product candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

We may not be able to protect our intellectual property rights throughout the world.

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions. The legal systems of some countries do not favor the enforcement of patents, trade secrets and other intellectual property, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing drugs in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in non-U.S. jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

We may become involved in lawsuits to protect or enforce our intellectual property rights, which could be expensive, time consuming and unsuccessful. Our patent rights relating to our product candidates could be found invalid or unenforceable if challenged in court or before USPTO or comparable non-U.S. authority.

Competitors may infringe our patent rights or misappropriate or otherwise violate our intellectual property rights. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. This can be expensive and time consuming. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. Many of our current and potential competitors have the ability to dedicate substantially greater resources to enforce and/or defend their intellectual property rights than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that patent rights or other intellectual property rights owned by us are invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent rights or other intellectual property rights do not cover the technology in question. An adverse result in any litigation proceeding could put our patent, as well as any patents that may issue in the future from our pending patent applications, at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

If we initiate legal proceedings against a third party to enforce our patents, or any patents that may issue in the future from our patent applications, that relate to one of our product candidates, the defendant could counterclaim that such patent rights are invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include ex parte re-examination, inter partes review, post-grant review, derivation and equivalent proceedings in non-U.S. jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. With respect to the validity of our patents, for example, there may be invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during this type of litigation.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as inventors or co-inventors. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose rights such as exclusive ownership of, or right to use, our patent rights or other intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Our commercial success depends in part on our avoiding infringement of the patents and other intellectual property rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final drug itself, the holders of any such patents may be able to prevent us from commercializing such product candidate unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the applicable product candidate unless we obtain a license, limit our uses, or until such patent expires or is finally determined to be held invalid or unenforceable. In any of these cases, such a license may not be available on commercially reasonable terms or at all.

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

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

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

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

The terms of our patents may not be sufficient to effectively protect our product candidates and business.

In most countries in which we file, including the U.S., the term of an issued patent is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Although various extensions may be available, the life of a patent and the protection it affords is limited. Even if patents covering our product candidates are obtained, we may be open to competition from other companies as well as generic medications once the patent life has expired for a drug. The granted U.S. patents directed to Plinabulin use, compositions, and polymorphic forms are scheduled to expire between 2033 and 2042, excluding any potential patent term restoration. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar legislation in other countries extending the terms of our patents, if issued, relating to our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our U.S. patents, if issued, may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. Patent term extensions, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval by the FDA, and only one patent can be extended for a particular drug.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension for a given patent or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be shortened and our competitors may obtain earlier approval of competing drugs, and our ability to generate revenues could be materially adversely affected.

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

Our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, these rulings have created uncertainty with respect to the value of patents once obtained, if any. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, the U.S. Supreme Court held that certain claims to naturally-occurring substances are not patentable. In the case, *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, the U.S. Supreme Court held that certain claims to methods of optimizing therapeutic efficacy constitute unpatentable laws of nature. Although we do not believe that our currently-issued patents directed to our product candidates and any patents that may issue from our pending patent applications if issued in their currently pending forms will be found invalid based on these decisions, future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patent rights. There could be similar changes in the laws of foreign jurisdictions that may impact the value of our patent rights or our other intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

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

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

We may not be successful in obtaining or maintaining necessary rights for our development pipeline through acquisitions and in-licenses.

Because our programs may subsequently include additional product candidates that require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire and maintain licenses or other rights to use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, or other third-party intellectual property rights from third parties that we identify. The licensing and acquisition of third-party intellectual property rights is a competitive area, and more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights, our business, financial condition and prospects for growth could suffer.

Risks Related to Our Reliance on Third Parties

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

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing preclinical studies and clinical programs. We rely on these parties for execution of our studies in animals 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 and third parties, such as our CROs, 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.

The manufacturing of Plinabulin drug substance or drug products involve the use of hazardous materials. We and our contract manufacturing partners contract with third parties for the disposal of these materials and waste. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our insurance coverage. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses that we may incur due to injuries to our employees resulting from the use of or exposure to hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of biological or hazardous materials.

Furthermore, we and third parties are subject to numerous international, national, municipal and local environmental, health and safety laws and regulations relating to, among other matters, safe working conditions, product stewardship and environmental protection. However, environmental and social laws and regulations have tended to become increasingly stringent. There has been increased global focus on environmental and social issues and it is possible that China may potentially adopt more stringent standards or new regulations in these areas. The extent regulatory changes occur in the future, they could result in, among other things, increased costs to us. In addition, we may incur substantial costs in order 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 or production efforts. Our failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions and also may materially adversely affect our business, financial condition, results of operations and future growth prospects.

We, our clinical investigators and our CROs are required to comply with GCPs, which are regulations and guidelines enforced by the FDA, NMPA, EMA and other comparable regulatory authorities for all of our drugs in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, our clinical investigators or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, NMPA, EMA or comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Upon inspection by a given regulatory authority, such regulatory authority may determine that one or more of our clinical trials do not comply with GCP regulations. In addition, our clinical trials must be conducted with drugs produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Due to general uncertainty with respect to the current U.S. legal, regulatory and policy environment, and specifically regarding positions that the Trump administration may take, we are unable to predict the impact of any future legislative, regulatory or third-party actions with respect to these and other issues. If enacted, we and any third parties we might engage may be unable to adapt to any changes implemented as a result of such measures, and we could face difficulties in maintaining or increasing profitability or otherwise experience a material adverse impact on our business, financial condition and results of operations.

Our CROs have the right to terminate their agreements with us in certain circumstances. 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 we are limited to remedies available to us under our agreements with such CROs, if they fail to devote sufficient time and resources to our ongoing clinical and preclinical studies. If CROs or clinical investigators do not successfully comply with legal and regulatory requirements, 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 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 product candidates. As a result, our results of operations and the commercial prospects for our product 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 requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially influence our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, we may nevertheless encounter similar challenges or delays in the future and these delays or challenges may have a material adverse effect on our business, financial condition and prospects.

We expect to rely on third parties to manufacture our product candidate supplies, and we intend to rely on third parties for the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or prices.

The manufacture of drug products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. We intend to rely on outside vendors to manufacture supplies and process our product candidates. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates.

Our anticipated reliance on 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 the FDA, NMPA, EMA or other comparable regulatory authorities must evaluate any manufacturers. This assessment requires new testing and cGMP-compliance inspections by the FDA, NMPA, EMA or other comparable regulatory authorities, which may be delayed or otherwise impeded by the COVID-19 pandemic, regulatory agency funding or staffing changes or other factors. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our drugs;
- our manufacturers may have little or no experience with manufacturing our product candidates, and therefore may require a significant amount of support from us to implement and maintain the infrastructure and processes required to manufacture our product candidates;
- our third-party manufacturers might be unable to timely manufacture our product candidates or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- our contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our contract manufacturers may not perform as agreed, may not devote sufficient resources to our product candidates, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our drugs;
- any potential third-party manufacturer may be unable to initially pass federal, state or international regulatory inspections in a timely or cost-effective manner;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies in the U.S. and other regulatory authorities to ensure strict compliance with cGMPs and other government regulations and corresponding non-U.S. requirements and our third-party manufacturers may fail to comply with these regulations and requirements;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- our third-party manufacturers could breach or terminate their agreements with us;
- our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters;
- our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields; and
- we may not be able to obtain raw materials and components used in the manufacturing process that are suitable or acceptable for use, particularly where we have no other source or supplier for the raw materials or components.

Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, NMPA, EMA or other comparable regulatory authorities, result in higher costs or adversely impact commercialization of our product candidates.

In addition to relying on third-party manufacturers and vendors to manufacture our product candidates, we will rely on third parties to perform certain specification tests on our product 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 the FDA, NMPA, EMA or other comparable regulatory authorities could place significant restrictions on our company until deficiencies are remedied.

Currently, raw materials for our manufacturing activities are supplied by multiple 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, if supplies are interrupted, it would materially harm our business.

We rely on BASF SE as the sole supplier of the stabilizing agent, Kolliphor HS15, used in Plinabulin's current formulation. If BASF SE becomes unable or unwilling to supply Kolliphor HS15, we will not be able to replace BASF SE and we would be required to reformulate Plinabulin. We will seek to find another formulation while continuing to use Kolliphor HS15, in accordance with our discussions with the FDA. Reformulation of our product candidates will cause delays for a number of reasons including, but not limited to, the fact that the supplier of any replacement agent would have to be evaluated by or qualified with the relevant regulatory authorities, which is an expensive and time-consuming process during which we may experience a supply interruption. Such reformulation would result in significant delays and is expected to reduce the overall activity of one or more of our product candidates. We may also be unsuccessful in negotiating favorable terms with such a supplier. As a result, our financial position and results of operations may be adversely affected.

Manufacturers of drug 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 our supply of our product 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. It is possible that stability failures or other issues relating to the manufacture of our product candidates may 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 product candidate to patients in clinical trials would be jeopardized. For example, BASF SE may not be able to produce sufficient quantities of stabilizing agent in a timely manner. 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 formed, and may form or seek collaborations, strategic alliances or acquisitions or enter into licensing arrangements in the future, and we may not realize the benefits of these arrangements.

We have formed, and may form or seek strategic alliances, create joint ventures or collaborations in the future. We may also acquire complimentary products, intellectual property rights, technologies or businesses or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. 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 shareholders, or disrupt our management and business. In addition, 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 partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party.

Further, collaborations involving our product 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 product candidates 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 product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or product candidates;
- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to their marketing and distribution;
- 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 product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaborators may own or co-own intellectual property covering our drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property;
- the collaboration may result in increased operating expenses or the assumption of indebtedness or contingent liabilities; and
- the collaboration arrangement may result in the loss of key personnel and uncertainties in our ability to maintain key business relationships.

As a result, if we enter into collaboration agreements and strategic partnerships or license our drugs, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. Following a strategic transaction or license, we may not achieve the revenue or specific net income that justifies 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 product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market and generate product sales revenue, which would harm our business prospects, financial condition and results of operations.

We have entered into an investigator-initiated clinical trial agreement with UCSD, and Dr. Lyudmila Bazhenova, an employee of UCSD and the principal investigator, and a clinical study agreement with the University of Washington, in connection with the investigator-initiated Phase 1/2 studies of Plinabulin in combination with Bristol-Myers Squibb's PD-1 antibody, nivolumab in patients with metastatic NSCLC. The UCSD study has completed the enrollment of 18 patients, and achieved its Phase 1 endpoint of safety evaluation and dose selection. The University of Washington study achieved the dose regimen endpoint and therefore the study site has been closed. We have also entered into an investigator-initiated research agreement with Hoosier Cancer Research Network, Inc. and the Rutgers University, in connection with the investigator-initiated Phase 1 and Phase 2 clinical trials with a triple combination therapy, consisting of Plinabulin, nivolumab, and CTLA-4 antibody, ipilimumab, for the treatment of ES-SCLC. In addition, we have entered into a sponsored research agreement with MD Anderson, in connection with research to evaluate the benefits of adding Plinabulin to radiation therapy plus immune checkpoint antibodies. We have entered into a sponsored clinical study agreement with MD Anderson in connection with the investigator-initiated Phase 1/2 study of Plinabulin in combination with radiation/immunotherapy in patients with select advanced malignancies after progression on PD-1 or PD-L1 targeted antibodies. We have also entered into an investigator sponsored research agreement with Memorial Sloan Kettering Cancer Center in connection with the investigator-initiated Phase 1 study of Plinabulin in combination with pegfilgrastim for the reduction of neutropenia burden in multiple myeloma patients who have undergone AHCT. In 2023, we entered into a sponsored research agreement with Peking Union Medical College Hospital in connection with the investigator-initiated Phase 2 study of Plinabulin in combination with Keytruda® (pembrolizumab), a PD-1 antibody, and docetaxel for the treatment of NSCLC patients who progressed from PD-1/PD-L1 antibodies. We have also entered into a sponsored research agreement with Wuhan Union Hospital in connection with the investigator-initiated Phase 2 study of Plinabulin in combination with pembrolizumab, a PD-1 antibody, and etoposide and platinum for the first-line treatment of ES-SCLC patients. See "Item 1. Business—Plinabulin, Our Lead Drug Candidate—Plinabulin in Combination with Immuno-oncology Agents in Anti-cancer Indications—Investigator-initiated studies in Plinabulin in immuno-oncology" and "—Plinabulin in Prevention of CIN— Investigator-initiated study in multiple myeloma (Plinabulin + Pegfilgrastim combination)." Each of these agreements provides that we will provide the financial support and access to Plinabulin for use in the studies, and they do not require that any intellectual property rights will be developed in connection with these studies. In addition, SEED has also entered into a research collaboration and license agreement with Eli Lilly, to discover and develop new chemical entities that could produce therapeutic benefit through targeted protein degradation, or TPD, as well as a research collaboration with Eisai, to discover and develop novel molecular glue degraders for neurodegeneration and oncology indications. Additionally, our subsidiary Wanchunbulin has entered into an exclusive commercialization and co-development agreement with Hengrui to develop additional indications for Plinabulin.

Risks Related to Our Industry, Business and Operation

We may be limited in the promotional claims we can make and may not be able to use information about competing therapies to promote or market Plinabulin, if approved, without incurring significant legal, regulatory or enforcement risks.

Various U.S. governmental agencies, including the FDA and the Federal Trade Commission, or the FTC, regulate the promotion and advertising of FDA approved medical products. Promotional materials and statements must not be false or misleading. Among other things, the FDA requires that promotional claims be supported by "substantial evidence," which requires adequate, well-controlled clinical trials. Promotional claims must also reflect "fair balance" between the risks and benefits of a medical product. The FDA has found comparative claims to be "false and misleading" when they are not supported by adequate, well-controlled, head-to-head comparison trials.

Disclaimers that the comparative claims are not based on head-to-head trials may not be sufficient to insulate the responsible party from an FDA or FTC enforcement action. False and misleading advertising and promotion is a violation of the FDCA, and subjects the responsible party to sanctions including, but not limited to, warning letters, injunctions, civil penalties and criminal prosecution. Additionally, a product is misbranded under the regulations if, in an effort to promote the product, a responsible party makes a false or misleading representation with respect to a competing drug, device or biologic.

We have limited intellectual property rights to Plinabulin inside China. We have also granted to Hengrui exclusive rights to commercialize and co-develop Plinabulin in the Greater China markets, including mainland China, Hong Kong, Macau and Taiwan.

Wanchunbulin, a partially owned subsidiary, holds the intellectual property rights to Plinabulin in China. We currently indirectly own 57.97% of the equity interest of Wanchunbulin. 42.03% of the equity interest of Wanchunbulin is held by certain other investors. As a result, any distributions resulting from Wanchunbulin on account of its equity ownership will not be fully received by us as the parent company, and any payment from us to Wanchunbulin will indirectly benefit said investors. In addition, under Chinese laws, rules and regulations, our subsidiaries incorporated in China are restricted in their ability to transfer a portion of their respective net assets to their shareholders as dividends. Registered share capital and capital reserve accounts are also restricted from withdrawal in China. As of December 31, 2025, these restricted net assets were approximately $12 thousand.

In August 2021, Wanchunbulin entered into an exclusive commercialization and co-development agreement with Hengrui to further develop and commercialize Plinabulin in Greater China. Under the terms of the agreement, Wanchunbulin granted Hengrui exclusive rights to commercialize and co-develop Plinabulin in the Greater China markets, including mainland China, Hong Kong, Macau and Taiwan. Wanchunbulin retains the manufacturing rights of Plinabulin in the Greater China markets and will receive all Plinabulin net sales proceeds in such markets. Hengrui will receive a pre-determined percentage of the net sales in each quarter. See "Item 1. Business—Commercialization" and "Item 1A. Risk Factors—Risks Related to our Industry, Business and Operation—We and our major shareholders have been, and may in the future become, subject to claims, litigation, arbitration and investigations, any of which may require significant management attention, could result in significant legal expenses and may result in unfavorable outcomes, all or any of which could have a material adverse impact on our financial condition and results of operations, harm our reputation or otherwise negatively impact our business."

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

We are highly dependent on Lan Huang, Ph.D., our Founder, Chairperson of our Board of Directors and Chief Executive Officer and the other principal members of our management and scientific teams. Although we have formal employment agreements with most of our executive officers, these agreements do not prevent our executives from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

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

Recruiting and retaining qualified scientific, clinical, sales and marketing personnel or consultants will also be critical to our success. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our discovery and preclinical studies development 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 and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Furthermore, replacing executive officers and 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 product candidates. 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.

In January 2022, we announced an organizational streamlining initiative to re-focus certain of our resources on extending our cash runway and preserving long-term sustainability in light of the Complete Response Letter from the FDA for the NDA seeking approval of Plinabulin in combination with G-CSF for the prevention of CIN. This streamlining initiative included a reduction in force program impacting a number of employees.

To meet our long-term growth strategy, we will need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.

As of February 27, 2026, we had 44 full-time employees, including 34 employed by SEED. Of these, 25 were engaged in full-time research and development and laboratory operations and 19 were engaged in full-time general and administrative functions. As of February 27, 2026, 16 of our employees were located in China and 28 were located in the U.S. We have also engaged and may continue to engage independent contractors who are not full-time employees, to assist us with our operations. As our development and commercialization plans and strategies develop, we will need to establish and maintain effective disclosure and financial controls and make changes in our corporate governance practices. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA or other comparable regulatory authority review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

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

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. These independent organizations, advisors and consultants may not continue to be available to us on a timely basis when needed, and in such case, we may not have the ability to find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. Furthermore, we may not 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 maintain our organization by retaining certain current employees, attracting potential new employees in the future and utilizing our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and other similar non-U.S. regulatory authorities; provide true, complete and accurate information to the FDA and other similar non-U.S. regulatory authorities; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the U.S. and similar non-U.S. fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those drugs in the U.S., our potential exposure under U.S. laws will increase significantly and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients and our use of information obtained in the course of patient recruitment for clinical trials, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally.

It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or 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 significant fines or other sanctions.

If we fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our ordinary shares.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm to the extent we are deemed to be a large accelerated filer or an accelerated filer. We do not expect our independent registered public accounting firm to attest to our management report on internal control over financial reporting for so long as we are a non-accelerated filer.

Our management evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report and has concluded that our disclosure controls and procedures were effective as of December 31, 2025. We have identified material weaknesses in our internal control over financial reporting in the past and may identify additional material weaknesses or significant deficiencies in our internal control over financial reporting in the future. More generally, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, if we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our ordinary shares could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

We are subject to the risk of doing business internationally.

We operate and expect to operate in various countries, and we may not be able to market our products in, or develop new products successfully for, these markets. We may also encounter other risks of doing business internationally including:

- unexpected changes in, or impositions of, legislative or regulatory requirements;
- the occurrence of economic weakness, including inflation or political instability;
- the effects of applicable non-U.S. tax structures and potentially adverse tax consequences;
- differences in protection of our intellectual property rights including third party patent rights;
- the burden of complying with a variety of foreign laws including difficulties in effective enforcement of contractual provisions;
- delays resulting from difficulty in obtaining export licenses, tariffs and other barriers and restrictions, potentially longer payment cycles, greater difficulty in accounts receivable collection and potentially adverse tax treatment; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

In addition, we are subject to general geopolitical risks in foreign countries where we operate, such as political and economic instability, international hostilities and changes in diplomatic and trade relationships, which could affect, among other things, customers' inventory levels and consumer purchasing, which could cause our results to fluctuate and our net sales to decline. The occurrence of any one or more of these risks of doing business internationally, individually or in the aggregate, could materially affect our business and results of operations adversely.

If we fail to comply with the U.S. Foreign Corrupt Practices Act, or FCPA, or other anti-bribery 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 FCPA, which 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 laws of other jurisdictions, particularly China. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. Our procedures and controls to monitor anti-bribery compliance may fail to protect us from reckless or criminal acts committed by our employees or agents. If we, due to either our own deliberate or inadvertent acts or those of others, fail to comply with applicable anti-bribery laws, our reputation could be harmed and we could incur criminal or civil penalties, other sanctions and/or significant expenses, which could have a material adverse effect on our business, including our financial condition, results of operations, cash flows and prospects.

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

Our operations, and those of our third-party research institution collaborators, CROs, suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, damage from computer viruses, material computer system failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, international hostilities and other natural or man-made disasters or business interruptions for which we are predominantly self-insured. In addition, we partially rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. A large portion of our contract manufacturer's operations is located in a single facility. Damage or extended periods of interruption to our corporate or our contract manufacturer's development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates.

We face risks related to health epidemics, pandemics and other outbreaks, which could significantly disrupt our operations.

The outbreak of COVID-19 resulted in the implementation of significant governmental measures globally, including closures of businesses and offices, quarantines of individuals, and travel bans. Our business had been negatively impacted by the effects of COVID-19. For example, enrollment of patients in our clinical trials in Ukraine was severely affected by the COVID-19 outbreak in 2020, and enrollment was shifted to other clinical sites. We also experienced minor delays in enrollment of patients in our clinical trials in general, which did not affect our ability to finish enrollment of patients in PROTECTIVE-2 and DUBLIN-3 studies globally. In addition, we rely on third-party CROs to monitor and manage data for our ongoing preclinical and clinical programs, and the pandemic has affected their ability to devote sufficient time and resources to our programs. Moreover, as a result of COVID-19, there was a general unease of conducting unnecessary activities in medical centers. As a result, the expected timeline for data readouts of our clinical trials and certain regulatory filings and regulatory review process had been negatively impacted. For example, we experienced minor delays in processing the clinical trials data due to COVID-19. In addition, restrictions or other circumstances related to COVID-19 caused delays in pre-approval inspections of our clinical or manufacturing facilities and delays in regulatory review process, thereby delaying the regulatory review and approval timeline of our product candidates. The outbreak of a similar health epidemic or pandemic in the future could have a material adverse effect on our business.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although, to our knowledge, we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we partially rely on our third-party research institution collaborators for research and development of our product candidates and on other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any drugs. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drugs;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our 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 product candidate; and
- a decline in our ordinary 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 drugs we develop, alone or with collaborators. Although we currently carry an aggregate maximum coverage amount of approximately $5.5 million of product liability insurance, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, 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 corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We have limited insurance coverage, and any claims beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

We maintain property insurance policies covering physical damage to, or loss of, our buildings and their improvements, equipment, office furniture and inventory. We hold employer's liability insurance generally covering death or work-related injury of employees. We also hold public liability insurance covering certain incidents involving third parties that occur on or in our premises, and directors and officers' liability insurance covering losses or advancement of defense costs resulting from certain legal actions brought against our directors and officers. We do not maintain "key-person" life insurance on any of our senior management or key personnel, or business interruption insurance. Our insurance coverage may be insufficient to cover any claim for damage to our fixed assets or employee injuries. Any liability or damage to, or caused by, our facilities or our personnel beyond our insurance coverage may result in our incurring substantial costs and a diversion of resources.

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 may in the future derive revenues, in currencies other than the U.S. dollars, in particular, the RMB. 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. For example, a significant portion of our clinical trial activities were conducted outside of the U.S., and associated costs were incurred in the local currency of the country in which the trial was being conducted, which costs were subject to fluctuations in currency exchange rates. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. A decline in the value of the U.S. dollar against currencies in countries in which we conduct clinical trials could have a negative impact on our research and development costs. Foreign currency fluctuations are unpredictable and 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 adopted by the Chinese and other non-U.S. governments. China, U.S. or other government policies may impact the exchange rate between the RMB, U.S. dollar and other currencies in the future in ways that adversely affect our business. There remains significant international pressure on the Chinese government to adopt a more flexible currency policy, which could result in greater fluctuation of the RMB against the U.S. dollar. Our costs are denominated in U.S. dollars, RMB, Australian dollars and Euros, and a large portion of our financial assets are in U.S. dollars. 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 our RMB into U.S. dollars for our operations or 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.

Our investments are subject to risks that could result in losses.

Our continuing operations had cash and cash equivalents of $7.8 million and $2.9 million at December 31, 2025 and 2024, respectively. We may invest our cash in a variety of financial instruments, principally short-term investment grade, interest-bearing instruments. Our continuing operations had short-term investments of $4.8 million and nil at December 31, 2025 and 2024, respectively. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. Our exposure to interest rate risk arises through movements in regard to interest income we earn on our deposits. To manage the risk, our cash is held at financial institutions that we believe to be of high credit quality. While we believe our cash position does not expose us to excessive risk, future investments may be subject to adverse changes in market value.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are currently subject to the reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We and our major shareholders have been, and may in the future become, subject to claims, litigation, arbitration and investigations, any of which may require significant management attention, could result in significant legal expenses and may result in unfavorable outcomes, all or any of which could have a material adverse impact on our financial condition and results of operations, harm our reputation or otherwise negatively impact our business.

We and our major shareholders have been, and may in the future become, subject to claims, litigation, arbitration or investigations arising in or outside the ordinary course of business that could negatively affect our business operations and financial condition. Such claims, litigation, arbitration and investigation proceedings may be brought by third parties, including our partners or collaborators, investors, service providers, competitors, advisors, employees, customers, and governmental or regulatory bodies. For example, as previously disclosed, the Company was party to an arbitration proceeding initiated by Hengrui with respect to a commercialization and co-development agreement with Hengrui. On January 10, 2024, the arbitral tribunal at China International Economic and Trade Arbitration Committee issued a final award, denying all claims made by Hengrui.

The outcome of any claim, litigation, arbitration or investigation, regardless of its merits, is inherently uncertain and may differ substantially from our expectations. Any claim, litigation, arbitration or investigation against the Company, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. In addition, any claim, litigation, arbitration or investigation against our major shareholders, and the disposition of such claims and lawsuits, may divert management attention and resources, limit their ability to influence corporate matters or cause them to make decisions that may not be aligned with the interests of holders of our ordinary shares. We may not be able to determine the amount of any potential losses and other costs we may incur due to the inherent uncertainties of litigation, arbitration and settlement negotiations. In the event we are required or decide to pay amounts in connection with any such proceedings, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operations.

Risks Related to Our Doing Business in China

The current tensions in international economic relations may negatively affect the process of our clinical trials, the cost of our operations and the growth of our business.

Since January 2025, the United States has announced significant new tariffs on imports from a wide range of countries, including China, which was followed by retaliatory tariffs by China and a number of countries and a cycle of further retaliatory tariff announcements and trade actions. Certain of the tariffs have been and may be delayed, but others have taken or may take effect. Further, tariffs announced or imposed by the United States could be altered or delayed through presidential action, bilateral negotiations, judicial orders or congressional action, and tariffs announced or imposed by other countries can be affected by similar developments. It is not clear what impact these tariff negotiations may have or what further actions the governments may take.

In light of existing and future measures, our clinical trials may be affected or delayed. The cost for conducting the clinical trials may also be increased. Similarly, our supply chain for supporting the clinical trials and other research may be negatively affected as well. Moreover, we may face much more uncertainty in receiving regulatory approval or commercializing our product candidates due to the political tensions between the United States and China. Rising political tensions could reduce levels of trades, investments, technological exchanges and other economic activities between the two major economies, which would have a material adverse effect on global economic conditions and the stability of global financial markets. Therefore, our business, financial condition and results of operations, might also be negatively affected, and Sino-U.S. economic and political relations may continue to deteriorate.

It may be difficult for overseas regulators to conduct investigation or collect evidence within China.

Shareholder claims or regulatory investigations that are common in the United States are generally difficult to pursue as a matter of law or practicality in China. For example, in China, there are significant legal and other obstacles to providing information needed for regulatory investigations or litigation initiated outside of China. Although the authorities in China may establish a regulatory cooperation mechanism with the securities regulatory authorities of another country or region to implement cross-border supervision and administration, such cooperation with the securities regulatory authorities in the United States may not be efficient in the absence of a mutual and practical cooperation mechanism. Furthermore, according to Article 177 of the PRC Securities Law, or Article 177, which became effective in March 2020, no overseas securities regulator is allowed to directly conduct investigation or evidence collection activities within the territory of the PRC.

The Provisions on Strengthening the Confidentiality and Archives Administration Related to the Overseas Securities Offering and Listing by Domestic Enterprises, which became effective on March 31, 2023, provides that the investigation and evidence collection in relation to the oversea securities offering and listing of the PRC domestic companies by the overseas securities regulatory authorities and relevant authorities shall be conducted through the cross-border cooperation mechanism for supervision and administration and the domestic companies in mainland China shall obtain the prior consent from the CSRC or relevant authorities before cooperating with such overseas securities regulatory authorities or relevant authorities in connection with relevant inspections or investigations or providing relevant documents to such overseas securities regulatory authorities or relevant authorities. The inability for an overseas securities regulator to directly conduct investigation or evidence collection activities within China may further increase difficulties faced by you in protecting your interests.

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

The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. See "Item 1. Business—Government Regulation—Chinese Regulation" for a discussion of regulatory requirements that are applicable to our current and planned business activities in China. In recent years, the regulatory framework in China regarding the pharmaceutical industry has been subject to change and amendment from time to time, and may continue to do so. Any such changes or amendments may result in increased compliance costs on our business or cause delays in or prevent the successful development or commercialization of our product candidates in China and reduce the current benefits we believe are available to us from developing and manufacturing drugs in China. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and 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. We believe our strategy and approach is aligned with the Chinese government's policies, but we cannot ensure that our strategy and approach will continue to be aligned.

Changes in the political and economic policies of the Chinese government or in relations between China and the United States may materially and adversely affect our business, financial condition, results of operations and the market price of our ordinary shares.

Due to our extensive operations in China, our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in China or changes in government relations between China and the United States or other governments. There is significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, government regulations and tariffs. China's economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources.

While China's economy has experienced significant growth over the past four decades, growth has been uneven across different regions and among various economic sectors. The 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 control over capital investments or changes in tax regulations that are currently applicable to us. In addition, in the past the Chinese government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause decreased economic activity in China, which may adversely affect our business and results of operations.

Additionally, the Chinese government has published new policies that significantly affect 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 our industry that could require us to obtain additional permission from Chinese authorities to continue to operate our business in China, which may adversely affect our business, financial condition and results of operations.

Furthermore, Chinese government have indicated an intent to increase the government's oversight and control over offerings of companies with significant operations in China that are to be conducted in foreign markets. On February 17, 2023, the CSRC promulgated Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies, or the Overseas Listing Trial Measures and relevant five guidelines, which became effective on March 31, 2023. The Overseas Listing Trial Measures comprehensively improves and reforms the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and regulates both direct and indirect overseas offering and listing of PRC domestic companies' securities by adopting a filing-based regulatory regime. The SEC also has imposed enhanced disclosure requirements on China-based companies seeking to register securities with the SEC. Although we do not have a VIE structure, due to our extensive operations in China, any future Chinese, U.S. or other rules and regulations that place restrictions on capital raising or other activities by companies with extensive operations in China could adversely affect our business and results of operations. If the business environment in China deteriorates from the perspective of domestic or international investment, or if relations between China and the United States or other governments deteriorate, the Chinese government may intervene with our operations and our business in China and United States, as well as the market price of our ordinary shares, may also be adversely affected.

Changes in U.S. and Chinese regulations may adversely impact our business, our operating results, our ability to raise capital and the market price of our ordinary shares.

The U.S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or China, including imposing several rounds of tariffs affecting certain products manufactured in China, imposing certain sanctions and restrictions in relation to China and issuing statements indicating enhanced review of companies with significant China-based operations. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the United States or to China, our industry or on us. We conduct clinical activities and have business operations both in the United States and China. Any unfavorable government policies on cross-border relations and/or international trade, including increased scrutiny on companies with significant China-based operations, capital controls or tariffs, may affect the hiring of scientists and other research and development personnel, the import or export of raw materials in relation to drug development, our ability to raise capital, or the market price of our ordinary shares. For example, in 2021, the Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in China, pursuant to which he stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with significant China-based operations. The statement also addressed risks inherent in companies with VIE structures.

There have also been Congressional legislative proposals to discourage contracting with Chinese companies on the development or manufacturing of pharmaceutical products. For example, the BIOSECURE Act was passed as part of the National Defense Authorization Act for Fiscal Year 2026 and prohibits U.S. government contracts, loans and grants being made to any "biotechnology company of concern" or to any entity that uses biotechnology equipment or services from a "biotechnology company of concern", including certain entities in China involved in the manufacturing, distribution, provision, or procurement of a biotechnology equipment or service. If our suppliers or our customers were to be designated under the BIOSECURE Act, this could potentially harm our business and could severely restrict our ability to purchase services or products from, or otherwise collaborate with "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

If any new legislation, executive orders, tariffs, laws and/or regulations are implemented, if existing trade agreements are renegotiated, if the U.S. or Chinese governments take retaliatory actions due to the recent U.S.-China tension or if the Chinese government exerts more oversight and control over securities offerings that are conducted in the United States, such changes could have an adverse effect on our business, financial condition and results of operations, our ability to raise capital and the market price of our ordinary shares.

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

A portion of our operations are conducted in China through our Chinese subsidiaries, and are governed by Chinese laws, rules and regulations. 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.

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

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

Chinese regulations relating to investments in offshore companies by Chinese residents may subject our future Chinese resident beneficial owners or our Chinese subsidiaries to liability or penalties, limit our ability to inject capital into our Chinese subsidiaries or limit our Chinese subsidiaries' ability to increase their registered capital or distribute profits.

The SAFE promulgated the Circular on Relevant Issues concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37, on July 4, 2014. SAFE Circular 37 requires Chinese residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such Chinese residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle." SAFE Circular 37 further requires an amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as an increase or decrease of capital contributed by Chinese individuals, share transfer or exchange, merger, division or other material event. On February 13, 2015, SAFE issued the Circular on Further Simplifying and Improving Foreign Exchange Administration Policy on Direct Investment, effective on June 1, 2015, pursuant to which the power to accept SAFE registration was delegated from local SAFE to local qualified banks where the assets or interest in the domestic entity was located. In the event that a Chinese shareholder holding interests in a special purpose vehicle fails to fulfill the required SAFE registration, the Chinese subsidiaries of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its Chinese subsidiary. Moreover, failure to comply with the various SAFE registration requirements described above could result in liability under Chinese law for evasion of foreign exchange controls.

We believe Mr. Linqing Jia, as one of our shareholders, is a Chinese resident under SAFE Circular 37. Although Mr. Linqing Jia has completed the foreign exchange registration under SAFE Circular 37, we do not have control over him and our other beneficial owners, and our Chinese resident beneficial owners may not have complied with, and may not in the future comply with, SAFE Circular 37 and subsequent implementation rules. The failure of Chinese resident beneficial owners to register or amend their SAFE registrations in a timely manner pursuant to SAFE Circular 37 and subsequent implementation rules, or the failure of future Chinese resident beneficial owners of our company to comply with the registration procedures set forth in SAFE Circular 37 and subsequent implementation rules, may subject such beneficial owners or our Chinese subsidiaries to fines and legal sanctions. Furthermore, SAFE Circular 37 is unclear how this regulation, and any future regulation concerning offshore or cross-border transactions, will be interpreted, amended and implemented by the relevant Chinese government authorities, and we cannot predict how these regulations will affect our business operations or future strategy. Failure to register or comply with relevant requirements may also limit our ability to contribute additional capital to our Chinese subsidiaries and limit our Chinese subsidiaries' ability to distribute dividends to us. These risks could in the future have a material adverse effect on our business, financial condition and results of operations.

Any failure to comply with Chinese regulations regarding our employee equity incentive plans may subject the PRC plan participants or us to fines and other legal sanctions.

We and our directors, executive officers and other employees who are Chinese citizens or who have resided in China for a continuous period of not less than one year and who will be granted restricted shares or options are subject to the Notices on Issues concerning the Foreign Exchange Administration for Domestic Individuals Participating in Share Incentive Plans of Overseas Publicly-Listed Companies, issued by SAFE in February 2012, according to which, employees, directors, supervisors and other management members participating in any share incentive plan of an overseas publicly listed company who are Chinese citizens or who are non-Chinese citizens residing in China for a continuous period of not less than one year, subject to limited exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain other procedures. In addition, an overseas entrusted institution must be retained to handle matters in connection with the exercise or sale of stock options and the purchase or sale of shares and interests. Failure to complete the SAFE registrations may subject them to fines and legal sanctions and may also limit our ability to make payments under our equity incentive plans or receive dividends or sales proceeds related thereto, or our ability to contribute additional capital into our foreign-invested enterprises in China and limit our foreign-invested enterprises' ability to distribute dividends to us. We also face regulatory uncertainties that could restrict our ability to adopt additional equity incentive plans for our directors and employees under Chinese law.

In addition, the SAT, has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in China who exercise share options, or whose restricted shares vest, will be subject to Chinese individual income tax. The Chinese subsidiaries of an overseas listed company have obligations to file documents related to employee share options or restricted shares with relevant tax authorities and to withhold individual income taxes of those employees related to their share options or restricted shares. If the employees fail to pay, or the Chinese subsidiaries fail to withhold applicable income taxes, the Chinese subsidiaries may face sanctions imposed by the tax authorities or other Chinese government authorities.

In the future, we may rely to some extent on dividends and other distributions on equity from our principal operating subsidiaries to fund offshore cash and financing requirements.

We are a holding company, incorporated in the Cayman Islands, and may in the future rely to some extent on dividends and other distributions on equity from our principal operating subsidiaries for our offshore cash and financing requirements, including the funds necessary to pay dividends and other cash distributions to our shareholders, fund inter-company loans, service any debt we may incur outside China and pay our expenses. The laws, rules and regulations applicable to our Chinese subsidiaries and certain other subsidiaries permit payments of dividends only out of their retained earnings, if any, determined in accordance with applicable accounting standards and regulations.

Under Chinese laws, rules and regulations, each of our subsidiaries incorporated in China is required to set aside 10% of its after-tax profits each year to fund certain statutory common reserve funds, until the aggregate amount of such funds reaches 50% of its registered capital. If the statutory common reserve funds are not sufficient to make up its losses in previous years (if any), such subsidiary shall use the profits of the current year to make up the losses before accruing the statutory common reserve funds. At the discretion of the shareholders, it may, after accruing the statutory common reserve funds, allocate a portion of its after-tax profits, based on PRC accounting standards, to discretionary common reserve funds. These statutory common reserve funds and discretionary common reserve funds, together with the registered equity, are not distributable as cash dividends. As a result of these laws, rules and regulations, our subsidiaries incorporated in China are restricted in their ability to transfer a portion of their respective net assets to their shareholders as dividends. In addition, registered share capital and capital reserve accounts are also restricted from withdrawal in China. As of December 31, 2025, these restricted net assets were approximately $12 thousand.

The EIT Law, and its implementation rules, both of which became effective on January 1, 2008 and have been amended certain times thereafter, provide that China-sourced income of foreign enterprises, such as dividends paid by a Chinese subsidiary to its equity holders that are non-Chinese resident enterprises, will normally be subject to Chinese withholding tax at a rate of 10%, unless any such foreign investor's jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. As a result, dividends paid to us by our Chinese subsidiaries are expected to be subject to Chinese withholding tax at a rate of 10%.

Pursuant to the Arrangement between Mainland China and Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with respect to Taxes on Income, or Hong Kong Tax Treaty, BeyondSpring (HK) Limited, or BeyondSpring HK, the shareholder of our Chinese subsidiaries, may be subject to a withholding tax at a rate of 5% on dividends received from our Chinese operating subsidiaries as a Hong Kong tax resident. Pursuant to the Hong Kong Tax Treaty, subject to certain conditions, this reduced withholding tax rate will be available for dividends from Chinese entities provided that the recipient can demonstrate it is a Hong Kong tax resident and it is the beneficial owner of the dividends. BeyondSpring HK currently does not hold a Hong Kong tax resident certificate from the Inland Revenue Department of Hong Kong and the reduced withholding tax rate may not be available.

Furthermore, if our subsidiaries in China incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us as the parent company. Any limitation on the ability of our subsidiaries to distribute dividends or other payments to us as the parent company in the future could materially and adversely limit our ability to make investments or acquisitions that could be beneficial to our businesses, pay dividends or otherwise fund and conduct our business.

We may be treated as a resident enterprise for Chinese tax purposes under the EIT Law and be subject to Chinese tax on our worldwide taxable income at a rate of 25%.

Under the EIT Law, an enterprise established outside China with "de facto management bodies" within China is considered a "resident enterprise," meaning that it is treated in a manner similar to a Chinese enterprise for EIT Law 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, the Notice regarding the Determination of Chinese-Controlled Offshore Incorporated Enterprises as PRC Tax Resident Enterprises on the Basis of De Facto Management Bodies, or Circular 82, specifies that certain Chinese-controlled offshore incorporated enterprises, defined as enterprises incorporated under the laws of foreign countries or territories and that have Chinese 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: senior management personnel and departments that are responsible for daily production, operation and management; financial and personnel decision-making bodies; key properties, accounting books, company seal and minutes of board meetings and shareholders' meetings; and half or more of senior management or directors having voting rights. Although Circular 82 only applies to offshore enterprises controlled by PRC enterprises or PRC enterprise groups, not those controlled by PRC individuals or foreigners, the criteria set forth in the circular may reflect the State Administration of Taxation's general position on how the "de facto management body" text should be applied in determining the tax resident status of all offshore enterprises.

We are not aware of any offshore holding company with a corporate structure similar to ours that has been deemed a Chinese "resident enterprise" by the Chinese tax authorities. Accordingly, we do not believe our company or any of our overseas subsidiaries should be treated as a Chinese resident enterprise.

However, the tax resident status of an enterprise is subject to determination by the PRC tax authorities. If the Chinese tax authorities determine that our Cayman Islands holding company is a resident enterprise for EIT Law purposes, a number of unfavorable Chinese tax consequences could follow and we may be subject to EIT at a rate of 25% on our worldwide taxable income, as well as to EIT reporting obligations. In that case, it is possible that dividends paid to us as the parent company by our Chinese subsidiaries will not be subject to Chinese withholding tax.

Dividends payable to our foreign investors may be subject to Chinese withholding tax and gains on the sale of our ordinary shares by our foreign investors may be subject to Chinese tax.

If we are deemed a Chinese resident enterprise as described under "—We may be treated as a resident enterprise for Chinese tax purposes under the EIT Law and be subject to Chinese tax on our worldwide taxable income at a rate of 25%," dividends paid on our ordinary shares, and any gain realized from the transfer of our ordinary shares, may be treated as income derived from sources within China. As a result, dividends paid to non-Chinese resident enterprise ordinary shareholders may be subject to Chinese withholding tax at a rate of 10% (or 20% in the case of non-Chinese individual ordinary shareholders) and gains realized by non-Chinese resident enterprises ordinary shareholders from the transfer of our ordinary shares may be subject to Chinese tax at a rate of 10% (or 20% in the case of non-Chinese individual ordinary shareholders). It is unclear whether if we or any of our subsidiaries established outside China are considered a Chinese resident enterprise, holders of our ordinary shares would be able to claim the benefit of income tax treaties or agreements entered into between China and other countries or areas. If dividends payable to our non-Chinese investors, or gains from the transfer of our ordinary shares by such investors are subject to Chinese tax, the value of your investment in the ordinary shares may decline significantly.

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

On February 3, 2015, the SAT issued the Bulletin on Issues of Enterprise Income Tax regarding Indirect Transfers of Assets by Non-PRC Resident Enterprises, or Bulletin 7. Pursuant to this Bulletin 7.Pursuant to Bulletin 7, an "indirect transfer" of PRC assets, excluding the transfer of PRC assets by a non-PRC resident enterprise from the purchase and sale of equities of the same listed overseas enterprise on the public market, by non-PRC resident enterprises may be re-characterized and treated as a direct transfer of the underlying PRC 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, and the transferee or other person who is obligated to pay for the transfer is obligated to withhold the applicable taxes.

On October 17, 2017, the State Administration of Taxation issued the Announcement of the State Administration of Taxation on Issues Concerning the Withholding of Non-resident Enterprise Income Tax at Source, or Bulletin 37, which came into effect on December 1, 2017 and was most-recently amended on June 15, 2018. Bulletin 37 further clarifies the practice and procedure of the withholding of nonresident enterprise income tax.

We face uncertainties on the reporting and consequences of potential future private equity financing transactions, share exchanges or other transactions involving the transfer of shares in our company by our non-PRC resident holding enterprise shareholders. The PRC tax authorities may pursue such non-resident enterprises with respect to a filing or the transferees with respect to withholding obligation, and request our PRC subsidiaries to assist in the filing. As a result, we and non-resident enterprises in such transactions may become at risk of being subject to filing obligations or being taxed under Bulletin 7 and Bulletin 37, and may be required to expend valuable resources to comply with them or to establish that we and our non-resident enterprises should not be taxed under these regulations, which may have a material adverse effect on our financial condition and results of operations.

There are uncertainties as to the application of Bulletin 7. Bulletin 7 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 Chinese subsidiaries may be requested to assist in the filing. Furthermore, we, our non-resident enterprises and Chinese subsidiaries may be required to spend valuable resources to comply with Bulletin 7 or to establish that we and our non-resident enterprises should not be taxed under Bulletin 7 and Bulletin 37, 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 Chinese tax authorities have the discretion under Bulletin 7 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 Chinese tax authorities make adjustments to the taxable income of the transactions under Bulletin 7 / Bulletin 37, 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.

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

The Chinese government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of China. A portion of our revenue may in the future be denominated in RMB. Shortages in availability of foreign currency may then restrict the ability of our Chinese 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 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 Chinese subsidiaries, which are foreign-invested enterprises, may purchase foreign currency for settlement of "current account transactions," without the approval of SAFE, by complying with certain procedural requirements. However, the relevant Chinese governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. Since a portion of our future revenue may be denominated in RMB, any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of China or pay dividends in foreign currencies to our shareholders, including holders of our ordinary shares. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant Chinese governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for our subsidiaries.

Recent litigation and negative publicity surrounding China-based companies listed in the U.S. may result in increased regulatory scrutiny of us and negatively impact the trading price of our ordinary shares and could have a material adverse effect upon our business, including its results of operations, financial condition, cash flows and prospects.

We believe that litigation and negative publicity surrounding companies with operations in China that are listed in the U.S. have negatively impacted stock prices for such companies. Various equity-based research organizations have published reports on China-based companies after examining, among other things, their corporate governance practices, related party transactions, sales practices and financial statements that have led to special investigations and stock suspensions on national exchanges. Any similar scrutiny of us, regardless of its lack of merit, could result in a diversion of management resources and energy, potential costs to defend ourselves against rumors, decreases and volatility in our ordinary share trading price, and increased directors and officers' insurance premiums and could have a material adverse effect upon our business, including its results of operations, financial condition, cash flows and prospects.

Historically, there has been legislation implemented which put our ordinary shares at risk of potential delisting. The delisting or the cessation of trading in the United States of our ordinary shares, or the threat of their being delisted or prohibited, may materially and adversely affect the value and/or liquidity of your investment.

The Holding Foreign Companies Accountable Act, or the HFCAA, was enacted on December 18, 2020. The HFCAA states that if the SEC determines that 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, the SEC shall prohibit the securities of the issuer from being traded on a national securities exchange or in the over the counter trading market in the United States.

On December 16, 2021, the PCAOB issued a report to notify the SEC of its determination that the PCAOB was unable to inspect or investigate completely registered public accounting firms headquartered in mainland China and Hong Kong, and our former auditor was subject to that determination. In May 2022, the SEC conclusively listed us as a Commission-Identified Issuer under the HFCAA following the filing of our annual report on Form 20-F for the fiscal year ended December 31, 2021. On December 15, 2022, the PCAOB removed mainland China and Hong Kong from the list of jurisdictions where it is unable to inspect or investigate completely registered public accounting firms. Our current auditor since April 9, 2025, CBIZ CPAs P.C., or CBIZ, as an auditor of companies that are traded publicly in the United States and a firm registered with the PCAOB, is subject to laws in the United States pursuant to which the PCAOB conducts regular inspections to assess its compliance with the applicable professional standards. CBIZ is headquartered in Cleveland, Ohio. CBIZ was not included in the list of PCAOB Identified Firms in the PCAOB Determination Report issued in December 2021, and was inspected by the PCAOB on a regular basis. For this reason, we do not expect to be identified as a Commission-Identified Issuer under the HFCAA.

However, if the PCAOB determines in the future that it no longer has full access to inspect and investigate completely accounting firms in mainland China and Hong Kong, and we use an accounting firm headquartered in one of these jurisdictions to issue an audit report on our financial statements filed with the SEC, we would be identified as a Commission-Identified Issuer following the filing of the annual report on Form 10-K for the relevant fiscal year. In accordance with the HFCAA, our ordinary shares would be prohibited from being traded on a national securities exchange or in the over-the-countertrading market in the United States if we are identified as a Commission-Identified Issuer for two consecutive years in the future. If our ordinary shares are prohibited from trading in the United States, there is no certainty that we will be able to list on a non-U.S. exchange or that a market for our ordinary shares will develop outside of the United States.

In addition, if the PCAOB were unable to conduct full inspections or investigations of our auditor in the future, we and investors in our ordinary shares would be deprived of the benefits of such PCAOB inspections. The inability of the PCAOB to conduct full inspections or investigations of auditors would make it more difficult to evaluate the effectiveness of our independent registered public accounting firm's audit procedures or quality control procedures as compared to auditors that are subject to the PCAOB inspections, which could cause investors and potential investors to lose confidence in the audit procedures and reported financial information and the quality of our financial statements.

If additional remedial measures are imposed on the "big four" PRC-based accounting firms in administrative proceedings brought by the SEC alleging such firms' failure to meet specific criteria set by the SEC with respect to requests for the production of documents, the market price of our ordinary shares may be materially and adversely affected.

In December 2012, the SEC brought administrative proceedings against five accounting firms in China, which do not include our independent registered public accounting firm, alleging that they had refused to produce audit work papers and other documents related to certain other China-based companies under investigation by the SEC. On January 22, 2014, an initial administrative law decision was issued, censuring these accounting firms and suspending four of these firms from practicing before the SEC for a period of six months. The decision is neither final nor legally effective unless and until reviewed and approved by the SEC. On February 12, 2014, four of these China-based accounting firms appealed to the SEC against this decision. In February 2015, each of the four China-based accounting firms agreed to a censure and to pay a fine to the SEC to settle the dispute and avoid suspension of their ability to practice before the SEC. These firms' ability to continue to serve all their respective clients is not affected by the settlement. The settlement requires these firms to follow detailed procedures to seek to provide the SEC with access to Chinese firms' audit documents via the CSRC. Under the terms of the settlement, the underlying proceeding against the four China-based accounting firms was deemed dismissed with prejudice four years after entry of the settlement. The four-year mark occurred on February 6, 2019.

While we cannot predict if the SEC will further challenge the four China-based accounting firms' compliance with U.S. law in connection with U.S. regulatory requests for audit work papers or if the results of such a challenge would result in the SEC imposing penalties such as suspensions, if the SEC restarts the administrative proceedings, depending upon the final outcome, listed companies in the U.S. with major Chinese operations may find it difficult or impossible to retain auditors with respect to their operations in China, which could result in financial statements being determined not to be in compliance with the requirements of the Exchange Act, including possible delisting. Moreover, any negative news about the proceedings against these audit firms may cause investor uncertainty regarding China-based, U.S.-listed companies and the market price of our ordinary shares may be adversely affected.

In the past, we had engaged certain China affiliates of one of the "big four" accounting firms as our independent registered public accounting firm. If, in the future, we engage a China affiliate of one of the "big four" accounting firms as our independent registered public accounting firm, and such firm was denied, even temporarily, the ability to practice before the SEC and we were unable to timely find another registered public accounting firm to audit and issue an opinion on our financial statements, our financial statements could be determined not to be in compliance with the requirements of the Exchange Act. Such a determination could ultimately lead to delisting of our ordinary shares from the Nasdaq Capital Market or deregistration from the SEC, or both, which would substantially reduce or effectively terminate the trading of our ordinary shares in the U.S. All these would materially and adversely affect the market price of our ordinary shares and substantially reduce or effectively terminate the trading of our ordinary shares in the U.S.

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

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

Regulatory authorities in China have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the Cyber Security Law of the PRC, or the Cyber Security Law, which became effective in June 2017 and amended in October 2025, created China's first national-level data protection regime for "network operators," which may include all organizations in China that provide services over the internet or another information network.

We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in China. We do, however, collect and maintain de-identified or pseudonymized health data for clinical trials in compliance with local regulations. These data could be deemed as personal data or important data. 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 Cyber Security Law, the Data Security Law (as defined below), the Personal Information Protection Law (as defined below), and various implementing regulations and standards.

In addition, the SCNPC, promulgated the Data Security Law of the People's Republic of China, or the Data Security Law, on June 10, 2021, which became effective on September 1, 2021. The Data Security Law imposes data security and privacy obligations on entities and individuals carrying out data processing activities, and introduces a data classification and hierarchical protection system. 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 legitimate rights and interests of individuals or organizations if such data is tampered with, destroyed, leaked, or illegally acquired or used. The security assessment mechanism was also included in the Personal Information Protection Law, or the Personal Information Protection Law, which was promulgated in August 2021 and became effective on November 1, 2021, for the Chinese government to supervise certain cross-border transfers of personal information.

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 will need to classify and take appropriate measures to address risks created by our data processing activities and use of networks. We will be obligated to notify affected individuals and appropriate Chinese regulators of and respond to any data security and network security incidents. Establishing and maintaining such systems takes substantial time, effort and cost, and we may not be able to establish and maintain such systems fully as needed to ensure compliance with our legal obligations. Despite our investment, such systems may not fully guard us or enable us to appropriately respond to or mitigate all data security and network security risks or incidents we 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. 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 China with judicial and law enforcement authorities outside of China. If judicial and law enforcement authorities outside China require us to provide data stored in 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 foreign authorities' requirements. The potential conflicts in legal obligations could have adverse impact on our operations in and outside of China.

The national security legal regime imposes stricter data localization requirements on personal information and human health-related data and requires us to undergo cybersecurity or other security review, obtain government approval or certification, or put in place certain contractual protections before transferring personal information and human health-related data out of China. As a result, personal information, important data and health and medical data that we or our customers, vendors, clinical trial sites, pharmaceutical partners and other third parties collect, generate or process in China may be subject to such data localization requirements and heightened regulatory oversight and controls. To comply with these requirements, maintaining local data centers in China, conducting security assessments or obtaining the requisite approvals from the Chinese government for the transmission outside of China of such controlled information and data could significantly increase our operating costs or cause delays or disruptions in our business operations in and outside China. We expect that the evolving regulatory interpretation and enforcement of the national security legal regime will lead to increased operational and compliance costs and will require us to continually monitor and, where necessary, make changes to our operations, policies, and procedures. If our operations, or the operations of our CROs, licensees or partners, are found to be in violation of these requirements, we may suffer loss or use of data, suffer a delay in obtaining regulatory approval for our products, be unable to transfer data out of Mainland China, be unable to comply with our contractual requirements, suffer reputational harm or be subject to penalties, including administrative, civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. If any of these were to occur, it could adversely affect our ability to operate our business and our financial results.

The General Office of the State Council passed the Scientific Data Administrative Measures in March 2018, which provides a regulatory framework for the collection, submission, retention, exploitation, confidentiality and security of scientific data. Scientific data is defined as data generated from basic research, applied research, experiments and developments in the fields of natural sciences, engineering and technology. It also includes the original and derived data by means of surveillance, monitoring, field studies, examination and testing that are used in scientific research activities. All scientific data generated by research entities, including research institutions, higher education institutions and enterprises that is created or managed with government funds, or funded by any source that concerns state secrets, national security, or social and public interests, must be submitted to data centers designated by the Chinese government for consolidation. Disclosure of scientific data will be subject to regulatory scrutiny.

The definition of scientific data is quite broad, but the Chinese government has not issued further guidance to clarify if clinical study data would fall within the definition of scientific data. To our understanding, the Chinese government has not required life sciences companies to upload clinical study data to any government-designated data centers, or prevented the cross-border transmission and sharing of clinical study data. We plan to closely monitor legal and regulatory developments in this area to see how scientific data is interpreted, and we may be required to comply with additional regulatory requirements for sharing clinical study data with our licensors or foreign regulatory authorities, although the scope of such requirements, if any, is currently unknown.

In addition, certain industry-specific laws and regulations affect the collection and transfer of personal data in China. For example, the Regulation on the Administration of Human Genetic Resources, or the HGR Regulation, promulgated by the State Council, which became effective on July 1, 2019 and revised in 2024, applies to activities that involve collection; biobanking; use of HGR, which includes the genetic materials with respect to organs, tissues, cells and other materials that contain the human genome, genes and other genetic substances, or the China Biospecimens; and derived data, in China (together with the China Biospecimens, the "China-Sourced HGR"), and provision of such items to foreign parties. The HGR Regulation prohibits both onshore and offshore entities established or actually controlled by foreign entities and individuals from collecting or biobanking any China-Sourced human generic resources, or HGR, in China, as well as providing such China-Sourced HGR out of China. Chinese parties are required to seek an advance approval for the collection of certain HGR and biobanking of all HGR. Approval for any export or cross-border transfer of China Biospecimens is required, and transfer of derived data by Chinese parties to foreign parties or entities established or actually controlled by them also requires the Chinese parties to file, before the transfer, a copy of the data with the health department of the State Council, for record. The HGR Regulation also requires that foreign parties ensure the full participation of Chinese parties in international collaborations and share all records and data with the Chinese parties.

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, we may lose our confidential information and be subject 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 delays in the initiation of new trials, confiscation of China-Sourced HGR, administrative fines, disgorgement of illegal gains or temporary or permanent debarment of our or our collaborators' entities and responsible persons from further clinical trials and, consequently, a de-facto ban on the debarred entities from initiating new clinical trials in China. So far, the HGRAO has disclosed a number of HGR violation cases. In one case, the sanctioned party was the Chinese subsidiary of a multinational pharmaceutical company that was found to have illegally transferred certain biospecimens to CROs for conducting certain unapproved research. In addition to a written warning and confiscation of relevant HGR materials, the Chinese subsidiary of the multinational pharmaceutical company was requested by the HGRAO to take rectification measures and was also banned by the HGRAO from submitting any clinical trial applications until the HGRAO was satisfied with the rectification results, which rendered it unable to initiate new clinical trials in China until the ban was lifted. In another case, the CRO engaged by the Chinese subsidiary of a multi-national pharmaceutical company was found to have forged an ethics committee approval in order to accelerate the HGRAO approval. Both the Chinese subsidiary of the multi-national pharmaceutical company and the CRO were debarred from initiating new applications for a period of six to 12 months, respectively.

To further tighten the control of China HGR, the SCNPC issued the Eleventh Amendment to the Criminal Law of the People's Republic of China on December 26, 2020, which became effective on March 1, 2021, criminalizing the illegal collection of China-Sourced HGR, the illegal transfer of China-sourced biospecimens outside of China. An individual who is convicted of any of these violations may be subject to public surveillance, criminal detention, a fixed-term imprisonment of up to seven years and/or a criminal fine. In October 2020, the SCNPC adopted the Biosecurity of the People's Republic of China, or the PRC Biosecurity Law, which became effective on April 15, 2021 and revised in 2024. The PRC Biosecurity Law established an integrated system to regulate biosecurity-related activities in China, including, among others, the security regulation of HGR and biological resources. The PRC Biosecurity Law for the first time expressly declares that China has sovereignty over its HGR, and further endorsed the HGR Regulation by recognizing the fundamental regulatory principles and systems established by it over the utilization of China-Sourced HGR by foreign entities in China. Though the PRC Biosecurity Law does not provide any specific new regulatory requirements on HGR, as it is a law adopted by China's highest legislative authority, it gives China's major regulator of HGR, the health department of the State Council, significantly more power and discretion to regulate HGR and it is expected that the overall regulatory landscape for China-Sourced HGR will evolve and become even more rigorous and sophisticated. In addition, the interpretation and application of data protection laws in China and elsewhere are often uncertain and in flux.

In addition, in the United States, at both the federal and state levels, and in territories outside of Mainland China where we have rights to and plan to develop and commercialize our in-licensed product candidates, including Hong Kong, Macau, Singapore, South Korea, Taiwan and Thailand, we are subject to laws and regulations that address privacy, personal information protection and data security. Numerous laws and regulations, including security breach notification laws, health information privacy laws and consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information. Given the variability and evolving state of these laws, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by regulators or courts in their interpretation.

We expect that these data protection and transfer laws and regulations will receive greater attention and focus from regulators going forward, and we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under data protection, privacy and security laws in China, the United States and other countries where we plan or conduct business will be sufficient.

Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, result in the suspension of ongoing clinical trials or ban on initiation of new trials, require us to change our business practices, increase our costs and materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical partners and other third parties could be negatively affected by any proceedings or actions against us or current or future data protection obligations imposed on them under applicable law, including the European Union General Data Protection Regulation, Cyber Security Law and HGR Regulation. In addition, a data breach affecting personal information, including health information, or a failure to comply with applicable requirements could result in significant management resources, legal and financial exposure and reputational damage that could potentially have a material adverse effect on our business and results of operations. Moreover, the legal uncertainty created by the Data Security Law and the recent Chinese government actions could materially adversely affect our ability, on favorable terms, to raise capital, including engaging in follow-on offerings of our securities in the U.S. market. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations.

The approval of or filing with the CSRC or other PRC government authorities may be required in connection with our offshore offerings under PRC law, and, if required, we cannot predict whether or for how long we will be able to obtain such approval.

On February 17, 2023, CSRC promulgated Trial Administrative Measures of the Oversea s Securities Offering and Listing by Domestic Companies, or the Overseas Listing Trial Measures and relevant five guidelines, which became effective on March 31, 2023. The Overseas Listing Trial Measures comprehensively improves and reforms the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and regulates both direct and indirect overseas offering and listing of PRC domestic companies' securities by adopting a filing-based regulatory regime. According to the Overseas Listing Trial Measures, any of our offering and listing in an overseas market in future may be subject to the filing with the CSRC.

According to the Overseas Listing Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information.

The Overseas Listing Trial Measures provides that if the issuer meets the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by PRC domestic companies: (i) 50% or more of any of the issuer's operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the main parts of the issuer's business activities are conducted in mainland China, or its main place(s) of business are located in mainland China, or the majority of senior management staff in charge of its business operations and management are PRC citizens or have their usual place(s) of residence located in mainland China.

Furthermore, according to the Overseas Listing Trial Measures, if a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, such domestic company may be subject to administrative penalties, such as order to rectify, warnings, fines, and its controlling shareholders, actual controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines.

On February 17, 2023, CSRC also issued the Notice on Administration for the Filing of Overseas Offering and Listing by Domestic Companies, which, among others, provided that the domestic companies that have already been listed overseas on or before the effective date of the Overseas Listing Trial Measures (i.e. March 31, 2023) shall be deemed as existing issuers, or the Existing Issuers. Existing Issuers are not required to complete the filling procedures immediately, and they shall be required to file with the CSRC when subsequent matters such as refinancing are involved.

Furthermore, according to the Negative List promulgated by the MOFCOM and the NDRC that became effective on November 1, 2024, domestic enterprises engaged in activities in any field prohibited from foreign investment under the Negative List shall be subject to review and approval by the relevant authorities of the PRC when listing and trading overseas. If it is determined that any approval, filing or other administrative procedure from the CSRC or other PRC governmental authorities is required for any future offering or listing, we cannot assure that we can obtain the required approval or accomplish the required filings or other regulatory procedures in a timely manner, or at all. If we fail to obtain the relevant approval or complete the filings and other relevant regulatory procedures, we may face sanctions by the CSRC or other PRC regulatory agencies, which may include fines and penalties on our operations in China, limitations on our operating privileges in China, restrictions on or prohibition of the payments or remittance of dividends by our subsidiaries in China, or other actions that could have a material and adverse effect on our business, financial condition, results of operations, reputation and prospects, as well as the trading price of our ordinary shares. The CSRC or other PRC regulatory authorities also may take actions requiring us, or making it advisable for us, to halt our offerings before settlement and delivery of the shares offered. Consequently, if investors engage in market trading or other activities in anticipation of and prior to settlement and delivery, they do so at the risk that settlement and delivery may not occur. In addition, if the CSRC or other regulatory authorities later promulgate new rules or explanations requiring that we obtain their approvals or accomplish the required filing or other regulatory procedures for our prior offshore offerings, we may be unable to obtain a waiver of such approval requirements, if and when procedures are established to obtain such a waiver. Any uncertainties or negative publicity regarding such approval requirement could materially and adversely affect our business, prospects, financial condition, reputation, and the trading price of our ordinary shares.

Risks Related to Our Ordinary Shares

The trading prices of our ordinary shares are likely to be volatile, which could result in substantial losses to you.

The trading price of our ordinary shares is likely to be volatile and could fluctuate widely in response to a variety of factors, many of which are beyond our control. In addition, the performance and fluctuation of the market prices of other companies with business operations located mainly in China that have listed their securities in the U.S. may affect the volatility in the price of and trading volumes for our ordinary shares. Some of these companies have experienced significant volatility. The trading performances of these Chinese companies' securities at the time of or after their offerings may affect the overall investor sentiment towards other Chinese companies listed in the U.S. and consequently may impact the trading performance of our ordinary shares.

In addition to market and industry factors, the price and trading volume for our ordinary shares may be highly volatile for specific business reasons, including:

- announcements of regulatory approval or a complete response letter, or specific label indications or patient populations for the use of our product candidates, or changes or delays in the regulatory review process;
- announcements of therapeutic innovations or new products 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 product candidates;
- variations in the level of expenses related to our existing product candidates or preclinical studies and clinical trials;
- any intellectual property infringement actions in which we may become involved;
- announcements concerning our competitors or the pharmaceutical industry in general;
- achievement of expected product sales and profitability;
- manufacturing, supply or distribution shortages;
- variations in our results of operations;
- announcements about our earnings that are not in line with analyst expectations;
- publication of operating or industry metrics by third parties, including government statistical agencies, that differ from expectations of industry or financial analysts;
- research reports and changes in financial estimates by securities research analysts;
- announcements made by us or our competitors of new product and service offerings, acquisitions, sales, strategic relationships, joint ventures or capital commitments;
- press reports, whether or not true, about our business;
- additions to, or departures of, our management;
- fluctuations of exchange rates between the RMB and the U.S. dollar;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares;
- sales or perceived potential sales of additional ordinary shares;
- sales of our ordinary shares by us, our executive officers and directors or our shareholders in the future;
- general economic and market conditions and overall fluctuations in the U.S. equity markets;
- changes in accounting principles; and
- changes or developments in the Chinese or global regulatory environment.

Any of these factors may result in large and sudden changes in the volume and trading price of our ordinary shares. In the past, following periods of volatility in the market price of a company's securities, shareholders have often instituted securities class action litigation against that company. If we are involved in a class action suit, it could divert the attention of management, and, if adversely determined, have a material adverse effect on our financial condition and results of operations.

In addition, the stock market, in general, and small pharmaceutical and biotechnology companies 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, regardless of our actual operating performance. Further, factors related to financial markets beyond our control may cause our ordinary shares price to decline rapidly and unexpectedly.

Sales or the availability for sales of substantial amounts of our ordinary shares in the public market could cause the price of our ordinary shares to decline significantly.

Sales of our ordinary shares or other equity securities in the public market, or the perception that these sales could occur, could cause the market price of our ordinary shares to decline significantly. As of February 27, 2026, we had 41,119,820 ordinary shares outstanding. Among these shares, 19,423,295 ordinary shares have been registered under the Securities Act and are freely transferable by persons other than our "affiliates" without restriction or registration; the remaining shares outstanding have not been registered under the Securities Act and may be offered or sold only pursuant to an effective registration statement or pursuant to an available exemption from the registration requirements. If these shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ordinary shares could decline.

Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ordinary 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 as a source for any future dividend income.

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

We are a Cayman Islands exempted company. Because judicial precedent regarding the rights of shareholders is more limited under Cayman Islands law than under U.S. law, shareholders may have fewer shareholder rights than they would have under U.S. law.

Our corporate affairs are governed by, among other things, our amended and restated memorandum and articles of association (as may be amended from time to time), the Companies Act (As Revised) of the Cayman Islands and the common law of the Cayman Islands, or the Companies Act. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, the decisions of those courts are persuasive, but not binding, on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are not as clearly established as they would be under statutes or judicial precedent in some jurisdictions in the U.S. In particular, the Cayman Islands has a less developed body of securities law than the U.S. Some states in the U.S., such as Delaware, have more fully developed and judicially interpreted bodies of corporate law than the Cayman Islands. In addition, Cayman Islands companies may not have standing to initiate a shareholder derivative action in a federal court of the United States.

In addition, as shareholders of a Cayman Islands exempted company, our shareholders have no general rights under Cayman Islands law to inspect corporate records (other than the memorandum and articles of association, our register of mortgages and charges and special resolutions passed by our shareholders), or to obtain a copy of our register of members. Under Cayman Islands law, the names of current directors can be obtained from a search conducted at the Registrar of Companies in the Cayman Islands. Our directors have discretion under our amended and restated articles of association to determine whether or not, and under what conditions, our corporate records may be inspected by our shareholders, but are not obliged to make them available to our shareholders. This may make it more difficult for you to obtain the information needed to establish any facts necessary for a shareholder motion or to solicit proxies from other shareholders in connection with a proxy contest. As a Cayman Islands exempted company, we may not have standing to initiate a derivative action in a federal court of the U.S. As a result, you may be limited in your ability to protect your interests if you are harmed in a manner that would otherwise enable you to sue in a U.S. federal court. In addition, shareholders of Cayman Islands companies may not have standing to initiate a shareholder derivative action in U.S. federal courts.

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

You may face difficulties in protecting your interests, and your ability to protect your rights through the U.S. federal courts may be limited because we are incorporated under Cayman Islands law, and some of our directors reside outside the U.S.

We are incorporated as an exempted company in the Cayman Islands. Some of our directors reside outside the U.S. and a substantial portion of their assets are located outside of the U.S. As a result, it may be difficult or impossible for you to bring an action against us or against these individuals in the Cayman Islands or in China in the event that you believe that your rights have been infringed under the securities laws of the U.S. or otherwise. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands and China may render you unable to enforce a judgment against our assets or the assets of our directors and officers. There is no statutory recognition in the Cayman Islands of judgments obtained in the U.S. or China, although the courts of the Cayman Islands will generally recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial of the merits of the underlying disputes based on the principle that a judgment of a competent foreign court imposes upon a judgment debtor an obligation to pay the sum for which judgment has been given, provided that such judgment (i) is given by a foreign court of competent jurisdiction; (ii) imposes on the judgment debtor a liability to pay a liquidated sum for which the judgment has been given; (iii) is final and conclusive; (iv) is not in respect of taxes, a fine or penalty; and (v) is not inconsistent with a Cayman Islands judgment in respect of the same manner, impeachable on the grounds of fraud and is not obtained in a manner and is not of a kind the enforcement of which is contrary to natural justice or the public policy of the Cayman Islands.

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

Our directors, executive officers and shareholders holding more than 10% of our ordinary shares beneficially owned approximately 18.17% of our ordinary shares as of February 27, 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. These actions may be taken even if they are opposed by our other shareholders, including the holders of our ordinary shares. In addition, these persons could divert business opportunities away from us to themselves or others.

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices. In addition, the loss of foreign private issuer status will result in significant additional costs and expenses.

As a public company, we incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives.

Under Section 404 of the Sarbanes-Oxley Act, we are required to furnish a report by our management on our internal control over financial reporting in connection with this Annual Report on Form 10-K. However, while we remain a non-accelerated filer, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 of the Sarbanes-Oxley Act, we have engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, we may not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. See "Item 1A. Risk Factors—Risks Related to Our Industry, Business and Operation—If we fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our ordinary shares."

In addition, as of January 1, 2025, we have lost our status as a "foreign private issuer," as defined in the SEC's rules and regulations and, consequently, we are now subject to all of the disclosure requirements applicable to public companies organized within the U.S. For example, we are required to comply with the rules under the Exchange Act that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act, including the U.S. proxy rules under Section 14 of the Exchange Act. In addition, our officers and directors need to comply with the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are required to file quarterly reports on Form 10-Q and current reports on Form 8-K under the Exchange Act. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer are expected to be significantly more than the costs we incurred as a foreign private issuer.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant share price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We may be a passive foreign investment company ("PFIC"), for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences for our U.S. shareholders.

A non-U.S. corporation such as the Company will be classified as a PFIC for U.S. federal income tax purposes for any taxable year if either: (i) 75% or more of its gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income. Whether we are a PFIC for a given taxable year is a factual determination that is made on an annual basis after the close of such taxable year. This determination will depend on, among other things, the composition of our income and assets, as well as the value of our assets (which generally will be determined by reference to the public price of our ordinary shares, which may fluctuate significantly), from time to time.

Based on the current and anticipated composition of our income, assets and operations and the price of our ordinary shares, we believe that it is likely that we were not a PFIC for U.S. federal income tax purposes for the taxable year that ended December 31, 2025. However, we have been classified as a PFIC in prior years and may again be classified as a PFIC in the future, which could result in adverse U.S. federal income tax consequences for our U.S. shareholders. Our PFIC status for the current taxable year ending December 31, 2026, will not be determinable until after the close of the taxable year. There can be no assurance that we will not be a PFIC for any taxable year.

If we are a PFIC for any taxable year during which U.S. shareholders hold our ordinary shares, such U.S. shareholders could be subject to adverse U.S. federal income tax consequences, including having gains realized on the sale of our ordinary shares treated as ordinary income, rather than as capital gains, in the case of U.S. shareholders who are individuals, losing the preferential rate applicable to dividends received on our ordinary shares, and having interest charges apply to distributions by us and the proceeds of sales of our ordinary shares. Additionally, if we are a PFIC for any taxable year during which U.S. shareholders hold our ordinary shares, we would generally continue to be treated as a PFIC with respect to such U.S. shareholders even if we do not satisfy either of the above tests to be classified as a PFIC in a subsequent year. See "Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities —Taxation—U.S. Federal Income Tax Considerations."

The Internal Revenue Service ("IRS") may not agree with the conclusion that we should not be treated as a U.S. corporation for U.S. federal income tax purposes.

Under current U.S. federal income tax law, a corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation. Thus, as a corporation incorporated under the laws of the Cayman Islands, we should generally be classified as a non-U.S. corporation (and therefore as a non-U.S. tax resident) for U.S. federal income tax purposes. In certain circumstances, however, under section 7874 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation organized outside the United States will be treated as a U.S. corporation (and, therefore, as a U.S. tax resident).

In July of 2015, we completed our internal restructuring. Based on the rules in effect at the time of the internal restructuring, we believe that the internal restructuring did not result in us being treated as a U.S. corporation for U.S. federal income tax purposes by virtue of section 7874 of the Code. Nevertheless, because the section 7874 rules and exceptions are complex and subject to factual and legal uncertainties, there can be no assurance that we will not be treated as a U.S. corporation for U.S. federal income tax purposes. See "Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities —Taxation—U.S. Federal Income Tax Considerations—Tax Residence of BeyondSpring Inc. for U.S. Federal Income Tax Purposes."

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

Risk Management and Strategy

As an active participant in the biopharmaceutical industry, our company operates within a landscape fraught with diverse cybersecurity risks. These risks have the potential to significantly impact our business, financial standing, and operational outcomes.

Our partnership with a trusted third-party service provider stands as a pivotal pillar in our cybersecurity strategy. Leveraging their expertise, they have crafted and implemented 58 automated lockdown policies, each strategically designed to create safeguards around our digital infrastructure. These policies serve as a sophisticated array of safeguards, actively working to thwart potential breaches before they can even manifest. Moreover, their commitment to our security extends to continuous monitoring measures that operate round-the-clock. This proactive surveillance ensures that any anomalies or suspicious activities are swiftly identified and addressed, minimizing the window of vulnerability.

Complementing this arsenal is the deployment of an EDR (Endpoint Detection and Response) agent, a cutting-edge technology that places us at the forefront of cybersecurity innovation. This agent is not merely a passive observer; it is our vigilant sentinel, constantly scanning and analyzing our network for any aberrations or patterns indicative of cyber threats. Through real-time monitoring, it provides us with invaluable insights into our system's health, promptly flagging any deviations from the norm.

Within our own operations, we uphold a culture of uncompromising security standards. To enhance access controls, we have implemented robust multifactor authentication methods for all personnel accessing our SharePoint and Outlook software. This additional layer of authentication not only bolsters our defenses but also ensures that only authorized individuals can gain entry to sensitive information. Moreover, our stringent email sign-in blocking policy exemplifies our proactive stance towards security. This policy is particularly pivotal during employee transitions, where the potential for security lapses is heightened. Upon an employee's departure, our Outlook administrators promptly deactivate their email sign-in functionalities, mitigating any risks associated with unauthorized access. These measures collectively form a cohesive and dynamic security framework, safeguarding our assets and ensuring the integrity of our operations in an increasingly digital landscape.

Governance

The Board of Directors oversees risks stemming from cybersecurity threats. Their strategic guidance and informed decisions serve as the cornerstone of our cybersecurity framework. Complementing this oversight, our third-party IT vendor plays a pivotal role in the implementation of comprehensive company-wide cybersecurity policies. Beyond this, they are entrusted with the deployment and management of critical protective software, serving as our frontline defenders against evolving cyber threats. To ensure seamless communication and swift action, they maintain a direct reporting line to the company's IT administrator. This structured reporting mechanism enables prompt notification and collaborative response to any detections or anomalies, fostering a proactive and vigilant stance towards safeguarding our digital assets and operations.

Item 2. Properties.

We currently lease office space in New Jersey, with total space of 9,727 square feet. The lease expires in February 2027. Our current rent is $26,344 per month. Starting in August 2026, our annual rent will increase by $0.50 per square foot leased. We additionally pay for the cost of utilities, as well as our share of building real estate taxes and building operating expenses. Payments under the lease are expensed on a straight-line basis over the period of the lease.

We lease office space in Dalian, China, with total space of 210.65 square meters and a monthly rent of RMB 10,252 (approximately $1,466). The lease expires on December 31, 2027. Payments under the lease are expensed on a straight-line basis over the period of the lease.

SEED currently leases permanent office space and lab space in Pennsylvania, with a total space of approximately 10,086 square feet. Its current rent is $41,327 per month. Starting in June 2026, SEED's annual rent will increase by 3%. SEED additionally pays for the cost of its utilities, as well as its proportionate share of building real estate taxes, and building operating expenses, and has paid approximately $0.9 million for improvements to the leased property on behalf of the lessor. Payments under the lease are expensed on a straight-line basis over the period of the lease. Additionally, SEED has also purchased lab equipment of approximately $1.9 million as of December 31, 2025.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows. 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.

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 ordinary shares have been listed on the Nasdaq Capital Market since March 9, 2017 under the symbol "BYSI."

Holders

As of February 27, 2026, we had approximately 70 holders of record of our ordinary shares. These numbers do not include beneficial owners whose ordinary shares are held by nominees in street name. Because many ordinary shares are held by broker nominees, we are unable to estimate the total number of beneficial holders represented by these record holders.

Dividends

We have never declared or paid cash dividends to our shareholders, and we do not intend to pay cash dividends in the foreseeable future. We intend to reinvest any earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

See "Item 1A. Risk Factors—Risks Related to Our Ordinary Shares—Because we do not expect to pay dividends in the foreseeable future, you must rely on price appreciation of the ordinary shares for return on your investment."

We are a holding company incorporated in the Cayman Islands. We will rely to some extent on dividends from our U.S. and PRC subsidiaries for payment of any dividends to our shareholders. PRC regulations may restrict the ability of our PRC subsidiaries to make such dividend payments to us. See "Item 1A. Risk Factors—Risks Related to Our Doing Business in China—In the future, we may rely to some extent on dividends and other distributions on equity from our principal operating subsidiaries to fund offshore cash and financing requirements" and "Item 1. Business—Government Regulation—Chinese Regulation—Regulations Relating to Foreign Exchange and Dividend Distribution—Regulation of Dividend Distribution."

Securities Authorized for Issuance Under Equity Compensation Plans

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

Performance Graph

The performance graph has been omitted as permitted under rules applicable to smaller reporting companies.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Taxation

The following is a summary of the Cayman Islands, Chinese and U.S. federal income tax considerations relevant to the ownership and disposition of our ordinary shares. This summary is not intended to be, nor should it be construed as, legal or tax advice to any particular prospective investor. This summary is based on laws and relevant interpretations thereof as of the date of this Form 10-K, all of which are subject to change or different interpretations, possibly with retroactive effect. This summary does not address all possible tax considerations relating to an investment in our ordinary shares, such as the considerations under U.S. state or local tax laws, or tax laws of jurisdictions other than the Cayman Islands, China and the United States. Potential investors should consult their tax advisors with respect to the considerations relevant to the ownership and disposition of our ordinary shares.

Cayman Islands Taxation

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciation, and there is no taxation in the nature of inheritance tax or estate duty. There are no other taxes likely to be material to us levied by the government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within, the jurisdiction of the Cayman Islands. The Cayman Islands is not party to any double tax treaties that are applicable to any payments made to or by our company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

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

People's Republic of China Taxation

Under the EIT Law, an enterprise established outside of China with a "de facto management body" within China is considered a "resident enterprise," which means that it is treated in a manner similar to a Chinese enterprise for enterprise income tax purposes and is generally subject to a uniform 25% enterprise income tax rate on its worldwide income. Although the implementation rules of the EIT Law define "de facto management body" as a managing body that exercises substantive and overall management and control over the production and business, personnel, accounting books and assets of an enterprise, the only official guidance for this definition currently available is set forth in Circular 82, issued by the SAT, which provides guidance on the determination of the tax residence status of a Chinese-controlled offshore incorporated enterprise, defined as an enterprise that is incorporated under the laws of a foreign country or territory and that has a Chinese enterprise or enterprise group as its primary controlling shareholder. Although BeyondSpring Inc. does not have a Chinese 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 BeyondSpring Inc. and its subsidiaries organized outside China.

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 Chinese 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 China;
- decisions relating to the enterprise's financial and human resource matters are made or are subject to approval by organizations or personnel in China;

- the enterprise's primary assets, accounting books and records, company seals, and board and shareholder meeting minutes are located or maintained in China; and
- 50% or more of voting board members or senior executives habitually reside in China.

Currently, none of our executive officers are located in China, and almost all of our board members are located outside of China. BeyondSpring Inc. and its offshore subsidiaries are incorporated outside China. 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 China. Moreover, we are not aware of any offshore holding companies with a corporate structure similar to ours that has been deemed a Chinese "resident enterprise" by the Chinese tax authorities. Accordingly, we believe that BeyondSpring Inc. and its offshore subsidiaries should not be treated as a "resident enterprise" for Chinese 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 China or (2) if gains are realized from transferring equity interests of enterprises domiciled in China, 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 Chinese tax resident enterprise for Chinese tax purposes, any dividends we pay to our overseas shareholders as well as gains realized by such shareholders from the transfer of our shares may be regarded as China-sourced income. If we are considered a "non-resident enterprise" by the PRC tax authorities, the dividends paid to us by our PRC subsidiaries will be subject to a 10% withholding tax. The EIT Law also imposes a withholding income tax of 10% on dividends distributed by an foreign-invested enterprise to its immediate holding company outside of China, if such immediate holding company is considered as a non-resident enterprise without any establishment or place within China or if the received dividends have no connection with the establishment or place of such immediate holding company within China, unless such immediate holding company's jurisdiction of incorporation has a tax treaty with China that provides for a different withholding arrangement. The Cayman Islands, where we are incorporated does not have such tax treaty with China. Under the Hong Kong Tax Treaty, the dividend withholding tax rate may be reduced to 5%, if a Hong Kong resident enterprise that receives a dividend is considered a non-PRC tax resident enterprise and directly holds at least 25% of the equity interests in the PRC enterprise distributing the dividends as the beneficial owner, subject to approval of the PRC local tax authority. However, if the Hong Kong resident enterprise is not considered to be the beneficial owner of such dividends under applicable PRC tax regulations, such dividends may remain subject to withholding tax at a rate of 10%. In February 2018, the SAT promulgated the Announcement on Issues relating to "Beneficial Owner" in Tax Agreements, which provides the criteria of determination of "Beneficial Owner." For determination of "Beneficial Owner", actual conditions of the specific case shall be taken into account to conduct a comprehensive analysis. Accordingly, BeyondSpring HK may be able to enjoy the 5% withholding tax rate for the dividends it receives from its PRC subsidiaries if it satisfies the relevant conditions under tax rules and regulations and obtains the approvals as required.

U.S. Federal Income Tax Considerations

The following is a summary of U.S. federal income tax considerations generally applicable to the ownership and disposition of our ordinary shares by U.S. Holders (as defined below). Unless otherwise noted, this summary addresses only U.S. Holders that hold our ordinary shares as "capital assets" (generally, property held for investment) for U.S. federal income tax purposes. This summary is based on the Code, U.S. Treasury regulations promulgated thereunder, or the Regulations, judicial decisions, administrative pronouncements, the income tax treaty between the United States and China, or the Treaty, and other relevant authorities, all as in effect as of the date hereof and all of which are subject to change or differing interpretations (possibly with retroactive effect).

This summary does not address U.S. federal estate, gift or other non-income tax considerations, the alternative minimum tax, the Medicare tax on certain net investment income, or any state, local or non-U.S. tax considerations, relating to the ownership or disposition of our ordinary shares, nor does it address all aspects of U.S. federal income taxation that may be relevant to a particular U.S. Holder in light of that U.S. Holder's particular circumstances or that may be relevant to certain types of U.S. Holders subject to special treatment under U.S. federal income tax law, such as:

- banks and other financial institutions;
- insurance companies;
- pension plans;
- cooperatives;
- regulated investment companies;
- real estate investment trusts;
- broker-dealers;
- traders that elect to use a mark-to-market method of accounting;
- certain former citizens or long-term residents of the United States;
- tax-exempt entities (including private foundations);
- persons that acquire our ordinary shares pursuant to any employee share option or otherwise as compensation;
- persons that hold our ordinary shares as part of a straddle, hedge, conversion, constructive sale or other integrated transaction for U.S. federal income tax purposes;
- persons whose functional currency is not the U.S. Dollar;
- persons that actually or constructively own 10% or more of our stock (by vote or value); and
- partnerships or other entities or arrangements subject to tax as partnerships for U.S. federal income tax purposes.

The information set forth below is of a general nature only and is not intended to be tax advice. Each prospective investor should consult its tax advisor with respect to the U.S. federal, state, local and non-U.S. income and other tax considerations relevant to the ownership and disposition of our ordinary shares in light of its particular circumstances.

For purposes of this discussion, a "U.S. Holder" is a beneficial owner of our ordinary shares that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created in, or organized in or under the laws of, the United States or any political subdivision thereof;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (i) a United States court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have the authority to control all of the trust's substantial decisions, or (ii) that has validly elected to be treated as a U.S. person for U.S. federal income tax purposes.

If a partnership (or other entity or arrangement treated as a partnership for U.S. federal income tax purposes) owns our ordinary shares, the U.S. federal income tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. Partnerships holding our ordinary shares and their partners should consult their tax advisors regarding an investment in our ordinary shares.

Tax Residence of BeyondSpring Inc. for U.S. Federal Income Tax Purposes

Under current U.S. federal income tax law, a corporation is generally considered a tax resident in the jurisdiction of its organization or incorporation. Thus, as a corporation incorporated under the laws of the Cayman Islands, we should generally be classified as a non-U.S. corporation (and therefore as a non-U.S. tax resident) for U.S. federal income tax purposes. In certain circumstances, however, under section 7874 of the Code a corporation organized outside the United States will be treated as a U.S. corporation (and, therefore, as a U.S. tax resident).

In July of 2015, we completed our internal restructuring. Based on the rules in effect at the time of the internal restructuring, we believe that the internal restructuring did not result in us being treated as a U.S. corporation for U.S. federal income tax purposes by virtue of section 7874 of the Code. Nevertheless, because the section 7874 rules and exceptions are complex and subject to factual and legal uncertainties, there can be no assurance that we will not be treated as a U.S. corporation for U.S. federal income tax purposes.

The remainder of this discussion assumes that we are not treated as a U.S. corporation for U.S. federal income tax purposes.

Notwithstanding the foregoing, in 2025, we became a domestic issuer for purposes of U.S. federal securities law. As a domestic issuer for purposes of U.S. federal securities law, we, among other obligations, must file this Annual Report on Form 10-K and not Form 20-F. Our characterization as a domestic issuer for purposes of U.S. federal securities law does not, however, alter our characterization as a non-U.S. corporation for U.S. federal income tax purposes.

Distributions

The gross amount of any distributions received by a U.S. Holder on our ordinary shares (including any amounts withheld in respect of PRC withholding taxes) will generally be subject to tax as dividends to the extent paid out of our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes, and will be includible in the gross income of such U.S. Holder on the day actually or constructively received. Such dividends will not be eligible for the dividends received deduction generally allowed to U.S. corporations under the Code. The following discussion assumes that any dividends will be paid in U.S. dollars. Distributions in excess of our current and accumulated earnings and profits will be treated as a non-taxable return of capital to the extent of the U.S. Holder's adjusted tax basis in our ordinary shares and thereafter generally as capital gain. We do not intend to determine our earnings and profits in accordance with U.S. federal income tax principles. Therefore, U.S. Holders should expect that the full amount of any distribution we pay will be treated as a dividend for U.S. federal income tax purposes even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above.

An individual or other non-corporate U.S. Holder of our ordinary shares may be eligible for reduced rates of taxation on dividends: (i) received from a qualified foreign corporation if such qualified foreign corporation is neither a PFIC nor treated as such with respect to such U.S. Holder for the taxable year in which the dividend is paid or for the preceding taxable year, and (ii) provided that certain holding period and other requirements are met. A foreign corporation that is not classified as a PFIC is generally treated as a qualified foreign corporation with respect to dividends paid on ordinary shares if such ordinary shares are "readily tradable" on an "established securities market" in the United States. Although our ordinary shares are listed on the Nasdaq Capital Market, our ordinary shares may not be considered readily tradable on an established securities market in the current year or subsequent years. As discussed below under "—Passive Foreign Investment Company," although there can be no assurances regarding our PFIC status for any taxable year, we believe that we were not a PFIC for our 2025 taxable year. Thus, dividends paid on our ordinary shares to individuals and other non-corporate U.S. Holders may constitute "qualified dividend income" eligible for reduced rates of taxation if we are a qualified foreign corporation and we are not a PFIC with respect to such U.S. Holders for the taxable year in which the dividend is paid or in the preceding taxable year.

For U.S. foreign tax credit purposes, dividends received on our ordinary shares will generally be treated as income from sources outside the United States and will generally constitute passive category income. If we are deemed to be a PRC resident enterprise under the EIT Law (see "—People's Republic of China Taxation"), a U.S. Holder may be subject to PRC withholding taxes on such dividends. Subject to certain conditions and limitations and depending on the individual facts and circumstances, a Treaty-eligible U.S. Holder may be entitled to claim a foreign tax credit in respect of any PRC income taxes paid or withheld with respect to dividends on our ordinary shares to the extent such taxes are nonrefundable under the Treaty. A U.S. Holder that does not elect to claim a foreign tax credit for foreign taxes withheld may instead elect to deduct such taxes in computing its taxable income for U.S. federal income tax purposes. A U.S. Holder's election to deduct foreign taxes instead of claiming foreign tax credits applies to all creditable foreign income taxes paid or accrued in the relevant taxable year. The rules regarding foreign tax credits and the deductibility of foreign taxes are complex and the application thereof depends in large part on the U.S. Holder's individual facts and circumstances. All U.S. Holders, whether or not they are Treaty-eligible, should consult their tax advisors regarding the availability of foreign tax credits and the deductibility of foreign taxes in light of their particular circumstances.

Sale or Other Disposition of Our Ordinary Shares

A U.S. Holder will generally recognize gain or loss on the sale or other disposition of our ordinary shares in an amount equal to the difference between the amount realized on the disposition and the U.S. Holder's adjusted tax basis in our ordinary shares. Any such gain or loss will generally be long-term capital gain or loss if the U.S. Holder's holding period in our ordinary shares exceeds one year at the time of disposition and will generally be U.S. source gain or loss for U.S. foreign tax credit purposes. Long-term capital gains of individuals and certain other non-corporate U.S. Holders are generally eligible for a reduced rate of taxation relative to the rate applicable to ordinary income. The deductibility of capital losses may be subject to limitations.

Any gain or loss on the sale or other disposition of our ordinary shares will generally be treated as U.S. source income or loss for U.S. foreign tax credit purposes. However, if as described in "—People's Republic of China Taxation," gains from the sale or other disposition of our ordinary shares may be subject to PRC income tax, a Treaty-eligible U.S. Holder may apply the Treaty to treat such gains as foreign source-gains for U.S. foreign tax credit purposes. Treaty-eligible U.S. Holders that do not apply the Treaty and U.S. Holders that are not Treaty-eligible may not be able to claim a foreign tax credit for any PRC tax imposed on a sale or other disposition of our ordinary shares. Any such U.S. Holder may instead elect to deduct such taxes in computing its taxable income for U.S. federal income tax purposes, but only for a year in which such U.S. Holder elects to do so for all foreign taxes paid or accrued during such year. The rules regarding foreign tax credits and the deductibility of foreign taxes are complex and the application thereof depends in large part on the U.S. Holder's individual facts and circumstances.

U.S. Holders should consult their tax advisors regarding the tax consequences if a foreign tax is imposed on their disposition of our ordinary shares, including with respect to the availability of the foreign tax credit or deduction in lieu thereof in light of their particular circumstances.

Passive Foreign Investment Company

A non-U.S. corporation, such as our company, will be classified as a PFIC for U.S. federal income tax purposes for any taxable year in which either (i) 75% or more of its gross income for such year consists of certain types of "passive" income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income.

Passive income generally includes dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. Passive assets are those which give rise to passive income and include assets held for investment, as well as cash, assets readily convertible into cash, and (subject to certain exceptions) working capital. Our company's goodwill and other unbooked intangibles are taken into account and may be classified as active or passive depending on the income such assets generate or are held to generate. We will be treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which we own, directly, indirectly or constructively, 25% or more (by value) of its stock.

Based on an analysis of our income and the value of our assets, we believe that we were not a PFIC for the taxable year ended December 31, 2025, although no assurance can be given due to the highly factual nature of such analysis. Our PFIC status for the current taxable year ending December 31, 2026, will not be determinable until after the close of the year, and it is possible that we may be classified as a PFIC for the current taxable year and for future taxable years. We believe we were a PFIC for each of the 2016–2020 taxable years, and we may have been a PFIC in prior taxable years as well. No assurance can be given with respect to our PFIC status for the current taxable year or any future taxable year, however. The determination of whether we are or will become a PFIC is uncertain, because it is a fact-intensive inquiry made on an annual basis that depends, in part, on the composition of our income and assets. Fluctuations in the market price of our ordinary shares may influence whether we are classified as a PFIC for the current or subsequent taxable years because the value of our assets for the purpose of the asset test may be determined by reference to the market price of our ordinary shares from time to time (which may be volatile for biopharmaceutical companies, such as ours, that have not yet achieved commercialization with respect to any of their products). The composition of our income and assets may also be affected by how, and how quickly, we use our liquid assets. Under circumstances where our revenue from activities that produce passive income increases relative to our revenue from activities that produce non-passive income, or where we determine not to deploy cash for active purposes, our risk of being classified as a PFIC will substantially increase. Furthermore, prior to the commercialization of any of our drug candidates, interest and other passive income could constitute more than 75% of our gross income for any taxable year.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares, the U.S. Holder will be subject to special tax rules with respect to any "excess distribution" that the holder receives on our ordinary shares and any gain the U.S. Holder recognizes from a sale or other disposition (including a pledge) of our ordinary shares, unless the U.S. Holder makes a "mark-to-market" election as discussed below. Distributions received by a U.S. Holder on our ordinary shares in a taxable year that are greater than 125% of the average annual distributions the U.S. Holder received in the three preceding taxable years or, if shorter, such U.S. Holder's holding period for our ordinary shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated pro rata over the U.S. Holder's holding period for our ordinary shares;
- amounts allocated to the current taxable year and to any taxable years in the U.S. Holder's holding period prior to the first taxable year in which we are classified as a PFIC (each, a "pre-PFIC year") will be subject to tax as ordinary income;
- amounts allocated to each prior taxable year, other than a pre-PFIC year, will be subject to tax at the highest marginal tax rate in effect applicable to the U.S. Holder for that year; and
- an additional tax equal to the interest charge generally applicable to underpayments of tax will be imposed on the tax attributable to each prior taxable year, other than a pre-PFIC year.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares, we will continue to be treated as a PFIC with respect to such U.S. Holder's ordinary shares in future taxable years unless (i) we cease to be a PFIC and (ii) the U.S. Holder has made a "deemed sale" election under the PFIC rules. If a U.S. Holder makes a deemed sale election, the U.S. Holder will be deemed to have sold our ordinary shares at their fair market value as of the last day of the last year for which we were a PFIC. Any gain from such deemed sale would be treated as an excess distribution subject to the excess distribution rules described above.

Alternatively, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election for such stock of a PFIC to elect out of the excess distribution tax treatment discussed in the second preceding paragraph. If a U.S. Holder makes a valid mark-to-market election for our ordinary shares, the U.S. Holder will include in income each year an amount equal to the excess, if any, of the fair market value of our ordinary shares as of the close of such U.S. Holder's taxable year over such U.S. Holder's adjusted basis in such ordinary shares. The U.S. Holder is allowed a deduction for the excess, if any, of such U.S. Holder's adjusted basis in our ordinary shares over their fair market value as of the close of the taxable year. Deductions are allowable, however, only to the extent of any net mark-to-market gains on our ordinary shares included in the U.S. Holder's income for prior taxable years. Amounts included in the U.S. Holder's income under a mark-to-market election, as well as gain on the actual sale or other disposition of our ordinary shares, will be treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on our ordinary shares, as well as to any loss realized on the actual sale or disposition of our ordinary shares, to the extent that the amount of such loss does not exceed the net mark-to-market gains previously included in income with respect to such ordinary shares. The U.S. Holder's basis in our ordinary shares will be adjusted to reflect any such income or loss amounts. If a U.S. Holder makes such a mark-to-market election, then, in any taxable year for which we are a PFIC, tax rules that apply to distributions by corporations which are not PFICs would apply to distributions by us (except that the lower applicable capital gains rate for qualified dividend income would not apply). If a U.S. Holder makes a valid mark-to-market election, and we subsequently cease to be classified as a PFIC, such U.S. Holder will not be required to take into account the mark-to-market income or loss described above during any period that we are not classified as a PFIC.

The mark-to-market election is available only for "marketable stock" which is stock that is traded in other than de minimis quantities on at least 15 days during each calendar quarter("regularly traded") on a qualified exchange or other market, as defined in applicable regulations. We expect that our ordinary shares will continue to be listed on the Nasdaq Capital Market, which is a qualified exchange for these purposes, and, consequently, assuming that our ordinary shares are regularly traded, if a U.S. Holder holds our ordinary shares, it is expected that the mark-to-market election would be available to such U.S. Holder were we to be or become a PFIC.

In addition, because, as a technical matter, a mark-to-market election cannot be made for any lower-tier PFICs that we may own, a U.S. Holder may continue to be subject to the PFIC rules with respect to such U.S. Holder's indirect interest in any such lower-tier PFICs.

We do not intend to provide the information necessary for U.S. Holders to make qualified electing fund elections, which, if available, would result in tax treatment different from the general tax treatment for PFICs described above.

A U.S. Holder that owns our ordinary shares during any taxable year that we are a PFIC must generally file an annual report with the IRS regarding their ownership of such shares. U.S. Holders should consult their tax advisors concerning the U.S. federal income tax considerations with respect to holding and disposing of our ordinary shares if we were, are, or become a PFIC, including the availability and possibility of making a mark-to-market election and the annual PFIC filing requirements, if any.

THE PRECEDING SUMMARY OF U.S. FEDERAL INCOME TAX CONSIDERATIONS IS INTENDED FOR GENERAL INFORMATION ONLY AND DOES NOT CONSTITUTE TAX ADVICE. U.S. HOLDERS SHOULD CONSULT THEIR TAX ADVISORS AS TO THE U.S. FEDERAL, STATE, LOCAL, AND NON-U.S. TAX CONSIDERATIONS GENERALLY APPLICABLE TO THE OWNERSHIP AND DISPOSITION OF OUR ORDINARY SHARES IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES.

Item 6. [Reserved]

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

The following discussion and analysis of the Company's financial condition and results of operations should be read in conjunction with the audited consolidated financial statements and the notes related thereto which are included in "Item 8. Financial Statements and Supplementary Data" of this Annual Report on Form 10-K. Certain information contained in the discussion and analysis set forth below includes forward-looking statements. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those set forth under "Forward-Looking Statements," "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

We are a clinical stage global biopharmaceutical company focused on developing innovative therapies to improve clinical outcomes for patients with high unmet medical needs. Our first-in-class lead asset, Plinabulin is a novel brain-penetrant microtubule modulator with dendritic cell maturation and vasculature modulation mechanism, which has the potential to help mitigate "acquired resistance" from prior ICI treatment in cancer patients. Plinabulin has been administered to over 700 cancer patients with generally good tolerability and is being developed as a potential "pipeline in a drug" in various cancer indications as a direct anti-cancer agent with safety benefit of CIN. We are also developing three small molecule immune agents, which are currently in pre-clinical stages. In addition, we founded and continue to own an equity stake in SEED. See "Item 1. Business—SEED's Targeted Protein Degradation (TPD) Platform and Pipeline—SEED's relationship with BeyondSpring" for additional information. SEED is utilizing a proprietary TPD drug discovery platform, or "molecular glue" technology, to develop innovative therapeutic agents from internal research and development efforts and with our collaborators on currently undruggable protein targets. SEED has advanced its wholly owned lead oncology asset, a novel RBM39 degrader into phase 1 clinical studies in January 2026. SEED is partnering with Eli Lilly and Eisai to discover and develop new chemical entities through this proprietary TPD platform which could produce therapeutic benefits to patients suffering from oncology and CNS disease, among others.

Plinabulin is being studied as an anti-cancer agent in a number of company-sponsored studies and investigator-initiated studies. After a successful phase 3 study (DUBLIN-3) in NSCLC, Plinabulin regimen is in a confirmatory global phase 3 study in second- and third-line NSCLC with epidermal growth factor receptor (EGFR) wild type after progression on prior immune checkpoint inhibitors, a severe unmet medical need. The DUBLIN-3 study enrolled 559 patients at 58 clinical sites globally and the final results from the study showed that the Plinabulin and docetaxel combination had statistically significant and clinically meaningful overall survival benefit compared to standard of care docetaxel alone with doubling 2-year and 3-year OS rate. Key secondary endpoints were also achieved with additional clinically significant benefits in progression free survival (PFS) and objective response rate (ORR), coupled with a significant reduction in grade 4 neutropenia, with over 80% reduction. The finding was published in LANCET Respiratory Medicine journal in September 2024, and at the same time we made an oral presentation at the IASLC conference. We plan to use our best efforts to file an NDA with the NMPA as soon as possible. Because DUBLIN-3 study had over 80% patients from Asia, we plan to initiate a confirmatory global phase 3 study in second- and third-line non-squamous NSCLC with epidermal growth factor receptor (EGFR) wild type after progression on prior immune checkpoint inhibitors, based on productive discussion with US regulatory agency.

The current standard of care for first-line EGFR wild type NSCLC is PD-1/PD-L1 antibodies with or without platinum doublet. However, over 60% patients progress on these therapies, defined as “acquired resistance” due to “T cell exhaustion” and/or “APC pathway mutation” (Memon et al., Cancer Cell 2024). Once patients progress on these regimens, docetaxel, a drug approved over 25 years ago, is recommended in the second- and third-line, but it has modest clinical benefit and high severe neutropenia. To address the significant unmet need in this population, our collaborators at Peking Union Medical College Hospital in China are conducting an investigator-initiated Phase 2 study (Study 303): Plinabulin in combination with Keytruda® (pembrolizumab), a PD-1 antibody, and docetaxel for the treatment of NSCLC patients who progressed from PD-1/PD-L1 antibodies. We presented clinical meaningful data of high disease control rate and prolonged PFS from this study at ESMO 2024, SITC 2024, and ASCO 2025. In addition, our collaborators at MD Anderson Cancer Center have completed a phase 1 IIT study in Plinabulin combination with PD-1 or PD-L1 antibodies and radiation for the treatment of patients in eight cancers who progressed from PD-1/PD-L1 antibodies, with disease control rate of 54%. This paper was published in Cell Press “Med” in June 2025. Plinabulin’s rapid DC maturation biomarker analysis was observed in responding patients.

Plinabulin is also being studied in a Phase 2 investigator-initiated study (Study 302) in combination with Keytruda®, etoposide and platinum for the first-line treatment of ES-SCLC patients at Wuhan Union Hospital in China, where the current standard of care has limited median PFS.

Additional completed investigator initiated studies with Plinabulin include: 1) in combination with nivolumab, a PD-1 antibody, for the treatment of NSCLC at UCSD and the University of Washington (Phase 1 completed); and 2) in combination with nivolumab and ipilimumab, a CTLA-4 antibody, for the treatment of ES-SCLC at the Rutgers University and other U.S. clinical centers (Phase 1 completed, Phase 2 completed for patients who progressed on PD-1/PD-L1 antibodies).

We expect each of these studies to benefit from our previous investigation of Plinabulin as an agent that has been studied in two randomized, controlled Phase 3 clinical studies to have demonstrated a statistically significant reduction in CIN. In total, over 700 patients have been treated with Plinabulin, where improvements in CIN have been repeatedly observed. Our strategy is to develop Plinabulin in multiple indications with the potential for Plinabulin to be an important component of the multiple-agent combination with immune checkpoint inhibitor regimes to elevate the anti-cancer benefit for cancer patients, supported by Plinabulin’s potent dendritic cell maturation mechanism. To implement our strategy, we use a highly efficient business model that integrates clinical resources in the U.S. and China. We work with global CRO companies, such as ICON and Covance (now Labcorp), to ensure data quality with studies conducted under U.S. GCP. Our drug development capabilities are facilitated by strong interest from clinical investigators in the U.S. as well as by our understanding of the pharmaceutical industry, clinical resources and regulatory system in China.

We have partnered with Hengrui to commercialize Plinabulin, if approved, in Greater China through our subsidiary, Wanchunbulin. China recognized Plinabulin as a National Science and Technology Major Project for "essential new drug research and development." Also, with receipt of the 2017 Grant, Plinabulin has been included in the National Drug Priority Review List. We believe that, pending drug approval and successful pricing negotiations with the Chinese government, the 2017 Grant could help position Plinabulin for inclusion in the National Insurance System, which would allow for faster access to patients and reimbursement. In the U.S. and for the rest of the world, we currently plan to seek a co-development and commercialization partner to maximize Plinabulin's potential in multiple cancer indications, if approved.

Since the inception of Wanchun Biotech, the former holding company of our U.S. subsidiary, in 2010, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, including protecting the rights to Plinabulin, and conducting studies in animals and clinical trials of Plinabulin. We do not have any product candidates approved for sale and have not generated any revenue from product sales. We have financed our operations with a combination of equity financings, shareholder and third-party loans, including bank loans, sale of subsidiary interests and collaboration arrangements.

Through December 31, 2025, we have raised approximately $301.0 million in equity financings, $10.2 million of issuance of non-controlling interests, $37.0 million from the sale of preferred shares of SEED in connection with its Series A-2/A-3 financings and $7.4 million from the sale of preferred shares of SEED by the Company to third-party investors, $2.1 million from bank loans, of which $0.6 million has been forgiven in July 2021 and $1.5 million has been repaid in March 2022, $2.5 million in third party loans, of which $1.0 million has since been converted into an equity investment and $1.5 million has been repaid, and $14.4 million in shareholder loans, of which $6.0 million has been repaid and $8.4 million was assumed by Wanchun Biotech, the former holding company of our U.S. subsidiary, on July 20, 2015 pursuant to our internal restructuring, $10.0 million upfront payment to SEED from Eli Lilly, and approximately $31.0 million upfront payment to Wanchunbulin from Hengrui. As of December 31, 2025, our continuing operations had cash and cash equivalents of $7.8 million.

Since inception we have incurred operating losses. Our consolidated net losses were $14.2 million and $16.7 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $408.4 million and $407.4 million, respectively. Substantially all of our losses have resulted from funding our preclinical studies, clinical trials, manufacturing our drug product, our research and development programs and from general and administrative expenses associated with our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses may increase in connection with our ongoing activities, as we:

- continue preclinical studies and clinical development of our programs including in connection with the clinical development programs for Plinabulin in NSCLC and combination studies with immune agents and related chemistry, manufacturing, and controls (CMC) and regulatory activities;
- incur additional costs associated with operating as a domestic issuer;
- maintain, expand and protect our intellectual property portfolio; and
- fund the discovery and development of new product candidates.

We will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval and prepare for and, if any of our product candidates are approved, proceed to commercialization. We continue to explore strategic options in the United States and globally to support the execution of our business plan and to maximize shareholder value. These options may include licensing and partnership arrangements, a sale of the Company or its assets, equity or debt financing, or a combination of the above. Adequate funding may not be available to us on acceptable terms, or at all. In particular, inflation and high interest rates across the global economy, governments' monetary policy in response to inflation concerns, concerns around tariffs and a possible recession, the ongoing hostilities between Russia and Ukraine and escalating geopolitical tensions and military conflicts in the Middle East, including conflicts involving Israel, Hamas, Iran and other regional actors, have caused, and may continue to cause, market volatility, and under such market conditions, we may not be able to obtain funding on reasonable terms or at all.

Discontinued Operations

SEED was founded by us in 2019. As of December 31, 2025, the BYSI Entities owned an aggregate of 10,289,545 Series A-1 Preferred Shares of SEED.

In January 2025, we entered into definitive agreements to sell a portion of our Series A-1 Preferred Shares of SEED for $35.4 million, or $4.25 per share, to certain third-party investors in three installments. The first closing of 1,730,454 shares for approximately $7.35 million occurred in February 2025. The second closing of 3,103,055 shares for approximately $13.19 million is expected to be completed in 2026. Under the terms of the definitive agreements, the third closing of 3,500,128 shares for approximately $14.88 million is scheduled to occur no later than December 15, 2026. Each agreement contains specified termination rights for us and each purchaser, including a mutual termination right in the event a closing shall not have occurred by such specified date as set forth in each agreement.

In September 2025, SEED entered into share purchase agreements with certain third-party investors to sell an aggregate of 1,411,761 of its Series A-3 Preferred Shares for an aggregate purchase price of $6 million at a cash purchase price of $4.25 per share.

As of the date of this Annual Report on Form 10-K, the BYSI Entities own approximately 38.03% of the outstanding equity interest in SEED, and are expected to own approximately 26.56% and 13.62% of the outstanding equity interest in SEED after the second and third closings, respectively, in each case calculated on an as-converted basis (excluding any shares that may be reserved under an employee stock ownership plan, or similar arrangement), and assuming there is no other change to SEED's share capital prior to such closings. For so long as the BYSI Entities remain holders of a majority of the Series A-1 Preferred Shares of SEED, they have the right to elect two directors of SEED. In addition, holders of a majority of the Series A-1 Preferred Shares and ordinary shares of SEED will have the right to elect two independent directors of SEED.

As a result, SEED's operations met the criteria under ASC 205-20 as discontinued operations for financial reporting purposes. We reclassified the financial results of SEED to Discontinued Operations in the Consolidated Statements of Comprehensive Loss for all periods presented. In connection with the first closing described above, we recorded a gain on sale of subsidiary interests of $7.0 million. We also reclassified the related assets and liabilities as current and noncurrent assets and liabilities of discontinued operations on the accompanying Consolidated Balance Sheets as of December 31, 2025 and 2024. Cash flows from discontinued operations are not reclassified in the Consolidated Statements of Cash Flows but are disclosed in the accompanying financial footnotes. See Note 3 (Discontinued operations) to our consolidated financial statements for additional information.

Segments

From 2022 to 2024, we operated in two reportable segments, namely Plinabulin pipeline and TPD platform. The TPD platform segment was comprised of SEED's operations. As a result of SEED's operations being reclassified as discontinued operations, the TPD platform segment is excluded from the Company's continuing operations.

See Note 14 (Segment reporting and geographic information) to our consolidated financial statements for additional information.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. In 2025, our discontinued operations generated $2.0 million of revenue through SEED's research collaboration and license agreement with Eli Lilly and our continuing operations did not generate any revenue. The RMB 200 million (approximately $28.6 million) upfront payment received by Wanchunbulin from Hengrui is recorded as deferred revenue and will be recognized as revenue over time after product approval using unit of delivery measure of progress. In the future, we may generate revenue from a combination of product sales, reimbursements, upfront payments, milestone payments and royalties in connection with existing and future collaborations. If we fail to complete the development of our product candidates in a timely manner or fail to obtain their regulatory approval, we will not generate revenue from product sales in the future.

Operating Expenses

Research and Development Expenses

The largest component of our total operating expenses has historically been our investment in research and development activities. Research and development expenses consist of costs associated with our research and development activities, conducting preclinical studies and clinical trials of Plinabulin and development of our pipeline of immune-oncology product candidates. Research and development expenses also include activities related to:

- employee-related expenses, including salaries, benefits, share-based compensation and travel expense for research and development personnel;
- expenses incurred under agreements with CROs, contract manufacturing organizations, and consultants that conduct and support clinical trials and preclinical studies;
- costs associated with preclinical studies and development activities;
- costs associated with regulatory operations;
- costs associated with protecting intellectual property;
- other expenses, which include direct and allocated expenses for rent, insurance and other supplies used in research and development activities.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to continue to be significant over the next several years as we continue to develop our product pipeline through additional preclinical studies and clinical trials.

We expense research and development costs when we incur them. We record costs for some development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information our vendors provide to us.

There are numerous factors that will impact research and development costs, including future clinical trials and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial requirements and regulatory factors beyond our control will impact our clinical development programs and plans. The successful development of our product candidates is highly uncertain. Due to the inherently unpredictable nature of preclinical studies and clinical development and commercialization of product candidates, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from, any of our other product candidates. This unpredictability is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials and commercialization of product candidates, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the design of the trial and changes to the design of the trial;
- establishing an appropriate safety profile;

- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up;
- the results of our clinical trials;
- making arrangements with third-party manufacturers;
- receipt of marketing approvals from applicable regulatory authorities;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with others;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- continued acceptable safety profiles of the products following approval; and
- retention of key research and development personnel.

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

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including executive, finance and human resource functions, and information technology, and share-based compensation costs. Other general and administrative expenses include professional fees for legal, consulting, auditing and tax services as well as other direct expenses for rent, insurance and supplies used in general and administrative activities. We currently do not expect to incur significant pre-commercialization costs in the near future. We also incur legal, compliance, accounting, directors and officers insurance, and investor and public relations expenses associated with being a public company.

Other Income (Expenses)

Other income consists primarily of foreign exchange gains and interest income earned on our cash and cash equivalents. Other expenses consist primarily of foreign exchange losses.

Results of Operations

Comparison of Years Ended December 31, 2025 and 2024

The following table summarizes the results of our operations for the years ended December 31, 2025 and 2024, respectively, together with the percentage changes in those items:

	Years Ended December 31,		
	2025	2024	Change
	(in thousands of U.S. Dollars ("$"))		%
Revenue	—	—	—
Operating expenses			
Research and development	(4,388)	(2,644)	66%
General and administrative	(4,557)	(6,110)	-25%
Loss from operations	(8,945)	(8,754)	2%
Other income (expense)			
Foreign exchange gain (loss), net	165	(96)	-272%
Interest income	78	59	32%
Other income, net	77	22	250%
Total other income (expense)	320	(15)	-2233%
Net loss before income tax	(8,625)	(8,769)	-2%
Income tax expenses	(90)	(96)	-6%
Net loss from continuing operations	(8,715)	(8,865)	-2%
Discontinued operations:			
Loss from discontinued operations	(12,488)	(7,828)	60%
Gain on sale of subsidiary interests	6,986	—	—
Income tax expenses	—	—	—
Net loss from discontinued operations	(5,502)	(7,828)	-30%
Net loss	(14,217)	(16,693)	-15%

Research and Development Expenses

Research and development (R&D) expenses were $4.4 million for the year ended December 31, 2025 compared to $2.6 million for the year ended December 31, 2024. The $1.8 million increase was primarily due to expanded drug manufacturing activities to prepare for potential future study initiation, increased data management efforts related to NSCLC study data cleaning and validation, increased Plinabulin combination therapy research supporting strategic business development and partnership initiatives, higher regulatory affairs related professional service expenses, and higher personnel costs.

The following table summarizes the research and development expenses for the years ended December 31, 2025 and 2024:

	Year Ended December 31,		
	2025	2024	Change
	(in thousands of U.S. Dollars ("$"))		%
Clinical expenses	1,235	417	196%
Preclinical expenses	395	45	778%
Professional services	1,170	994	18%
Personnel compensation and related costs	1,336	1,015	32%
Facility and other expenses	252	173	46%
Total research and development	4,388	2,644	66%

General and Administrative Expenses

General and administrative (G&A) expenses were $4.6 million for the year ended December 31, 2025, compared to $6.1 million for the year ended December 31, 2024. The $1.5 million decrease was primarily attributable to lower personnel costs resulting from reduced headcount, decreased professional service expenses related to business development and partnership consulting, and lower corporate overhead including D&O insurance premiums and investor marketing advisory expenses.

Other Income (Expenses)

Other income for the year ended December 31, 2025 consisted primarily of foreign exchange gains and interest income earned on our cash and cash equivalents. Other income for the year ended December 31, 2024 consisted primarily of foreign exchange losses, offset by interest income.

Non-Accelerated Filer

As a non-accelerated filer, we intend to rely on an exemption from the rule requiring us to provide an auditor's attestation report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and potential exemptions from the rule requiring us to comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis.

Liquidity and Capital Resources

Since inception, we have incurred net losses and negative cash flows from our operations. Substantially all of our negative cash flows have resulted from funding our research and development programs and general and administrative expenses associated with our operations. We incurred consolidated net losses of $14.2 million and $16.7 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $408.4 million and $407.4 million, respectively. Our primary use of cash is to fund research and development costs and for general and administrative expenses. Our operating activities used $19.8 million and $16.4 million of cash, including $12.3 million and $7.7 million used in discontinued operating activities, during the years ended December 2025 and 2024, respectively. We have financed our operations with a combination of equity offerings, shareholder and third-party loans, including bank loans, sale of subsidiary interests and collaboration arrangements. For the year ended December 31, 2025, we have received aggregate net cash proceeds of $2.0 million from the issuance of our equity securities. As of December 31, 2025, our continuing operations had cash and cash equivalents of $7.8 million.

Our liquidity is affected by financing activities, our clinical trials, and research and development and general and administrative expenses. We anticipate that our current financial resources will allow us to meet our operational expenses and capital expenditures in the next 12 months after the date of this Annual Report on Form 10-K. We are evaluating various financing alternatives to fund our operations in the medium to long term, including equity and debt financings, potential licensing and partnership arrangements, sale of subsidiary or investee interests, as well as other strategic transactions. There can be no assurance that capital will be available as necessary to meet our working capital requirements or, if the capital is available, that it will be on terms acceptable to us. The issuances of additional equity securities by us may result in dilution in the equity interests of our current shareholders. Obtaining commercial loans, assuming those loans will be available, will increase our liabilities and future cash commitments and may include financial covenants and restrictions. If we are unable to obtain financing in the amounts and on terms deemed acceptable, our business and future success will be materially and adversely affected.

The following table provides information regarding our consolidated cash flows for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands of U.S. Dollars ("$"))	
Net cash used in operating activities	(19,769)	(16,443)
Net cash provided by (used in) investing activities	10,787	(12,012)
Net cash provided by financing activities	4,968	26,785
Net effect of foreign exchange rate changes	105	(33)
Net decrease in cash and cash equivalents	(3,909)	(1,703)

The following table provides information regarding cash flows of discontinued operations for the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
	2025	2024
	(in thousands of U.S. Dollars ("$"))	
Net cash used in discontinued operating activities	(12,314)	(7,665)
Net cash provided by (used in) discontinued investing activities	8,207	(12,012)
Net cash provided by discontinued financing activities	2,980	23,815

Cash inflows generated by our discontinued operations were used to support their own operations, including funding their own R&D activities, rather than being transferred to or used by the continuing operations. As such, we believe the liquidity of our continuing operations will not be negatively affected by the absence of discontinued operation's cash flows.

Net Cash Used in Operating Activities

The cash used in operating activities for the years ended December 31, 2025 and 2024 resulted primarily from our net losses of $14.2 million and $16.7 million, respectively, adjusted for non-cash charges and changes in components of working capital. During 2025, these non-cash charges mainly consisted of $7.0 million of gain on sale of subsidiary interests, $0.7 million of non-cash share-based compensation and $0.7 million of non-cash operating lease expenses. Net cash used in operating activities was $19.8 million for the year ended December 31, 2025, compared to $16.4 million for the year ended December 31, 2024. The $3.4 million increase was primarily due to increase of operating cash expenditures by our discontinued operations to fund their own R&D activities.

The primary use of our cash in the periods presented was to fund our research and development, regulatory and other clinical trial costs and related administrative expenses. Our advances to suppliers and other current assets, accounts payable and accrued expense balances in all periods presented were affected by the timing of vendor invoicing and payments.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the year ended December 31, 2025 was $10.8 million. Net cash used in investing activities for the year ended December 31, 2024 was $12.0 million. During 2025, net cash was primarily provided by maturity of time deposits, partially offset by cash used in acquiring structured deposits. During 2024, net cash was primarily used for acquiring time deposits.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 and 2024 was $5.0 million and $26.8 million, respectively. During 2025, we received aggregate net cash proceeds of $2.0 million from the issuance of our equity securities. SEED received $3.0 million from the sale of its Series A-3 Preferred Shares. During 2024, we received aggregate net cash proceeds of $3.0 million from the issuance of our equity securities. SEED received $20.0 million from the sale of its Series A-3 Preferred Shares.

Future Liquidity and Material Cash Requirements

We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize any of our current product candidates. We anticipate that we will continue to generate losses for the foreseeable future as we continue the development of, and seek regulatory approvals for, our current product candidates. In addition, as we have begun reporting with the SEC as a domestic issuer since January 1, 2025, we expect our general and administrative expenses to further increase. Accordingly, we anticipate that we will need additional funding in connection with our future operations.

Our liquidity is affected by financing activities, our clinical trials, and research and development and general and administrative expenses. We will need, among other things, additional capital resources to fund our business activities. There can be no assurance that capital will be available as necessary to meet our working capital requirements or, if the capital is available, that it will be on terms acceptable to us. If we are unable to obtain financing in the amounts and on terms deemed acceptable, our business and future success will be materially and adversely affected. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development, regulatory approval and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development, regulatory filing and commercialization of our product candidates.

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

- the costs, timing and outcome of regulatory reviews and approvals;
- the ability of our product candidates to progress through clinical development successfully;
- the initiation, progress, timings, costs and results of studies in animals and clinical trials for our other programs and potential product candidates;
- the number and characteristics of the product candidates we pursue;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies;
- our ability to establish and maintain arrangements partnership with other pharmaceutical companies for the development, licensing and commercialization of our assets; and
- our ability to maintain and establish collaboration arrangements on favorable terms, if at all.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financing, potential licensing and partnership arrangements, sale of subsidiary or investee interests, or other strategic transactions. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Debt financing, if available, will increase our liabilities and future cash commitments and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute the ownership interest of our shareholders. If we raise additional funds through collaborations, strategic alliances, marketing or distribution arrangements or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or research programs or to grant licenses on terms that may not be favorable to us. Sale of subsidiary or investee interests, such as the sale of our Series A-1 Preferred Shares of SEED as described under “Item 1. Business—SEED’s Targeted Protein Degradation (TPD) Platform and Pipeline,” will cause our controlling power over such subsidiary or investee to diminish and limit our ability to benefit from potential growth of its business. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

Lease commitments

The principal commitments from continuing operations consist of obligations under our operating leases for office space.

We lease all of our facilities and believe our current facilities are sufficient to meet our needs. Our principal executive offices are located in New Jersey, and we also have offices in Beijing and Dalian, China.

We currently lease office space in New Jersey, with total space of 9,727 square feet. The lease expires in February 2027. Our current rent is $26,344 per month. Starting in August 2026, our annual rent will increase by $0.50 per square foot leased. We additionally pay for the cost of utilities, as well as our share of building real estate taxes and building operating expenses. Payments under the lease are expensed on a straight-line basis over the period of the lease.

We lease office space in Dalian, China, with total space of 210.65 square meters and a monthly rent of RMB 10,252 (approximately $1,466). The lease is set to expire on December 31, 2027. Payments under the lease are expensed on a straight-line basis over the period of the lease.

Other contractual obligations

We enter into agreements in the normal course of business with CROs and institutions to license intellectual property. These contracts are cancelable at any time by us with prior written notice.

Our subsidiary Wanchunbulin has entered into a government grant agreement with specific local authorities in the PRC. Wanchunbulin commits to staying within designated districts, maintaining current tax jurisdictions, and retaining its registered capital, until 2033. Wanchunbulin also undertakes not to establish additional entities in other jurisdictions within Greater China for the purposes of conducting research, development, and commercialization activities related to Plinabulin, provided such activities fall within the scope of the government grant agreement. Otherwise, Wanchunbulin may be required to refund the grants.

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 U.S. GAAP. The preparation of these financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, costs and expenses. We evaluate our estimates and judgments on an ongoing basis, and our actual results may differ from these estimates. We base our estimates on historical experience, known trends and events, contractual milestones and other various factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

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 estimate is summarized below. For a summary of significant accounting policies and the effect on our financial statements, see Note 2 to our consolidated financial statements included in this Annual Report.

Research Contract Costs and Accruals

We have entered into various research and development contracts with research institutions and other companies in China, the U.S., and Europe. Related payments are recorded as research and development expenses as incurred. We record accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from our estimates. Our historical accrual estimates have not been materially different from the actual costs.

Recent Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosure About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information otherwise required under this item.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
BeyondSpring Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of BeyondSpring Inc. (the "Company") as of December 31, 2025, the related consolidated statements of comprehensive loss, shareholders' deficit and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("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 the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

Critical Audit Matters

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

Accrual for research contract costs

As described in Note 2 to the financial statements, the Company has entered into various research and development contracts with research institutions and other companies primarily in China, U.S. and Europe. Related payments are recorded as research and development expenses, and accruals are recorded for estimated ongoing research costs. When evaluating the adequacy of the accrual for research contract costs, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of the reporting period and actual results could differ from the Company's estimates.

The principal consideration for our determination in performing procedures related to the accrual for research contract costs is a critical audit matter is that there was judgment by management in determining the achievement of milestones and occurrence of other events that creates a present obligation for the Company to pay the research institutions and other companies for their services.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included, among others, (i) obtaining an understanding of the design and implementation of certain key controls and how management estimates and records the accrued research contract costs; (ii) inspecting research and development related contract terms and conditions, and assessing the status of contracts with research institutions and other companies through corroborative inquiries with the in-house research personnel; (iii) reviewing subsequent disbursements to determine whether any invoices belong to the period under audit were properly accrued for to identify any unrecorded accrued expenses at year end; (iv) evaluating management's estimate by testing the activities of the expenses and payments recorded in the current period; (v) comparing and reconciling the confirmation responses from the research institutions and other companies with the accrual balances.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2023 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Costa Mesa, CA
March 25, 2026

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
BeyondSpring Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of BeyondSpring Inc. (the "Company") as of December 31, 2024, the related consolidated statements of comprehensive loss, shareholders' deficit and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("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 the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor from 2023 to 2025.

Costa Mesa, CA
March 27, 2025

BEYONDSPRING INC.

CONSOLIDATED BALANCE SHEETS

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

	As of December 31,	
	2024	**2025**
	$	$
Assets		
Current assets:		
Cash and cash equivalents	2,922	7,786
Short-term investments	-	4,775
Advances to suppliers	240	227
Prepaid expenses and other current assets	68	71
Current assets of discontinued operations	25,347	8,023
Total current assets	28,577	20,882
Noncurrent assets:		
Property and equipment, net	239	166
Operating right-of-use assets	513	305
Other noncurrent assets	213	224
Noncurrent assets of discontinued operations	4,773	4,356
Total noncurrent assets	5,738	5,051
Total assets	34,315	25,933
Liabilities and equity		
Current liabilities:		
Accounts payable	295	363
Accrued expenses	840	938
Current portion of operating lease liabilities	282	320
Other current liabilities	780	822
Current liabilities of discontinued operations	8,813	11,133
Total current liabilities	11,010	13,576
Noncurrent liabilities:		
Operating lease liabilities	307	-
Deferred revenue	27,400	28,600
Other noncurrent liabilities	3,686	3,981
Noncurrent liabilities of discontinued operations	6,197	3,766
Total noncurrent liabilities	37,590	36,347
Total liabilities	48,600	49,923
Commitments and contingencies (Note 13)		
Shareholders' deficit		
Ordinary shares ($0.0001 par value; 500,000,000 shares authorized; 40,316,320 and 41,122,320 shares issued and outstanding as of December 31, 2024 and 2025, respectively)	4	4
Additional paid-in capital	373,185	375,664
Accumulated deficit	(407,425)	(408,431)
Accumulated other comprehensive income	1,336	602
Total BeyondSpring Inc.'s shareholders' deficit	(32,900)	(32,161)
Noncontrolling interests	18,615	8,171
Total shareholders' deficit	(14,285)	(23,990)
Total liabilities and shareholders' deficit	34,315	25,933

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

BEYONDSPRING INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Year ended December 31,	
	2024	**2025**
	$	$
Revenue	-	-
Operating expenses		
Research and development	(2,644)	(4,388)
General and administrative	(6,110)	(4,557)
Loss from operations	(8,754)	(8,945)
Foreign exchange gain (loss), net	(96)	165
Interest income	59	78
Other income, net	22	77
Loss before income tax	(8,769)	(8,625)
Income tax expenses	(96)	(90)
Net loss from continuing operations	(8,865)	(8,715)
Discontinued operations		
Loss from discontinued operations	(7,828)	(12,488)
Gain on disposal of discontinued operations	-	6,986
Income tax expenses	-	-
Net loss from discontinued operations	(7,828)	(5,502)
Net loss	(16,693)	(14,217)
Less: Net loss attributable to noncontrolling interests from continuing operations	(388)	(242)
Less: Net loss attributable to noncontrolling interests from discontinued operations	(5,182)	(12,969)
Net loss attributable to BeyondSpring Inc.	(11,123)	(1,006)
Net earnings (loss) per share, basic and diluted		
Continuing operations	(0.21)	(0.21)
Discontinued operations	(0.07)	0.19
Basic and diluted loss per share	(0.28)	(0.02)
Weighted-average shares outstanding		
Basic and diluted	39,733,191	40,406,347
Other comprehensive loss, net of tax of nil:		
Foreign currency translation adjustment gain (loss) from continuing operations	710	(1,147)
Foreign currency translation adjustment gain (loss) from discontinued operations	17	(107)
Comprehensive loss	(15,966)	(15,471)
Less: Comprehensive loss attributable to noncontrolling interests from continuing operations	(131)	(655)
Less: Comprehensive loss attributable to noncontrolling interests from discontinued operations	(5,154)	(13,076)
Comprehensive loss attributable to BeyondSpring Inc.	(10,681)	(1,740)

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

BEYONDSPRING INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT

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

	BeyondSpring Inc.'s shareholders							
	Ordinary share		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) gain	Subtotal	Noncontrolling interests	Total deficit
	Shares	Amount						
		$	$	$	$	$	$	$
Balances at January 1, 2024	39,029,163	4	368,599	(396,302)	894	(26,805)	(8,530)	(35,335)
Issuance of ordinary shares, net of issuance costs	1,271,187	-	2,970	-	-	2,970	-	2,970
Share-based compensation	-	-	2,073	-	-	2,073	195	2,268
Exercise of share options	15,970	-	-	-	-	-	-	-
Capital contribution from noncontrolling interests	-	-	-	-	-	-	20,000	20,000
Issuance costs incurred by noncontrolling interests	-	-	-	-	-	-	(96)	(96)
Accretion of contingently redeemable noncontrolling interest	-	-	(457)	-	-	(457)	-	(457)
Reclassification of noncontrolling interests from mezzanine equity to permanent equity	-	-	-	-	-	-	12,331	12,331
Other comprehensive income	-	-	-	-	442	442	285	727
Net loss	-	-	-	(11,123)	-	(11,123)	(5,570)	(16,693)
Balances at December 31, 2024	40,316,320	4	373,185	(407,425)	1,336	(32,900)	18,615	(14,285)
Issuance of ordinary shares, net of issuance costs	800,000	-	1,980	-	-	1,980	-	1,980
Share-based compensation	6,000	-	499	-	-	499	225	724
Capital contribution from noncontrolling interests	-	-	-	-	-	-	2,720	2,720
Issuance costs incurred by noncontrolling interests	-	-	-	-	-	-	(26)	(26)
Ownership interests in subsidiary transferred to third parties	-	-	-	-	-	-	368	368
Other comprehensive income	-	-	-	-	(734)	(734)	(520)	(1,254)
Net loss	-	-	-	(1,006)	-	(1,006)	(13,211)	(14,217)
Balances at December 31, 2025	41,122,320	4	375,664	(408,431)	602	(32,161)	8,171	(23,990)

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

BEYONDSPRING INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Amounts in thousands of U.S. Dollars ("$"))

	Year ended December 31,	
	2024	**2025**
	$	$
Cash flows from operating activities:		
Net loss	(16,693)	(14,217)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation expenses	285	87
Share-based compensation	2,255	722
Non-cash operating lease expenses	702	747
Unrealized gain on short-term investments	(3)	-
Gain on sale of subsidiary interests	-	(6,986)
Changes in assets and liabilities:		
Short-term investments	(64)	254
Advances to suppliers	(19)	(18)
Prepaid expenses and other current assets	10	64
Other noncurrent assets	(117)	(42)
Accounts payable	(607)	(76)
Accrued expenses	(387)	1,842
Operating lease liabilities	(631)	(709)
Other current liabilities	(163)	268
Deferred revenue	(1,001)	(2,001)
Other noncurrent liabilities	(10)	296
Net cash used in operating activities	(16,443)	(19,769)
Cash flows from investing activities:		
Acquisitions of property and equipment	(224)	(50)
Purchase of short-term investments	(12,788)	(14,949)
Proceeds from maturity of short-term investments	1,000	18,432
Proceeds from sale of subsidiary interests	-	7,354
Net cash (used in) provided by investing activities	(12,012)	10,787
Cash flows from financing activities:		
Proceeds from issuance of ordinary shares	3,000	2,000
Capital contribution from noncontrolling interests	20,000	2,720
Payments of offering costs	(30)	(12)
Payments of issuance costs of noncontrolling interests	(96)	(26)
Proceeds from loans	3,911	286
Net cash provided by financing activities	26,785	4,968
Effect of foreign exchange rate changes	(33)	105
Net decrease in cash and cash equivalents	(1,703)	(3,909)
Cash and cash equivalents from continuing operations at beginning of year	15,337	2,922
Cash and cash equivalents and from discontinued operations at beginning of year	2,413	13,125
Less: cash and cash equivalents from discontinued operations at end of year	13,125	4,352
Cash and cash equivalents from continuing operations at end of year	2,922	7,786
Supplemental disclosures of cash flow information		
Interest paid	-	-
Interest received	148	311
Income taxes paid	7	2
Non-cash activities:		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	-	40
Issuance costs accrued in accrued expenses	-	8

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

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

1. Nature of the business

BeyondSpring Inc. (the "Company") was incorporated in the Cayman Islands on November 21, 2014. The Company and its subsidiaries (collectively, the "Group") are principally engaged in clinical stage biopharmaceutical activities focused on the development of innovative cancer therapies. The Company is under the control of Mr. Linqing Jia and Dr. Lan Huang as a couple (collectively, the "Founders") since its incorporation.

On March 14, 2017, the Company completed its initial public offering ("IPO") on the NASDAQ Capital Market.

On June 14, 2019 and July 3, 2019, certain investors led by Shenzhen Efung 9th Venture Investment Center (Limited Partnership) ("Efung Capital") entered into investment agreements with Dalian Wanchunbulin Pharmaceuticals Ltd. ("Wanchunbulin"), a subsidiary of the Company, to invest $14,537 (RMB100,000) for a total of 4.76% equity interest of Wanchunbulin. In 2019, the Company received aggregate gross proceeds of $10,083 (RMB70,000) from this equity financing.

In August 2024, SEED Therapeutics Inc. ("SEED") completed the first close of its Series A-3 financing, where SEED sold an aggregate of 5,647,059 of its Series A-3 Preferred Shares to Eisai Co., Ltd ("Eisai") and certain other third-party investors, for an aggregate purchase price of $24,000, each at a cash purchase price of $4.25 per share.

In January 2025, the Company entered into definitive agreements with three investors to sell a portion of Series A-1 Preferred Shares of SEED owned by the Company, for gross proceeds of approximately $35,418. Upon completion of the transactions, the Company and SEED Technology Limited ("SEED Technology"), a majority-owned indirect subsidiary of the Company (collectively, the "BYSI Entities") are expected to retain approximately 13.62% of SEED's outstanding shares. See Note 3 – Discontinued operations for further information.

In September 2025, SEED entered into share purchase agreements with certain third-party investors and a related party (see Note 15 – Related Party Transactions) to sell an aggregate of 1,411,761 of its Series A-3 Preferred Shares for an aggregate purchase price of $6,000 at a cash purchase price of $4.25 per share. As of December 31, 2025, the BYSI Entities owns approximately 34.29% of the outstanding equity interest in SEED, calculated on an as-converted basis. SEED continues to be consolidated into the financial statements of the Company since the Company remains substantive control of SEED.

As of December 31, 2025, the subsidiaries of the Company are as follows:

Name of company	Place of incorporation	Date of incorporation	Percentage of ownership by the Group	Principal activities
BeyondSpring Pharmaceuticals Inc. ("BeyondSpring US")	Delaware, U.S.	June 18, 2013	100%	Clinical trial activities
BeyondSpring Ltd.	The British Virgin Islands ("BVI")	December 3, 2014	100%	Holding company
BeyondSpring (HK) Limited ("BeyondSpring HK")	Hong Kong	January 13, 2015	100%	Holding company
Wanchun Biotechnology Limited ("BVI Biotech")	BVI	April 1, 2015	100%	Holding company
Wanchun Biotechnology (Dalian) Ltd. ("Wanchun Dalian")	People's Republic of China ("PRC")	April 23, 2015	100%	Holding company
Dalian Wanchunbulin Pharmaceuticals Ltd. ("Wanchunbulin")	PRC	May 6, 2015	57.97%	Clinical trial activities
Beijing Wanchun Pharmaceutical Technology Ltd. ("Beijing Wanchun")	PRC	May 21, 2018	57.97%	Holding company
SEED Therapeutics Inc. ("SEED")	BVI	June 25, 2019	36.61%	Pre-clinical development activities
SEED Technology Limited ("SEED Technology")	BVI	December 9, 2019	57.97%	Holding company
SEED Therapeutics US, Inc. ("SEED US")	Delaware, U.S.	November 25, 2020	36.61%	Pre-clinical development activities
Wanchun Hongji (Dalian) Pharmaceuticals Ltd. ("Wanchun Hongji")	PRC	March 22, 2022	36.61%	Pre-clinical development activities
SEED LH Inc.	BVI	September 30, 2025	36.61%	Holding company
SEED LH MG Inc.	Delaware, U.S.	October 6, 2025	36.61%	Product development activities

2. Summary of significant accounting policies

Basis of presentation

The consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP").

Basis of consolidation

The consolidated financial statements include the financial statements of the Company and its subsidiaries. All intercompany transactions and balances between the Company and its subsidiaries are eliminated upon consolidation.

Discontinued operations

The Company presents discontinued operations when there is a disposal of a component group or a group of components that represents a strategic shift that will have a major effect on operations and financial results. The Company aggregates the results of operations for discontinued operations into a single line item in the Consolidated Statements of Comprehensive Loss for all periods presented. See Note 3 for additional information.

Use of estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the period. Areas where management uses subjective judgment include, but are not limited to, share-based compensation, clinical trial accruals, valuation allowance for deferred tax assets, estimating uncertain tax positions ("UTP"), measurement of right-of-use assets and lease liabilities, fair value of financial instruments, impairment of long-lived assets and estimating of useful life for property and equipment. Management bases the estimates on historical experience, known trends and various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results could differ from these estimates.

Research and development ("R&D") costs

The Company accounts for R&D costs in accordance with ASC 730, *Research and Development*. R&D costs primarily are comprised of costs incurred in performing research and development activities, including related personnel and consultant's salaries, benefits and related costs, raw materials and supplies to develop product candidates, patent-related costs incurred in connection with filing patent applications, costs incurred related to clinical approval, and external costs of outside vendors engaged to conduct clinical development activities and trials. The Company expenses R&D costs as they are incurred.

Costs incurred related to nonrefundable advance payments for goods or services that will be used in future research and development activities are deferred and capitalized. The capitalized amounts are expensed as R&D costs when the related goods are delivered or the services are performed, or when the Company does not expect it will need the goods to be delivered or the services to be rendered.

Research contract costs and accruals

The Company has entered into various R&D contracts with research institutions and other companies primarily in the PRC, the U.S., and Europe.

Related payments are recorded as R&D expenses and are expensed as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Foreign currency translation and transactions

Functional currency

The Company currently uses the U.S. dollar as the functional currency for all its entities, except for entities in the PRC, which adopt the RMB as their functional currency. The determination of the respective functional currency is based on the criteria of ASC 830, *Foreign Currency Matters*. The Company uses the U.S. dollar as its reporting currency.

2. Summary of significant accounting policies (continued)

Foreign currency translation and transactions (continued)

Functional currency translation

For subsidiaries whose functional currencies are not the U.S. dollar, the Company uses the average exchange rate for the year and the exchange rate at the balance sheet date, to translate the operating results and financial position to U.S. dollar, the reporting currency, respectively. Translation differences are recorded in accumulated other comprehensive (loss) income, a component of shareholders' deficit. Transactions denominated in currencies other than the functional currency are translated into the functional currency at the exchange rates prevailing on the transaction dates. Foreign currency denominated financial assets and liabilities are remeasured at the exchange rates prevailing at the balance sheet date. Exchange gains and losses are included in the consolidated statements of comprehensive loss.

Cash and cash equivalents

Cash and cash equivalents consist of cash on hand and bank deposits, and highly liquid investments with an original maturity date of three months or less at the date of purchase and are stated at cost which approximates their fair value. All cash and cash equivalents are unrestricted as to withdrawal and use.

Short-term investments

Short-term investments consist of time deposits with original maturities of greater than three months but less than twelve months and structured deposits with maturities of less than twelve months. These structured deposits are classified as short-term investments as they are not readily convertible to known amounts of cash. Financial products issued by commercial banks expected to be realized in cash within the next twelve months are also included in short-term investments.

Advances to suppliers

Advances to suppliers consist of cash to contractors and vendors for services and materials that have not been provided or received. Advances to suppliers are reviewed periodically to determine whether their carrying values have become impaired. The Company considers the assets to be impaired if it is doubtful that the services and materials will be or can be provided by the suppliers. As of December 31, 2024, and 2025, there were no allowances provided.

Leases

The Company determines if an arrangement is a lease or contains a lease at lease inception. For leases with lease and non-lease components, the Company has elected to apply the practical expedient to not separate the lease component and its associated non-lease component. Leases are classified as operating or finance leases in accordance with the recognition criteria in ASC 842, *Leases* ("ASC842"). The Company's lease portfolio consists entirely of operating leases as of December 31, 2024 and 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 right-of-use ("ROU") assets and lease liabilities. ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. ROU assets and lease liabilities are calculated as the present value of the lease payments not yet paid. Variable lease payments not dependent on an index or rate are excluded from the ROU asset and lease liability calculations and are recognized in expense in the period which the obligation for those payments is incurred. As the rate implicit in the Company's leases is not typically readily available, the Company uses an incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. This incremental borrowing rate reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. ROU assets include any lease prepayments and are reduced by lease incentives. Operating lease expense for lease payments is recognized on a straight-line basis over the lease term. Lease terms are based on the non-cancelable term of the lease and may contain options to extend the lease when it is reasonably certain that the Company will exercise that option.

The Company reassesses whether a contract is or contains a lease whenever a substantive change is made to the terms and conditions of the contract. Such changes are not limited to those that meet the definition of a lease modification, which is a specific type of modification characterized by a change in the scope of or consideration for a lease. When a modification does not meet the definition of a lease modification, the Company reassesses whether the contract is or contains a lease but would not apply the lease modification framework if the conclusion regarding whether the contract is or contains a lease is unchanged. If there is a lease modification, the Company considers whether the lease modification results in a separate contract. If so, the Company accounts for the separate contract the same manner as any other new lease, in addition to the original unmodified contract. Otherwise, the Company remeasures and reallocates the remaining consideration in the contract, reassesses the classification of the lease at the effective date of the modification and accounts for any initial direct costs, lease incentives and other payments made to or by the lessee. If the modification fully or partially terminates the existing lease, the Company remeasures the lease liability and decreases the carrying amount of the ROU assets in proportion to the full or partial termination of the existing lease and recognizes in profit or loss any difference between the reduction in the lease liability and the reduction in the ROU assets.

Operating leases are included in operating lease right-of-use assets and lease liabilities on the consolidated balance sheets. 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 short-term leases. The Company has elected to apply the practical expedient to not record short-term leases on the consolidated balance sheets. Lease expense for short-term leases is recognized on a straight-line basis over the lease term.

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

2. Summary of significant accounting policies (continued)

Property and equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets as follows:

Category	Estimated useful life
Office equipment	5~10 years
Laboratory equipment	3-8 years
Motor vehicles	4 years
Leasehold improvements	Lower of lease term or economic life

Repair and maintenance costs are charged to expense as incurred, whereas the cost of renewals and betterment that extends the useful lives of plant and equipment are capitalized as additions to the related assets. Retirements, sales and disposals of assets are recorded by removing the cost and accumulated depreciation from the assets and accumulated depreciation accounts with any resulting gain or loss reflected in the consolidated statements of comprehensive loss.

Impairment of long-lived assets

The Company evaluates long-lived assets such as laboratory equipment for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable in accordance with ASC 360-10, *Property, Plant and Equipment: Overall* ("ASC 360-10"). The Company recognizes an impairment loss when the fair value less cost to sell, if any, is less than their carrying values. For the years ended December 31, 2024 and 2025, the Company did not record any impairment losses on its long-lived assets.

Fair value measurements

The Company applies ASC 820, *Fair Value Measurements and Disclosures* ("ASC 820"), 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—Other inputs that are directly or indirectly observable in the marketplace.
- Level 3—Unobservable inputs which are supported by little or no market activity.

ASC 820 describes three main approaches to measuring the fair value of assets and liabilities: (1) market approach; (2) income approach and (3) cost approach. The market approach uses prices and other relevant information generated from market transactions involving identical or comparable assets or liabilities. The income approach uses valuation techniques to convert future amounts to a single present value amount. The measurement is based on the value indicated by current market expectations about those future amounts. The cost approach is based on the amount that would currently be required to replace an asset.

Financial instruments of the Company primarily include cash and cash equivalents, short-term investments, and accounts payable. The Company measures its financial products issued by commercial banks at fair value on a recurring basis based on quoted subscription/redemption price published by the relevant banks. The carrying values of cash and cash equivalents, short-term investments, accounts payable, and time deposits approximated their fair values due to their short-term nature.

2. Summary of significant accounting policies (continued)

Segment reporting

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 (the "CODM") in deciding how to allocate resources and in assessing performance. The Company operates in two reportable segments, Plinabulin pipeline and Targeted Protein Degradation ("TPD") platform, as the CODM manages and assesses the Company's performance and operating results of Plinabulin pipeline and TPD platform separately to allocate resources. The Plinabulin pipeline focuses on developing innovative cancer therapies to improve clinical outcomes for patients who have high unmet medical needs. The Company's lead asset, Plinabulin, is being developed as a "pipeline in a drug" in a number of cancer indications. The TPD platform is utilizing a unique "molecular glue" technology to develop innovative therapeutic agents and discover and develop new chemical entities for the most debilitating diseases and disorders.

On December 13, 2024, the Company's Board of Directors discussed and approved a divestiture plan to sell and transfer about 90% to 100% of the Company's interests in SEED to potential investors at a determined price. The TPD platform segment was comprised of SEED's operations. As a result, the TPD platform segment qualified for discontinued operations reporting.

The consolidated financial statements include segment information which reflects the current composition of the reportable segments in accordance with ASC 280, *Segment Reporting*. See Note 14 – Segment reporting and geographic information for further information.

Revenue recognition

Under ASC 606, *Revenue from Contracts with Customers* ("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.

The Company recognizes a contract asset or a contract liability in the consolidated balance sheets, depending on the relationship between the entity's performance and the customer's payment. Contract liabilities represent the excess of payments received as compared to the consideration earned, and is recorded as deferred revenue in the consolidated balance sheets. The Company had no contract assets for the periods presented.

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 the Company fulfills its obligations under each of the agreements, the Company performs the five-step model under ASC 606 noted above.

The 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 transaction price is generally comprised of an upfront payment due at contract inception and variable consideration in the form of payments for the Company's services and materials and milestone payments due upon the achievement of specified events. In general, the consideration allocated to the performance obligation is recognized when the 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 deferred revenue.

Licenses of Intellectual Property: Upfront non-refundable payments allocated to the licensing of 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. For licenses determined to be not distinct from other promised goods or services, the Company accounts for the promise to grant a license and other promised goods or services together as a single performance obligation, and the Company considers the nature of the combined goods or services in determining whether the performance obligation is satisfied over time or at a point in time.

Research and Development Service: Upfront non-refundable payment allocated to research and development services performance obligations is deferred and recognized overtime.

Milestone Payments: At the inception of each arrangement that includes 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. Due to the uncertainty involved in meeting these discovery or 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 discovery and clinical trials. Upon changes to constraint associated with the discovery or developmental milestones, variable consideration will be included in the transaction price when a significant reversal of revenue recognized is not expected to occur.

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).

2. Summary of significant accounting policies (continued)

Comprehensive income (loss)

Comprehensive income (loss) is defined as the changes in equity (deficit) of the Company during a period from transactions and other events and circumstances excluding transactions resulting from investments by owners and distributions to owners. For each of the periods presented, the Company's comprehensive income (loss) includes net loss and foreign currency translation adjustments, and is presented in the consolidated statements of comprehensive loss.

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. All deferred income tax assets and liabilities are classified as non- current on the consolidated balance sheets.

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.

Share-based compensation

The Company applies ASC 718, *Compensation—Stock Compensation* ("ASC 718"), to account for its share-based payments for both employees and non-employees. In accordance with ASC 718, the Company determines whether an award should be classified and accounted for as a liability award or equity award. Equity classified share-based awards are recognized in the consolidated financial statements based on their grant date fair values. Liability classified awards are measured at the fair value of the award on the grant date and remeasured at each reporting period at fair value until the award is settled. The Company has elected to recognize compensation expense on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in-substance, multiple awards for all employee equity awards granted with graded vesting based on service condition. The Company uses the accelerated method for all awards granted with performance and/or market conditions. Compensation expense is recognized for awards containing performance conditions only to the extent that it is probable that those performance conditions will be met. Market conditions are included in the determination of the estimated grant-date fair value of share-based awards. Compensation costs related to awards with a market condition are recognized over the requisite service period regardless of whether the market condition is satisfied. The Company elected to account for forfeitures in the period they occur as a reduction to expense.

Modification, replacements or cancellation of awards

A change in 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. Cancellation of an award accompanied by the concurrent grant of (or offer to grant) a replacement award or other valuable consideration shall be accounted for as a modification of the terms of the cancelled award. Cancellation of an award without the concurrent grant or offer of a replacement award is treated as a settlement for no consideration.

Loss per share

Loss per share is calculated in accordance with ASC 260, *Earnings per Share*. Basic loss per ordinary share for continuing operations and for discontinued operations are computed by dividing net loss from continuing operations and from discontinued operations, respectively, attributable to ordinary shareholders, by the weighted average number of ordinary shares outstanding during the period.

Diluted loss per share for continuing operations and for discontinued operations are calculated by dividing net loss from continuing operations and from discontinued operations, respectively, 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 share options and the vesting of restricted shares, using the treasury stock method. Ordinary share equivalents are excluded from the computation of diluted loss per share if their effects would be anti-dilutive. The effects of all share options and unvested restricted shares were excluded from the calculation of diluted loss per share as their effect would have been anti-dilutive during the years ended December 31, 2024, and 2025. Basic and diluted loss per ordinary share is presented in the Company's consolidated statements of comprehensive loss.

Concentration of risks

Concentration of credit risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company's cash and cash equivalents are held at financial institutions that management believes to be of high credit quality. As of December 31, 2024 and 2025, cash and cash equivalents, and short-term investments were held by financial institutions located in the U.S. and PRC.

PRC state-owned banks, such as China Merchants Bank and Bank of China, are subject to a series of risk control regulatory standards, and PRC bank regulatory authorities are empowered to take over the operation and management when any of those banks faces a material credit crisis. The Company does not foresee substantial credit risk with respect to cash and cash equivalents, and short-term investments held at the PRC state-owned banks. Meanwhile, China does not have an official deposit insurance program, nor does it have an agency similar to what was the Federal Deposit Insurance Corporation (FDIC) in the U.S. In the event of bankruptcy of one of the financial institutions in which the Company has deposits or investments, it may be unlikely to claim its deposits or investments back in full. The Company selected reputable financial institutions with high rating rates to place its currencies. The Company regularly monitors the rating of the financial institutions to avoid any potential defaults. The Company has not experienced any losses on cash and cash equivalents or short-term investments to date. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

2. Summary of significant accounting policies (continued)

Concentration of risks (continued)

Business, customer, political, social and economic risks

The Company participates in a dynamic biopharmaceutical industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: changes in the overall demand for services and products; competitive pressures due to existing competitors and new entrants; advances and new trends in new drugs and industry standards; changes in clinical research organizations and other key vendors; changes in certain strategic relationships or customer relationships; regulatory considerations; intellectual property considerations; and risks associated with the Company's ability to attract and retain employees necessary to support its operations. The Company's operations could also be adversely affected by significant political, economic and social uncertainties in PRC and in relations between PRC and the U.S.

Business risk

The Company relies on third parties to support clinical development activities, trials and the manufacturing process for product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, the Company may not be able to obtain regulatory approval for the Company's drug candidates and the Company's business could be substantially impacted. The Company's main activities are in the U.S. and PRC.

Currency convertibility risk

The Company incurs portions of expenses in currencies other than the U.S. dollars, in particular, the RMB. On January 1, 1994, the PRC government abolished the dual rate system and introduced a single rate of exchange as quoted daily by the People's Bank of China (the "PBOC"). However, the unification of the exchange rates does not imply that the RMB may be readily convertible into U.S. dollars or other foreign currencies. All foreign exchange transactions continue to take place either through the PBOC or other banks authorized to buy and sell foreign currencies at the exchange rates quoted by the PBOC. Approvals of foreign currency payments by the PBOC or other institutions require submitting a payment application form together with suppliers' invoices, shipping documents and signed contracts.

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

Foreign currency exchange rate risk

From July 21, 2005, the RMB is permitted to fluctuate within a narrow and managed band against a basket of certain foreign currencies. The depreciation of RMB against the U.S. dollar was approximately 2.8% for the year ended December 31, 2024, and the appreciation of RMB against the U.S. dollar was approximately 4.2% for the year ended December 31, 2025. It is difficult to predict how market forces or PRC or U.S. government policy may impact the exchange rate between the RMB and the U.S. dollar in the future.

To the extent that the Company needs to convert U.S. dollars into RMB for capital expenditures and working capital and other business purposes, appreciation of the RMB against the U.S. dollar would have an adverse effect on the RMB amount the Company would receive from the conversion. Conversely, if the Company decides to convert RMB into U.S. dollars for the purpose of making payments for dividends on ordinary shares, strategic acquisitions or investments or other business purposes, appreciation of the U.S. dollar against the RMB would have a negative effect on the U.S. dollar amount available to the Company. In addition, a significant depreciation of the RMB against the U.S. dollar may significantly reduce the U.S. dollar equivalent of the Company's earnings or losses.

Recent accounting pronouncements

New accounting standards which have been adopted

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This update requires that public entities on an annual basis, (1) in the rate reconciliation, disclose specific categories and provide additional information for reconciling items that meet a quantitative threshold; (2) about income taxes paid, disclose the amount of income taxes paid (net of refunds received) disaggregated by federal, state, and foreign taxes and by individual jurisdiction in which income taxes paid (net of refunds received) is equal to or greater than 5 percent of total income taxes paid (net of refunds received); and (3) disclose income (or loss) from continuing operations before income tax expense (or benefit) disaggregated between domestic and foreign and income tax expense (or benefit) disaggregated by federal, state, and foreign. This update is effective for annual periods beginning after December 15, 2024. Early adoption is permitted. This guidance should be applied on a prospective basis. Retrospective application is permitted. The Company adopted ASU 2023-09 for the year ended December 31, 2025 on a prospective basis. See Note 6 for income tax disclosures.

New accounting standards which have not yet been adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses. This update requires that at each interim and annual reporting period public entities disclose (1) the amounts of purchases of inventory, employee compensation, depreciation, amortization, and depletion) in commonly presented expense captions; (2) certain amounts that are already required to be disclosed under current GAAP in the same disclosure as the other disaggregation requirements; (3) a qualitative description of the amounts remaining in relevant expense captions that are not separately disaggregated quantitatively; and (4) the total amount of selling expenses and, in annual reporting periods, the definition of selling expenses. In January 2025, the FASB issued ASU 2025-01, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Clarifying the Effective Date. This update clarifies that ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

In December 2025, the FASB issued ASU 2025-10, Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities. The amendments in this update establish the accounting for a government grant received by a business entity, including guidance for (1) a grant related to an asset and (2) a grant related to income. The amendments in this update are effective for annual reporting periods beginning after December 15, 2028, and interim reporting periods within those annual reporting periods. Early adoption is permitted in both interim and annual reporting periods in which financial statements have not yet been issued or made available for issuance. The Company is currently evaluating the impact on its financial statements of adopting this guidance.

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that recently issued standards that are not yet effective will not have a material impact on the Company's consolidated financial statements.

3. Discontinued operations

On December 13, 2024, the Company's Board of Directors discussed and approved a divestiture plan to sell and transfer about 90% to 100% of the Company's interests in SEED to potential investors at a determined price. The divestiture of SEED represents a strategic shift in the Company's reallocation and optimization of the available resources to pipelines with greater potential. In accordance with ASC 205-20, all assets and liabilities of SEED were classified as held-for-sale in the consolidated balance sheet as of December 31, 2024 and 2025, and the results of operations of SEED were reflected as discontinued operations in the consolidated statement of operations for the years ended December 31, 2024 and 2025.

On January 24, 2025, the Company entered into a Preferred Share Purchase Agreement (each, an "Agreement" and collectively, the "Agreements") with each of Winning View Investment Limited, a business company organized in the BVI, FULL TECH CORPORATE DEVELOPMENT LIMITED, a business company organized in the BVI, and Mapfil Investment Limited, a limited company organized in Hong Kong, respectively (each, a "Purchaser" and collectively, the "Purchasers"). On February 17, 2025, the Company and Winning View Investments Limited entered into the First Amendment to Purchase Agreement (the "Amendment"). Pursuant to the Agreements and the Amendment, the Company agreed to sell a total of 8,333,637 Series A-1 Preferred Shares (the "Shares") of SEED to the Purchasers at a price per share of $4.25, in exchange of aggregate cash proceeds of $35,418.

The Agreements, as amended, will be executed in three separate closings as described below. The below ownership percentage for the First Closing is calculated after taking into account the issuance of an aggregate of 5,647,059 Series A-3 Preferred Shares in August 2024, and the ownership percentages for the Second Closing and Third Closing are calculated after taking into account the additional issuance of an aggregate of 1,411,761 Series A-3 Preferred Shares in September 2025, assuming there is no other changes to SEED's share capital prior to such Closings and excluding any shares that may be reserved under an employee stock ownership plan or similar arrangement.

(i) On February 19, 2025, the First Closing (as defined in each Agreement, as amended) was completed. The Company sold and transferred a total of 1,730,454 Shares, comprised of 980,427 Shares to Winning View Investment Limited, 250,009 Shares to FULL TECH CORPORATE DEVELOPMENT LIMITED and 500,018 Shares to Mapfil Investment Limited. Immediately upon the First Closing, the Company's direct and indirect ownership in SEED decreased to 40.12%, but still retained the controlling interest of SEED through the control of the SEED Board. The Company's noncontrolling interests increased by 6.75% upon the First Closing.

(ii) At the Second Closing (as defined in each Agreement, as amended, which management expects to be completed in 2026), the Company will sell and transfer to the Purchasers a total of 3,103,055 Shares, comprised of 1,436,327 Shares to Winning View Investment Limited, 555,576 Shares to FULL TECH CORPORATE DEVELOPMENT LIMITED and 1,111,152 Shares to Mapfil Investment Limited. Immediately upon the Second Closing, the Company's direct and indirect ownership in SEED will further decrease to 26.56%. The Company will lose the controlling interest of SEED due to the loss of control of the SEED Board.

(iii) At the Third Closing (as defined in each Agreement, as amended, which shall be no later than December 15, 2026), the Company will sell and transfer to the Purchasers a total of 3,500,128 Shares, comprised of 1,750,064 Shares to Winning View Investment Limited, 583,355 Shares to FULL TECH CORPORATE DEVELOPMENT LIMITED and 1,166,709 Shares to Mapfil Investment Limited. Immediately upon the Third Closing, the Company's direct and indirect ownership in SEED will ultimately decrease to 13.62%.

The Company determined that the multiple arrangements of the SEED sales with the Purchasers and the three-tranche closings should be accounted for as a single transaction in accordance with ASC 810-10-40-6, as the transactions were entered in contemplation of one another and were essentially a single transaction designed to achieve an overall commercial effect.

The following tables set forth the assets, liabilities, statement of operations, and cash flows of discontinued operations which were included in the Company's consolidated financial statements (in thousands).

	As of December 31,	
	2024	2025
Assets		
Current assets:		
Cash and cash equivalents	$ 13,125	$ 4,352
Short-term investments	12,044	3,531
Advances to suppliers	86	117
Prepaid expenses and other current assets	92	23
Total current assets	25,347	8,023
Noncurrent assets:		
Property and equipment, net	1,323	1,373
Operating right-of-use assets	3,182	2,683
Other noncurrent assets	268	300
Total noncurrent assets	4,773	4,356
Total assets	$ 30,120	$ 12,379
Liabilities and equity		
Current liabilities:		
Short-term loans	$ 3,911	$ 4,369
Accounts payable	505	361
Accrued expenses	1,354	3,105
Current portion of operating lease liabilities	400	430
Deferred revenue	2,001	2,001
Other current liabilities	642	867
Total current liabilities	8,813	11,133
Noncurrent liabilities:		
Operating lease liabilities	2,375	1,945
Deferred revenue	3,822	1,821
Total noncurrent liabilities	6,197	3,766
Total liabilities	$ 15,010	$ 14,899

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

3. Discontinued operations (continued)

	Year ended December 31,	
	2024	2025
Revenue	$ 2,001	$ 2,001
Operating expenses		
Research and development	(7,503)	(10,853)
General and administrative	(2,660)	(3,929)
Loss from operations	(8,162)	(12,781)
Foreign exchange gain, net	-	1
Interest income	149	176
Other income, net	185	116
Loss before income tax	(7,828)	(12,488)
Income tax expense	-	-
Net loss from discontinued operations	(7,828)	$ (12,488)

	Year ended December 31,	
	2024	2025
Net cash used in discontinued operating activities	$ (7,665)	$ (12,314)
Net cash provided by (used in) discontinued investing activities	$ (12,012)	$ 8,207
Net cash provided by discontinued financing activities	$ 23,815	$ 2,980

In connection with the First Closing, the Company recorded a gain on the sale of subsidiary interests:

	Gain recognized on the First Closing
Fair value of consideration received	$ 7,354
Less: Adjustments to noncontrolling interests (6.75% of the equity interests)	368
Gain on sale of subsidiary interests	$ 6,986

4. Collaboration agreements

Jiangsu Hengrui Pharmaceuticals Co., Ltd.

On August 25, 2021, the Company's subsidiary, Wanchunbulin, entered into an exclusive commercialization and co-development agreement ("Hengrui Collaboration Agreement") with Hengrui, pursuant to which Wanchunbulin granted Hengrui exclusive rights to commercialize Plinabulin in all indications (the "Plinabulin Products") in mainland China, Hong Kong, Macau and Taiwan (the "Greater China"). Under the terms of Hengrui Collaboration Agreement, Hengrui assumed all commercialization responsibilities for the Plinabulin Products effective September 22, 2021, including sales and marketing, and Wanchunbulin agreed to provide services to Hengrui, including manufacture and supply of the Plinabulin Products. Wanchunbulin and Hengrui may further participate in the research and development of the Plinabulin Products for additional indications other than prevention of chemotherapy-induced neutropenia ("CIN") and 2nd/3rd line treatment of non-small cell lung cancer ("NSCLC"), and each will share 50% of the research and development costs. The Hengrui Collaboration Agreement will remain effective until the patent protection period of all Plinabulin Products related intellectual properties expires.

Under the Hengrui Collaboration Agreement, Hengrui paid Wanchunbulin an upfront non-refundable fee of RMB 200,000 ($28,600) in September 2021. Wanchunbulin will be eligible to receive up to RMB 700,000 ($100,099) in potential regulatory development milestone payments, and up to RMB 400,000 ($57,199) in commercial milestone payments, respectively. In addition, Wanchunbulin will be eligible to receive royalty payments based on net sales of the Plinabulin Products, which sets forth minimum royalties to be received by Wanchunbulin for a specified period.

The Hengrui 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 identified the following material components under the agreement: (1) license of exclusive commercialization rights of the Plinabulin Products (the "License"), (2) the manufacturing and supply of the Plinabulin Products (the "Manufacturing and Supply Services"), and (3) research and development of the Plinabulin Products for additional indications. The Company further determined the license of exclusive commercialization rights of the Plinabulin Products and the manufacturing and supply of the Plinabulin Products are reflective of a vendor-customer relationship and therefore within the scope of ASC 606, and research and development of the Plinabulin Products for additional indications is not a promise to a customer within the scope of ASC 606.

The Company determined that the License and the Manufacturing and Supply Services are not distinct from each other and represent a single performance obligation. The transaction price of the arrangement was the upfront payment of RMB 200,000 ($28,600). The development and commercialization milestone payments and the minimum royalty payments are fully constrained at contract inception due to uncertainty of achievement and are not included in the transaction price. The transaction price allocated to the License and Manufacturing and Supply Services, as a combined performance obligation, will be recognized as revenue over time using unit of delivery measure of progress, as the Company believes that it faithfully depicts the Company's performance toward complete satisfaction of the performance obligation. The Company did not recognize any revenues from the Hengrui Collaboration Agreement for the years ended December 31, 2024 and 2025, and recorded the entire upfront non-refundable fee received as deferred revenue.

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

4. Collaboration agreements (continued)

Eli Lilly and Company

On November 12, 2020, the Company's subsidiary, SEED, entered into a research collaboration and license agreement (the "Lilly Collaboration Agreement") with Eli Lilly and Company ("Lilly"). Under the Lilly Collaboration Agreement, SEED controls certain rights to an intellectual property and other materials related to a platform technology for ubiquitin ligase agonist screening (the "Ub Platform Technology"), and Lilly and SEED shall use commercially reasonable efforts to conduct a research and development program to generate, identify and/or optimize active compounds ("Lilly Compounds") that directed against no more than three targets selected by Lilly ("Lilly Targets"), using the Ub Platform Technology in accordance with the applicable research plans for each of the Lilly Targets.

Under the Lilly Collaboration Agreement, Lilly paid SEED an upfront non-refundable fee of $10,000 in November 2020. In addition, SEED will also be eligible to receive up to approximately $780,000 in potential pre-clinical discovery, clinical and regulatory development milestone payments, as well as commercial milestones and royalty payments based on net sales of products that result from the collaboration. As of December 31, 2025, SEED has received $3,000 of these milestone payments for pre-clinical discovery. The Lilly 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 further determined the collaboration is reflective of a vendor-customer relationship and therefore within the scope of ASC 606.

Under ASC 606, the Company determined the license under the Ub Platform Technology is not distinct within the context of the contract because it is used as inputs to produce and deliver the combined outputs, i.e. the identification of Lilly Compounds. The Company determined that it has a single performance obligation which is the stand ready obligation to provide the research and development services to Lilly throughout the shorter of the period up to the completion of research and development activities under the research plans for three Lilly Targets or the contract period of 7 years. Transaction price allocated to the research and development services is recognized as revenue over time on a straight-line basis because the customer simultaneously receives and consumes the benefits as the Company performs throughout a fixed term. The preclinical discovery, clinical and regulatory development milestone payments were fully constrained at contract inception, and are not included in the transaction price.

SEED recognized collaboration revenue of $2,001 and $2,001 related to the Lilly Collaboration Agreement for the years ended December 31, 2024 and 2025, respectively. Revenue recognized in each year were from amounts included in contract liabilities at the beginning of the year and milestone payments received during the year, if any. These recognized revenues were included in loss from discontinued operations and the related contract liabilities were included in current and noncurrent liabilities of discontinued operations, for all the periods presented.

5. Property and equipment, net

Property and equipment of continuing operations consisted of the following:

	December 31,	
	2024	2025
	$	$
Office equipment	317	323
Laboratory equipment	111	115
Motor vehicles	94	98
Leasehold improvements	271	271
	793	807
Less: accumulated depreciation	(554)	(641)
Property and equipment, net	239	166

Depreciation expenses of continuing operations for the years ended December 31, 2024 and 2025 were $72 and $87, respectively.

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

6. Income taxes

Cayman Islands

The Company is incorporated in the Cayman Islands and is not subject to income tax under the current laws of the Cayman Islands.

BVI

BeyondSpring Ltd., SEED Technology, BVI Biotech, SEED, and SEED LH Inc. are all incorporated in the BVI and are not subject to income tax under the current laws of the BVI.

U.S.

BeyondSpring US, SEED US, and SEED LH MG Inc. are incorporated in Delaware, the U.S. They are subject to statutory U.S. Federal corporate income tax at a rate of 21% for all years presented

Hong Kong

BeyondSpring HK is incorporated in Hong Kong. Companies registered in Hong Kong are subject to Hong Kong Profits Tax on the taxable income as reported in their respective statutory financial statements adjusted in accordance with relevant Hong Kong tax laws. The applicable tax rate is 16.5% in Hong Kong. BeyondSpring HK had no taxable income for all years presented and therefore, no provision for income taxes is required.

PRC

Wanchun Dalian, Wanchunbulin, Beijing Wanchun, and Wanchun Hongji are subject to the statutory tax rate of 25% in accordance with the PRC Enterprise Income Tax Law ("EIT Law"), which was effective since January 1, 2008. In accordance with the implementation rules of EIT Law, a qualified "High and New Technology Enterprise" ("HNTE") is eligible for a preferential tax rate of 15%. The HNTE certificate is effective for a period of three years. An entity must file required supporting documents with the tax authority and ensure fulfillment of the relevant HNTE criteria before using the preferential rate. An entity could re-apply for the HNTE certificate when the prior certificate expires. Starting from 2022, Wanchunbulin is designated as the qualified HNTE and is subject to the preferential statutory tax rate of 15% for 3 years. In 2025, the tax rate of Wanchunbulin is 25%.

The components of loss (income) before income tax of continuing operations are as follows:

	2024	2025
	$	$
Cayman Islands	3,613	2,129
U.S.	2,023	3,023
PRC	975	596
BVI	2,158	2,877
Loss before income tax	$ 8,769	$ 8,625

Income tax expenses of continuing operations for the years ended December 31, 2024and 2025 are as follows:

	2024	2025
	$	$
Current income tax	(96)	(90)
Deferred income tax	-	-
Income tax expense	(96)	(90)

A reconciliation of the differences between income tax expenses and the amount computed by applying the U.S. Federal corporate income tax rate of 21% for the years of 2024 and 2025 are as follows. The U.S. statutory tax rate is being used as this is the jurisdiction of the primary operations:

	2024	
	Amount $	Percent of Pretax Income
Loss before income tax	8,769	
Expected income tax benefit	$ 1,841	21.0%
Tax rate differential	(1,138)	-13.0%
Non-deductible expenses	(20)	-0.2%
Research tax credits	(79)	-0.9%
Preferential rate	(166)	-1.9%
Current and deferred tax rate differences	147	1.7%
Stock compensation expense-windfall	(44)	-0.5%
Research and development super-deduction	424	4.8%
UTP - interest expense	(525)	-6.0%
Others	41	0.5%
Changes in valuation allowance	(577)	-6.6%
Income tax expense	(96)	-1.1%

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

6. Income Taxes (continued)

Upon adoption of ASU 2023-09, Improvements to Income Tax Disclosures, as described in Note 2, Summary of Significant Accounting Policies, the reconciliation of the differences between income tax expenses and the amount computed by applying the U.S. Federal corporate income tax rate of 21% for the year ended December 31, 2025 was as follows:

	2025	
	Amount $	Percent of Pretax Income
Loss before income tax	8,625	
Expected income tax benefit	$ 1,811	21.0%
Foreign tax effects		
Cayman		
Statutory tax rate difference between Cayman and United States	(447)	-5.2%
BVI		
Statutory tax rate difference between BVI and United States	(604)	-7.0%
PRC		
Statutory tax rate difference between PRC and United States	165	1.9%
Statutory GAAP prior year adjustment	310	3.6%
Research and development	442	5.1%
Change in valuation allowance	(1,033)	-12.0%
Other	(9)	-0.1%
Nontaxable or non-deductible items		
Stock Compensation Expense	(34)	-0.4%
Other	(9)	0.1%
Tax Credits		
Research and development tax credits	86	1.0%
Change in unrecognized tax benefits	(2,318)	-26.9%
Changes in valuation allowance	1,551	18.0%
Income tax expense	(90)	-1.0%

Net deferred tax assets as of December 31, 2024 and 2025 consisted of the following:

	December 31, 2025	
	2024	2025
	$	$
Deferred tax assets:		
Net operating loss carryforward	28,181	29,675
Capitalization of R&D expense under PRC tax	6,729	6,749
Section 174 mandatory R&E capitalization	2,870	2,152
Share-based compensation	1,695	756
Deferred incentive compensation	15	19
Research tax credits	5,403	5,489
Lease liability obligation	124	71
Deferred revenue	6,075	5,652
Accruals and reserves	48	76
Deferred tax assets from discontinued operations	7,855	10,682
Total deferred tax assets	58,995	61,321
Deferred tax liabilities:		
Depreciation	(29)	(20)
Unrealized gain/loss	(41)	(68)
Right of use lease assets	(108)	(62)
Deferred tax liabilities from discontinued operations	(1,005)	(909)
Total deferred tax liabilities	(1,183)	(1,059)
Total gross deferred tax assets	57,812	60,262
Less: valuation allowance	(57,812)	(60,262)
Net deferred tax assets	-	-

The Company operates through several subsidiaries and valuation allowances are considered for each of the subsidiaries on an individual basis. The Company recorded a valuation allowance against deferred tax assets of those subsidiaries that are individually in a three-year cumulative loss, or in a cumulative loss and not forecasting profits in the foreseeable future as of December 31, 2024 and 2025. As of December 31, 2025, the Company continues to assert indefinite reinvestment on the excess of the financial reporting bases over tax bases in the Company's investments in foreign subsidiaries. A deferred tax liability of nil has not been established for the approximately nil of cumulative undistributed foreign earnings that may be subject to withholding taxes.

As of December 31, 2024 and 2025, the Company had gross net operating loss carryforwards of approximately $133,383 and $149,963, respectively. As of December 31, 2025, the Company had U.S. and PRC tax loss carryforwards of approximately $128,309 and $21,654, respectively. For losses incurred in the U.S. in years after December 31, 2017, the Tax Cuts and Jobs Act included a limitation on the deduction for net operating losses to 80% of current year taxable income and a provision where such losses can be carried forward indefinitely. $18,347 of loss carryforwards generated prior to 2018 are not limited in their current usage and can be carried forward for 20 years after the year they were generated and begin to expire in 2035. The Company has $5,489 R&D credits which begin to expire in 2040.

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

6. Income Taxes (continued)

NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50% as defined under Sections 382 and 383 in the Internal Revenue Code ("IRC"). This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company's value immediately prior to the ownership change. As a result of ownership changes in the Company from its inception through December 31, 2024, the Company's NOL and tax credit carryforwards allocable to the periods preceding each such ownership change could be subject to limitations under IRC Section 382, however the Company has not yet completed an IRC Section 382 study.

As of December 31, 2024 and 2025, the Company had unrecognized tax benefits of $3,053 and $10,460, respectively. The gross unrecognized tax benefits for the years ended December 31, 2024 and 2025 were as follows:

	Year Ended December 31,	
	2024	2025
	$	$
Beginning balance, as of January 1	3,194	3,053
Additions based on tax positions related to prior tax years	197	7,842
Reductions based on tax positions related to prior tax years	(434)	(435)
Additions based on tax positions related to current tax year	96	-
Ending balance, as of December 31	3,053	10,460

The Company recognizes interest and penalties accrued related to unrecognized tax benefits in income tax expenses. For the year ended December 31, 2021, the Company did not recognize interest and penalties accrued related to unrecognized tax benefits in income tax expenses. For the years end December 31, 2024 and 2025, the Company recognized $96 interest accrued and $193 reversal of interest expense related to unrecognized tax benefits in income tax expense. The Company had approximately $1,566 and $1,373 in accumulated accrued interest and penalties recorded in other current liabilities as of December 31, 2024 and 2025, respectively.

The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly change within the next 12 months, and the fluctuation in deferred taxes would essentially be offset by a valuation allowance. The Company's subsidiaries in the U.S. and PRC filed income tax returns in the U.S. and PRC, respectively. For the entities in the U.S., the tax returns are subject to U.S. federal and state income tax examination by tax authorities for tax years beginning in 2022. For entities in the PRC, the tax returns for tax years after 2020 are open to examination by the PRC tax authorities.

The Company is currently under federal audit for the 2023 tax year for BeyondSpring US. The Company believes no material adjustments will result from this examination.

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

7. Share-based compensation

General

On February 24, 2017, in connection with the IPO, the Company's board of directors and shareholders approved an equity compensation plan, the 2017 Omnibus Incentive Plan (the "2017 Plan"), which became effective on March 9, 2017, to provide an additional incentive to selected officers, employees, non-employee directors, independent contractors and consultants of the Company (the "Participants"). The share awards granted by the Company under the 2017 Plan contain service conditions, and will generally vest based on a time-based vesting schedule determined by the administrator of the 2017 Plan. Certain awards also contain (1) performance conditions with respect to research and development progress or/and business development progress, or/and (2) market conditions with respect to the share price of the Company. Under the 2017 Plan, the maximum number of the Company's ordinary shares reserved for issuance is 5,277,197 shares.

Restricted Shares

The following table summarizes the Company's restricted share activities under the 2017 Plan:

	Number of shares	Weighted average grant date fair value
		$
Outstanding at December 31, 2023	-	-
Granted	-	-
Vested	-	-
Forfeited	-	-
Outstanding at December 31, 2024	-	-
Granted	6,000	1.63
Vested	(3,000)	1.63
Forfeited	-	-
Outstanding at December 31, 2025	3,000	1.63
Expected to vest at December 31, 2025	3,000	1.63

The total fair value of restricted shares vested during the years ended December 31, 2024 and 2025 was nil and $5, respectively.

As of December 31, 2025, there was $1 of total unrecognized share-based compensation cost, related to unvested and expected to vest restricted shares. This unrecognized share-based compensation cost is expected to be recognized over an estimated weighted-average period of 0.21 years. Total unrecognized compensation cost may be adjusted for actual forfeitures occurring in the future.

Share options

The following table summarizes the Company's share option activities under the 2017 Plan:

	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, 2023	1,865,226	6.46		7.66	
Granted	838,939	3.02	2.53		
Exercised	(28,666)	0.95	0.77		34
Forfeited	(149,845)	7.50	5.73		
Outstanding at December 31, 2024	2,525,654	5.32		7.43	455
Granted	224,750	1.34	1.08		
Forfeited	(18,598)	2.67	2.07		
Outstanding at December 31, 2025	2,731,806	5.01		6.58	514
Exercisable as of December 31, 2025	2,059,124	4.88		6.61	362
Vested and expected to vest at December 31, 2025	2,452,926	4.32		6.81	514

As of December 31, 2025, there was $128 of total unrecognized share-based compensation cost, related to unvested and expected to vest share options. This unrecognized share-based compensation cost is expected to be recognized over an estimated weighted-average period of 0.41 years. Total unrecognized compensation cost may be adjusted for actual forfeitures occurring in the future. The intrinsic value of a share option is the difference between the market price of the ordinary share at the measurement date and the exercise price of the option.

The total fair value of share options vested during the years ended December 31, 2024 and 2025 was $1,412 and $246, respectively.

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

7. Share-based compensation (continued)

Fair value of options

The Black-Scholes-Merton formula was applied in determining the estimated fair value of the share options granted without market conditions. The model requires the input of assumptions including the estimated expected share price volatility and the expected terms of awards. The Company historically has limited available historical data to demonstrate consistent early exercise behavior. To determine the expected term of the awards, the Company applied a simplified method considering factors including the timing of achieving various performance conditions and their respective probabilities as well as the contractual life of the options. The determination of the expected terms for awards with performance conditions involves the application of management's judgment. The risk-free interest rates for the periods within the expected term of the option are based on the U.S. Treasury rate. The volatility assumption was estimated based on the historical volatility of the Company's share price.

The following table presents the assumptions used in Black-Scholes-Merton formula to estimate the fair values of the share options granted in the years presented:

	For the year ended December 31,					
	2024			2025		
Fair value of ordinary share	0.90	~	3.60			1.34
Risk-free interest rate	3.84%	~	4.52%	3.77%	~	4.03%
Expected term (years)	2.89	~	6.25	3.00	~	5.50
Expected volatility	110%	~	140%	105%	~	115%
Expected dividend yield			0%			0%
Contractual life (years)	5	~	10	5	~	10

Long-term incentives

During 2021, the Company issued long-term incentive with an aggregate value of $79,225 to certain of its senior management. The long-term incentive awards are subject to certain performance-based vesting conditions and certain awards also are subject to market conditions. 25% of the long-term incentive awards will be settled in the Company's ordinary shares, and the remaining 75% of the awards will be settled in cash or the Company's ordinary shares, all or in part, at the grantee's election.

The long-term incentive awards are classified as liability awards. As of December 31, 2025, the Company has issued a total of 3,486 ordinary shares with a total fair value of $37. Compensation expense recognized for the years ended December 31, 2024 and 2025 was $(13) and $(153) respectively. As of December 31, 2025, there was $60 of total unrecognized share-based compensation cost, related to unvested and expected to vest long-term incentive awards. This unrecognized share-based compensation cost is expected to be recognized over an estimated weighted-average period of 3.06 years. Total unrecognized compensation cost may be adjusted for actual forfeitures occurring in the future.

The following table summarizes total share-based compensation expense recognized under 2017 Plan for the years ended December 31, 2024 and 2025:

	Year ended December 31,	
	2024	2025
	$	$
Research and development	63	106
General and administrative	2,000	390
Total	2,063	496

SEED 2022 Share Incentive Plan

In 2022, SEED adopted its 2022 Share Incentive Plan (the "SEED Plan"). Under this plan, SEED has granted share options to some of its employees and consultants, which will be settled by SEED in its ordinary shares upon exercise of those options. These awards are generally subject to a four-year or five-year time-based vesting schedule as determined by the administrator of the plan.

The following table summarizes SEED's share option activities under the 2022 Plan:

	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, 2023	1,257,000	0.50		8.82	
Granted	651,333	0.60	0.26		
Forfeited	(9,500)	0.50	0.32		
Outstanding at December 31, 2024	1,898,833	0.53		7.63	1,760
Granted	375,344	1.46	1.30		
Exercised	(77,250)	1.12	0.84		26
Forfeited	(7,500)	0.50	0.23		
Outstanding at December 31, 2025	2,189,427	0.67		7.05	2,230
Exercisable as of December 31, 2025	989,749	0.50		6.69	946
Vested and expected to vest at December 31, 2025	2,124,427	0.65		6.98	2,215

As of December 31, 2025, there was $354 of total unrecognized share-based compensation cost, related to unvested and expected to vest share options under the SEED Plan. This unrecognized share-based compensation cost is expected to be recognized over an estimated weighted-average period of 1.32 years. The total fair value of share options vested during the years ended December 31, 2024 and 2025 was $88 and $23, respectively.

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

7. Share-based compensation (continued)

SEED 2022 Share Incentive Plan (continued)

The Black-Scholes-Merton formula was applied in determining the estimated fair value of the share options granted by SEED. The following table presents the assumptions used in Black-Scholes-Merton formula to estimate the fair values of the share options granted in the years presented:

	For the year ended December 31,					
	2024			2025		
Fair value of ordinary share	0.19	~	1.46	1.46	~	1.69
Risk-free interest rate	3.51%	~	4.31%	3.81%	~	4.44%
Expected term (years)	3.75	~	6.25	5.50	~	10
Expected volatility	117.10%		141.40%	114.02%		126.34%
Expected dividend yield			0%			0%
Contractual life (years)	5	~	10			10

The following table summarizes total share-based compensation expense recognized under the SEED Plan for the years ended December 31, 2024, and 2025. These expenses were included in loss from discontinued operations for all the periods presented.

	Year ended December 31,	
	2024	2025
	$	$
Research and development	50	29
General and administrative	142	196
Total	192	225

8. Employee defined contribution plan

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 funds and other welfare benefits are provided to employees. Chinese labor regulations require that the Company's PRC subsidiaries make contributions to the government for these benefits based on certain percentages of the employees' salaries. The Company has no legal obligation for the benefits beyond the contributions made. The total amounts for such employee benefits from continuing operations, which were expensed as incurred, were $45 and $47 for the years ended December 31, 2024 and 2025, respectively.

BeyondSpring US maintains a defined contribution 401(k) savings plan (the "401(k) Plan") for eligible employees in the U.S. employees. The 401(k) Plan allows participants to defer a portion of their annual compensation on a pretax or Roth basis. In addition, the Company matches up to 6% of the participant's base salary. Company contributions for continuing operations to the 401(k) Plan totaled $66 and $60 in the years ended December 31, 2024 and 2025, respectively.

9. 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 statutory 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 U.S. GAAP differ from those reflected in the statutory financial statements of the Company's PRC subsidiaries.

In accordance with the PRC Regulations on Enterprises with Foreign Investment and their articles of association, a foreign invested enterprise established in the PRC is required to provide certain statutory reserves, which are appropriated from net profit as reported in the enterprise's PRC statutory accounts. A foreign invested enterprise is required to allocate at least 10% of its annual after-tax profit to the general reserve until such reserve has reached 50% of its respective registered capital based on the enterprise's PRC statutory accounts.
Appropriations to other funds are at the discretion of the board of directors for all foreign invested enterprises. The aforementioned reserves can only be used for specific purposes and are not distributable as cash dividends. Wanchun Dalian and Wanchun Hongji were established as foreign invested enterprises and therefore are subject to the above mandated restrictions on distributable profits.

Additionally, in accordance with the Company Law of the PRC, a domestic enterprise is required to provide a statutory common reserve 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 dividends. Wanchunbulin and Beijing Wanchun were established as domestic invested enterprises and therefore are subject to the above mandated restrictions on distributable profits.

Foreign exchange and other regulations in the PRC further restrict the Company's PRC subsidiaries from transferring funds to the Company in the form of loans, advances or cash dividends. As of December 31, 2024 and 2025, amounts restricted were the net assets of the Company's PRC subsidiaries, which amounted to nil and $12, respectively.

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

10. Leases

The Company's continuing operations has operating leases for offices in the U.S. and China. Total expenses incurred under these operating leases for the years ended December 31, 2024 and 2025 were $267 and $281, respectively. Total expenses incurred under short-term leases for the years ended December 31, 2024 and 2025 were $31 and $1, respectively. The short-term lease commitments were nil as of December 31, 2025.

Maturities of operating lease liabilities as of December 31, 2025 are as follows:

	$
Year ending December 31, 2026	332
Total lease payments	332
Less: imputed interest	(12)
Present value of lease liabilities	320

Other supplemental information related to leases is summarized below:

	Year ended December 31,	
	2024	2025
Operating cash flows used in operating lease	$ 295	410

	As of December 31,	
	2024	2025
Weighted average remaining lease term (years)	2.16	1.20
Weighted average discount rate	5.1%	5.0%

11. Supplemental balance sheet information

Other noncurrent assets consist of the following:

	December 31,	
	2024	2025
	$	$
Deductible input value-added tax	113	125
Others	100	99
Total	213	224

Other current liabilities consist of the following:

	December 31,	
	2024	2025
	$	$
Compensation related	612	538
Professional services	71	2
Income tax and other taxes payable	1	248
Others	96	34
Total	780	822

Other noncurrent liabilities consist of the following:

	December 31,	
	2024	2025
	$	$
Compensation related	73	90
Income tax payable	3,240	3,474
Other taxes payable	373	417
Total	3,686	3,981

12. Noncontrolling interests

The main rights, preferences and privileges of Preferred Shares issued by SEED are as follows: Liquidation preferences

In the event of any voluntary or involuntary liquidation, dissolution or winding up of SEED, or in a deemed liquidation event, the assets of SEED shall be distributed in the following order:

a. before any payment shall be made to the holders of Series A-1 Preferred Shares or ordinary shares by reason of their ownership thereof, holders of Series A-2 Preferred Shares and Series A-3 Preferred Shares (the "Senior Series A Preferred Shares") shall be entitled to an amount per share equal to the greater of (i) the applicable original issue price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all Senior Series A Preferred Shares been converted into ordinary shares immediately prior to such liquidation, dissolution, winding up or deemed liquidation event.

b. after the payment in full of the amount distributable or payable on the Senior Series A Preferred Shares, the holders of Series A-1 Preferred Shares then outstanding shall be entitled to be paid out of the assets of SEED available for distribution to its Shareholders, and in the event of a deemed liquidation event, the holders of Series A-1 Preferred Shares then outstanding shall be entitled to be paid out of the consideration not payable to the holders of Senior Series A Preferred Shares or the remaining available proceeds, as applicable, before any payment shall be made to the holders of ordinary shares by reason of their ownership thereof, an amount per share equal to the greater of (i) the applicable original issue price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all Series A-1 Preferred Shares been converted into ordinary shares immediately prior to such liquidation, dissolution, winding up or deemed liquidation event.

c. after the payment in full of the amount distributable or payable on the Preferred Shares, the remaining assets of SEED available for distribution to the shareholders or, in the case of a deemed liquidation event, the consideration not payable to the holders of Preferred Shares or the remaining available proceeds, as the case may be, shall be distributed among the holders of ordinary shares, pro rata based on the number of ordinary shares held by each such holder.

Redemption rights

The Series A-2 Preferred Shares shall be redeemed by SEED at a price equal to the applicable original issue price per share plus an annual return of 8% of the applicable original issue price, in three annual installments commencing not more than sixty days after receipt by SEED at any time on or after November 10, 2025 from the holders of at least a majority of the outstanding Series A-2 Preferred Shares of written notice requesting redemption of all Series A-2 Preferred Shares. The redemption is not guaranteed by the Company. On July 26, 2024, the redemption rights associated with the Series A-2 Preferred Shares were removed upon the signing of A3 SPA.

Conversion rights

Each Preferred Share shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable ordinary shares of SEED as at an initial conversion ratio of 1:1 adjusted for share splits, share dividends, recapitalizations and similar transactions.

Each Preferred Shares shall automatically be converted into ordinary shares based on a one-for-one basis upon either (a) in the event of a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, in the Nasdaq Stock Market's National Market, the New York Stock Exchange or another exchange or marketplace approved by SEED's Board of Directors, at a price per share of at least $7.5375 resulting in at least $50,000 of gross proceeds to SEED (the "Qualified IPO") or (b) the date and time, or the occurrence of an event, specified by vote or written consent of either (x) at least a majority of the outstanding Preferred Shares voting together as a single class on an as-converted basis, which majority must include the approval of either Lilly or Eisai or (y) a majority of the Senior Series A Preferred Shares, voting together as a single class on an as-converted basis.

Voting rights

Each holder of outstanding Preferred Shares shall be entitled to cast the number of votes equal to the number of whole ordinary shares into which the Preferred Shares held by such holder are convertible as of the record date for determining shareholders entitled to vote on such matter.

12. Noncontrolling interests (continued)

Accounting for the Series A-2 Preferred Shares

Series A-2 Preferred Shares issued by SEED were previously classified as contingently redeemable noncontrolling interests within mezzanine equity because the shares were redeemable at the option of the holders upon the occurrence of certain events outside the control of SEED. The Company recognized changes in the redemption value by adjusting the carrying amount of the redeemable noncontrolling interests to the redemption value at each reporting date.

On July 26, 2024, the redemption rights associated with the Series A-2 Preferred Shares were removed upon the execution of the A3 SPA. As a result, the Series A-2 Preferred Shares no longer contain redemption features outside the control of the Company, and the carrying value previously classified as mezzanine equity was reclassified to permanent equity.

The accretion to redemption value associated with contingently redeemable noncontrolling interests totaled $457 and nil for the years ended December 31, 2024 and 2025, respectively.

Accounting for the Series A-3 Preferred Shares

The Series A-3 Preferred Shares were classified as permanent equity because the shares did not have redemption features that were not solely within the control of the Company, and their conversion option is clearly and closely related to the host instrument and the underlying ordinary shares are not publicly traded nor readily convertible into cash. The Series A-3 Preferred Shares are recorded at their initial fair value, equal to the original issuance price, less issuance costs, and are not subsequently remeasured.

13. Commitments and contingencies

Legal proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operation, financial condition or cash flows.

Commitments

Wanchunbulin, a subsidiary of the Company, has entered into a government grant agreement with specific local authorities in PRC. Wanchunbulin commits to staying within designated districts, maintaining current tax jurisdictions, and retaining its registered capital, until 2033. Wanchunbulin also undertakes not to establish additional entities in other jurisdictions within Greater China for the purposes of conducting research, development, and commercialization activities related to Plinabulin, provided such activities fall within the scope of the government grant agreement. Otherwise, Wanchunbulin may be required to refund the grants.

(Amounts in thousands of U.S. Dollars ("$") and Renminbi ("RMB"),
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14. Segment reporting and geographic information

For the years ended December 31, 2024 and 2025, the Company operated in two reportable segments: (i) Plinabulin pipeline and (ii) TPD platform.

On December 13, 2024, the Company's Board of Directors discussed and approved a divestiture plan to sell and transfer about 90% to 100% of the Company's interests in SEED to potential investors at a determined price. The TPD platform segment was comprised of SEED's operations. As a result, for the years ended December 31, 2024 and 2025, the TPD platform segment qualified for discontinued operations reporting. See Note 3 – Discontinued operations.

The Company presents segment information after elimination of inter-company transactions. In general, revenues and operating expenses are directly attributable, or are allocated, to each segment. The Company allocates operating expenses that are not directly attributable to a specific segment, such as those that support infrastructure across different segments, to different segments mainly on the basis of usage, headcount, depending on the nature of the relevant operating expenses.

The Company's Chief Executive Officer, as the CODM, uses segment net loss to allocate resources for each segment and to assess the performance of each segment, primarily by monitoring actual results versus approved budgets. Significant segment expenses are presented in the table below. Other segment items include interest income, other income, net, and income tax expenses. The CODM does not evaluate the performance of segments using asset or liability information.

	For the year ended December 31,	
	2024	2025
	$	$
Clinical and pre-clinical expenses	462	1,630
Patent expenses	928	792
Personnel costs	4,642	3,196
Professional services	1,442	1,958
Other operational expenses	1,280	1,369
Other segment items	111	(230)
Segment net loss	8,865	8,715
Reconciliation of net loss:		
Net loss from discontinued operations	7,828	5,502
Consolidated net loss	16,693	14,217

The Company's long-lived assets of continuing operations by geographic area are presented as follows:

	December 31,	
	2024	2025
	$	$
Property and equipment, net:		
PRC	34	11
U.S.	205	155
Total	239	166

15. Related Party Transactions

In September 2025, The JKNM Living Trust, dated November 27th, 2020 purchased 117,647 shares of SEED's Series A-3 Preferred Shares, at $4.25 per share. The aggregate purchase price is $500. One of the Company’s Board Member, Jiangwen Majeti, is the trustee of The JKNM Living Trust, dated November 27th, 2020. The investment was made on the same terms as those offered to third-party investors.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

On April 8, 2025, Marcum LLP ("Marcum") resigned as our independent registered public accounting firm. On November 1, 2024, CBIZ acquired the attest business of Marcum. Substantially all of the partners and staff that provided attestation services with Marcum joined CBIZ. On April 9, 2025, upon Marcum's resignation as our auditors and with the approval of our audit committee, CBIZ was engaged as our independent registered public accounting firm.

Marcum's audit reports on the Company's consolidated financial statements as of and for the years ended December 31, 2024 and 2023 did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles, except that the audit report on the consolidated financial statements of the Company for the year ended December 31, 2023 contained an explanatory paragraph regarding the Company stating that there was substantial doubt about the Company's ability to continue as a going concern.

During the audits for the fiscal years ended December 31, 2024 and 2023 and the subsequent interim period through April 8, 2025, there were (i) no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) between the Company and Marcum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Marcum, would have caused Marcum to make reference to the subject matter of the disagreements in connection with its reports on the consolidated financial statements for the years ended December 31, 2024 and 2023, and (ii) no "reportable events" (as defined in Item 304(a)(1)(v) of Regulation S-K and the related instructions).

During the Company's two most recent fiscal years ended December 31, 2024 and 2023 and the subsequent interim period prior to the engagement of CBIZ on April 9, 2025, neither the Company nor anyone on its behalf has consulted with CBIZ on either (a) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements, and neither a written report nor oral advice was provided to the Company by CBIZ that CBIZ concluded was an important factor considered by the Company in reaching a decision as to any accounting, auditing or financial reporting issue, or (b) any matter that was the subject of a disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K, or a reportable event as set forth in Item 304(a)(1)(iv) of Regulation S-K.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

Our management has evaluated, with the participation of our Chief Executive Officer, who performs the functions of Principal Executive and Financial Officer under Rule 13a-15 under the Exchange Act, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, our Principal Executive and Financial Officer has concluded that the design and operation of our disclosure controls and procedures were effective as of December 31, 2025.

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 our financial reporting and the preparation of financial statements for external purposes in accordance with the U.S. GAAP and 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 our company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with U.S. GAAP, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of the unauthorized acquisition, use or disposition of our company's assets that could have a material effect on the consolidated 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 risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As required by Section 404 of the Sarbanes-Oxley Act and related rules as promulgated by the SEC, our management including our Principal Executive and Financial Officer assessed the effectiveness of internal control over financial reporting as of December 31, 2024 using the criteria set forth in the report "Internal Control—Integrated Framework (2013)" published by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Our independent registered public accounting firm, CBIZ, was not required to perform an evaluation of our internal control over financial reporting as of December 31, 2025.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2025 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of the Registered Public Accounting Firm

As a non-accelerated filer, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (and the SEC rules and regulations thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III.

Item 10. Directors, Executive Officer and Corporate Governance.

Below is a list of the names and ages of our co-founder, directors and executive officers (including officers of BeyondSpring Pharmaceuticals, Inc., or BeyondSpring U.S.) as of the date of this Annual Report, and a brief account of the business experience of each of them. The business address for our directors and officers and the officers of BeyondSpring U.S. is c/o BeyondSpring Inc., 100 Campus Drive, West Side, 4th Floor, Suite 410, Florham Park, NJ 07932.

Name	Age	Position(s)
Executive Officers		
Lan Huang, Ph.D.	55	Co-Founder, Chairperson and Chief Executive Officer
June Lu, Ph.D.	60	Chief Scientific Officer
Non-Employee Directors		
Brendan Delaney, MBA	51	Director
Patrick Fabbio, MBA	58	Director
Matthew Kirkby, M.A.	57	Director
Jiangwen Majeti, Ph.D., MBA	58	Director
Sihai Xu, MBA	54	Director

Lan Huang, Ph.D. is our co-founder, Chairperson and Chief Executive Officer and has been a member of our board of directors since November 2014. Dr. Huang brings over 15 years of entrepreneurial experience in the Chinese and U.S. biotechnology industries. In 2010, Dr. Huang co-founded Wanchun Biotech, the former holding company of our U.S. subsidiary. In 2007, Dr. Huang co-founded Wuxi MTLH Biotechnology Co. Ltd, where she served as Chief Executive Officer in 2010 and continues to hold a directorship. The rights related to the development and marketing of the peptide drug in China, which drug Dr. Huang designed while at Wuxi MTLH Biotechnology Co. Ltd, were sold to Shanghai Pharmaceutical Group in 2010. Additionally, in 2008, Dr. Huang co-founded Paramax International Inc., a CRO that conducts clinical trials for global biopharmaceutical and medical device companies. Paramax International Inc. was acquired by ReSearch Pharmaceutical Services, Inc. in 2009. Currently, Dr. Huang serves on the board of directors of Sincere Efforts Foundations Inc., a non-profit organization. Dr. Huang was trained at Memorial Sloan Kettering Cancer Center from 1998 to 2002, where her research in cancer signaling pathways involving P53 degradation was published in Science. Her translational research in cancer signaling pathways involving RAS was published in two Nature papers. She has invented and holds patents for a number of biotech products for oncology and dermatology indications. Dr. Huang received her B.A., magna cum laude and Phi Beta Kappa, from Lawrence University, where she served as a trustee from 2012 to 2015. She received her Ph.D. in chemistry from the University of California at Berkeley, where she won the international-level Women's Opportunity Award given by Soroptimist International. She also studied at Fudan University in Shanghai, China. Dr. Huang also completed the Corporate Board Director Certificate program at Harvard Business School, further reinforcing her commitment to strong corporate governance and long-term value creation.

June Lu, Ph.D. is our Chief Scientific Officer, effective April 1, 2024. Prior to this appointment, she served as our Executive Director of Transitional Medicine. Dr. Lu has 25+ years of industry experience in innovative drug research and development from discovery to clinical studies. She is an accomplished professional in scientific, translational and strategic analysis aspects of R&D projects and pipeline assets. Her special expertise is in multidisciplinary, collaborative leadership experience in the biotech and pharmaceutical industry. Prior to BeyondSpring, she worked at Endocyte, which developed 177Lu-PSMA-617, now approved drug Pluvicto®, and at Advanced Accelerator Applications, a Novartis company, and Novartis Institute for Biomedical Research. Dr. Lu has led cross-functional project teams to develop small molecule-based strategies for cancer (FolateImmune; bispecific CAR-T cell therapy) and autoimmunity (DHFR/mTOR inhibitors). In addition, she has spearheaded deep-dive scientific efforts in drug resistance & IO combinations (PD-1/CTLA-4), macrophage-targeting, indication selections and novel target identification/pre-validation, and. She has authored over 30 peer-reviewed publications and is an inventor of multiple patents in diverse disease areas. Dr. June Lu received her Ph.D. in chemistry (biochemistry division) from Purdue University under the mentorship of Dr. Philip Low (co-founder of Endocyte and other biotech companies) and B.S. degree in analytical chemistry from Zhejiang University of Technology.

Brendan Delaney, MBA has served on our board since July 2021. Mr. Delaney brings more than 25 years of global product strategy and launch experience to his role leading commercial organizations. He currently serves as an independent consultant to emerging biotech companies. He was previously the Chief Operating Officer and Chief Executive Officer of Aadi Bioscience. Prior to joining Aadi Bioscience, he served as the Chief Commercial Officer of Constellation Pharmaceuticals before it was acquired by MorphoSys for $1.4B in June 2021. Prior to joining Constellation, Mr. Delaney was the Chief Commercial Officer at Immunomedics, where he led the buildout of the marketing, sales, market access and commercial operations teams. He was instrumental in successfully launching Trodelvy, the first TROP-2 directed antibody-drug conjugate for the treatment of triple-negative breast cancer. Immunomedics was acquired by Gilead Sciences for $21B in September 2020. Previously, he served as Vice President of U.S. Hematology-Oncology at Celgene Corporation. Prior to joining Celgene, he held various commercial roles at both Novartis Oncology and Genentech, where he led several successful product launches for blockbuster brands. Mr. Delaney also serves on the Board of Directors of MJH Life Sciences, one of the leading medical-media companies in the United States. He received an MBA from the Stern School of Business at the New York University and a B.A. in biology from Rutgers University.

Patrick Fabbio, MBA has served on our board since January 2018. Mr. Fabbio is currently the Chief Financial Officer of Protara Therapeutics, Inc. Mr. Fabbio has more than 30 years of financial, operational and transactional leadership experience in both publicly-traded and privately-held life science and pharmaceutical companies. Prior to joining Protara Therapeutics, Inc., Mr. Fabbio was Chief Financial Officer of Rafael Holdings, Inc. Previously he served as the Chief Financial Officer of WindMIL Therapeutics Inc., Progenics Pharmaceuticals, Inc., electroCore Medical, LLC; Vice President of Finance at NPS Pharmaceuticals, Inc.; Vice President of Finance, Innovation and Growth at Catalent Pharma Solutions Inc.; and Chief Financial Officer at Ikano Therapeutics. His other prior financial positions include roles at Sanofi, UniPath Diagnostics, BioMatrix and Coopers & Lybrand. He received his B.B.A. in accounting at Pace University and MBA from the Stern School of Business at New York University.

Matthew Kirkby, M.A. has served on our board since October 2016. Mr. Kirkby brings over 20 years of banking experience to our board. He has held senior management positions in London, Hong Kong and Singapore for a number of global banks including HSBC, RBS and ABN AMRO. He is currently a director or board adviser to a number of privately-held companies. He received his M.A. in jurisprudence at Pembroke College, University of Oxford in the United Kingdom. He is currently an Advisory Fellow and member of the Governing Body of Pembroke College. Mr. Kirkby is a qualified solicitor in England and Wales and Hong Kong.

Jiangwen Majeti, Ph.D., MBA has served on our board since August 2022. Dr. Majeti is an investor, biotech company advisor, and executive with more than 20 years of experience in the biotech and pharmaceutical industry. She carried out diverse roles with increasing responsibilities in both biotech and large multinational companies, encompassing cross-functional experiences in R&D, business development, supplier management, and outsourcing in the biopharmaceutical industry. Most recently, she was the Head of Global Collaborations and General Manager, China of Erasca, a NASDAQ traded company, managing global collaboration, and overseeing CROs to increase productivity and minimize costs. Prior to that, she was Global Category Leader for Roche External Alliance, Senior Director of Business Development for BioDuro, and Senior Scientist at Amgen. Dr. Majeti is the past president of the Chinese-American Biopharmaceutical Society, a non-profit organization with more than 3,000 members focused on building a stronger community among biopharmaceutical professionals in the U.S. She is also a member of the BayHelix Group, a non-profit professional organization of business leaders with a mission to shape the growth of the life sciences and healthcare industry globally with a strong presence in China and the U.S. Dr.
Majeti received her Ph.D. in molecular genetics from the University of Wisconsin at Madison, and obtained her postdoctoral training at the Howard Hughes Medical Institute of the University of California, San Francisco. She also earned an MBA from the Leavey School of Business at Santa Clara University, graduating as a member of the Beta Gamma Sigma Honor Society. She completed her undergraduate studies in biochemistry at Fudan University in China.

Sihai Xu, MBA has served on our board since August 2022. Mr. Xu was previously our employee and served as International Business Coordinator from November 2016 to January 2022. Mr. Xu has been an accomplished financial executive for almost 30 years in China. His most recent role since 2014 is the CFO and board member of BOJI Health Investment Management (Shanghai) Co., Ltd. Prior engagements include CFO of Henan Plastic Surgery Hospital, CFO of Shanghai BOJI Hospital Investment Management Co., Ltd., CFO of Henan Zhiyi Investment Management Co., Ltd., and Director of Finance of Luoyang Chundu Group. As a financial advisor and strategic investor, Mr. Xu has participated in pre-IPO, IPO, and major asset restructuring for dozens of public companies in China and Hong Kong, such as Henan Taloph Pharmaceutical Stock Co., Ltd., and Henan Lingrui Pharmaceutical Co., Ltd., Xinxiang Chemical Fiber Co. Ltd., Central China Land Media Co. Ltd., and China Molybdenum Co., Ltd. Mr. Xu received his MBA from Renmin University in China and his bachelor's degree from Henan University of Economics and Law in China, with a major in Financial Accounting. He is experienced with China GAAP.

There are no family relationships among any of our directors or executive officers.

Number, Terms of Office and Election of Officers and Director

Our board of directors currently consists of six members, all of whom were elected pursuant to our current articles of association. Our nominating and governance committee and board of directors consider a broad range of factors relating to the qualifications and background of nominees, which may include diversity and is not limited to race, gender or national origin. We have no formal policy regarding board diversity. Our nominating and governance committee's and board of directors' priority in selecting board members is identification of persons who will further the interests of our shareholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape and professional and personal experiences and expertise relevant to our growth strategy.

There is no Cayman Islands law requirement that a director must hold office for a certain term and stand for re-election unless the resolutions appointing the director impose a term on the appointment. Our amended and restated articles of association provide that our directors shall hold office until the expiration of his or her term and until his or her successor shall have been elected and qualified.

A director may be elected by ordinary resolution either to fill a casual vacancy on the board of directors or as an addition to the existing board of directors. In addition, the directors by the affirmative vote of a simple majority of the remaining directors present and voting at a board meeting shall have the power from time to time and at any time to appoint any person as a director to fill a casual vacancy on the board of directors or as an addition to the existing board of directors, subject to our compliance with director nomination procedures required under applicable corporate governance rules of the Nasdaq Capital Market, as long as our company's securities are traded on the Nasdaq Capital Market. A director may be removed from office by ordinary resolution at any time before the expiration of his or her term. The Director Agreement (defined below) does not provide for any benefits upon termination of service to our directors.

Our officers are appointed by the board of directors and serve at the discretion of the board of directors, rather than for specific terms of office. Our board of directors is authorized to appoint persons to the offices set forth in our amended and restated memorandum and articles of association as it deems appropriate.

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a separate charter adopted by our board of directors. The composition and functioning of all of our committees comply with all applicable requirements of the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Nasdaq Capital Market and SEC rules and regulations.

Audit Committee

Patrick Fabbio, Matthew Kirkby and Brendan Delaney currently serve on the audit committee, which is chaired by Mr. Fabbio. Our board of directors has determined that each member of the audit committee is "independent" for audit committee purposes as required by the Nasdaq Capital Market listing standards relating to audit committees and as contained in Rule 10A-3 under the Exchange Act. Our board of directors has also determined that Mr. Fabbio is an audit committee financial expert. The audit committee's responsibilities include:

- selecting and appointing our independent registered public accounting firm, and approving the audit and permitted non-audit services to be provided by our independent registered public accounting firm;
- evaluating the performance and independence of our independent registered public accounting firm;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements or accounting matters;
- reviewing the adequacy and effectiveness of our accounting and internal control policies and procedures;
- establishing procedures for the receipt, retention and treatment of accounting-related complaints and concerns;
- reviewing and discussing with the independent registered public accounting firm the results of our year-end audit, and recommending to our board of directors, based upon such review and discussions, whether our financial statements shall be included in our annual report on Form 10-K;
- reviewing all related party transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing the type and presentation of information to be included in our earnings press releases, as well as financial information and earnings guidance provided by us to analysts and rating agencies.

Compensation Committee

Matthew Kirkby and Jiangwen Majeti currently serve on the compensation committee, which is chaired by Mr. Kirkby. Our board of directors has determined that each member of the compensation committee is "independent" as that term is defined in the applicable rules of the Nasdaq Capital Market. The compensation committee's responsibilities include:

- reviewing the goals and objectives of our executive compensation plans, as well as our executive compensation plans in light of such goals and objectives;
- evaluating the performance of our executive officers in light of the goals and objectives of our executive compensation plans and recommending to our board of directors with respect to the compensation of our executive officers;
- reviewing the goals and objectives of our general compensation plans and other employee benefit plans, as well as our general compensation plans and other employee benefit plans in light of such goals and objectives;
- retaining and approving the compensation of any compensation advisors;
- reviewing all equity-compensation plans to be submitted for shareholder approval under the Nasdaq listing rules, and reviewing and approving all equity-compensation plans that are exempt from such shareholder approval requirement;
- evaluating the appropriate level of compensation for board and board committee service by non-employee directors; and
- reviewing and approving description of executive compensation included in our annual report on Form 10-K.

Nominating and Corporate Governance Committee

Matthew Kirkby and Jiangwen Majeti currently serve on the nominating and corporate governance committee, which is chaired by Dr. Majeti. Our board of directors has determined that each member of the nominating and corporate governance committee is "independent" as that term is defined in the applicable rules of the Nasdaq Capital Market. The nominating and corporate governance committee's responsibilities include:

- assisting our board of directors in identifying prospective director nominees and recommending nominees for election by the shareholders or appointment by our board of directors;
- advising the board of directors periodically with respect to significant developments in the law and practice of corporate governance as well as our compliance with applicable laws and regulations, and making recommendations to our board of directors on all matters of corporate governance and on any corrective action to be taken;
- overseeing the evaluation of our board of directors; and
- recommending members for each board committee of our board of directors.

Our board of directors may establish other committees from time to time.

Code of Ethics

In connection with our initial public offering, we have adopted a written code of ethics that applies to all of our directors, executive officers and employees. The code of ethics is available in the investors section of our website (https://beyondspringpharma.com/investors). Our website and the information contained on, or that can be accessed through, the website is not deemed to be incorporated by reference in, and is not considered part of, this Annual Report. We intend to disclose on our website any amendments to, or waivers from, the code of ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K within four business days following the date of the amendment or waiver.

Insider Trading Policies

We have adopted insider trading policies and procedures governing the purchase, sale and/or other disposition of our securities by directors, officers and employees that are reasonably designed to promote compliance with insider trading laws, rules and regulations and applicable listing standards of Nasdaq. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K.

Item 11. Executive Compensation.

In reviewing this Executive Compensation section, please note that the Company is a "smaller reporting company" as defined under applicable SEC rules and is permitted to include reduced disclosure with respect to certain executive compensation information otherwise required by Item 402 of Regulation S-K.

This section discusses the material components of the executive compensation program for our executive officers who are named in the "Summary Compensation Table for 2025" below. For the fiscal year ended December 31, 2025, our named executive officers ("NEOs") and their positions were as follows:

- Lan Huang, Ph.D., Co-Founder, Chairperson and Chief Executive Officer
- June Lu, Ph.D., Chief Scientific Officer

Summary Compensation Table for 2025

The following table provides information regarding the compensation earned by our NEOs from the Company and its subsidiaries for the years ended December 31, 2025 and December 31, 2024.

Name and Principal Position	Year	Salary (1) ($)	Bonus (2) ($)	Option Awards (3) (4) ($)	Nonequity Incentive Plan Compensation (5) ($)	All Other Compensation (6) ($)	Total ($)
Lan Huang	2025	452,920	-	37,522	201,323	10,417	702,182
Chief Executive Officer	2024	459,053	-	108,435	215,882	10,062	793,432
June Lu	2025	261,288	-	21,449	57,894	10,451	351,082
Chief Scientific Officer	2024	253,008	-	177,475	57,798	9,691	497,972

(1) Amounts reported in this column reflect the salary received by the NEOs during 2025 and 2024, respectively. For Dr. Huang, the amounts include her salary received from both the Company and SEED, a subsidiary of the Company. Refer to section entitled "—Executive Employment Agreements" below for a more detailed description of Dr. Huang's employment arrangement.

(2) There are no special bonuses earned by the NEOs with respect to services provided in 2025 and 2024.

(3) Amounts reported in this column reflect the aggregate grant date fair value of the options granted during 2025 and 2024, respectively, computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 for stock-based compensation ("ASC 718"). Such grant date fair values do not take into account any estimated forfeitures related to service-based vesting conditions. Assumptions used in the calculation of these amounts are included in Note 7 to our consolidated financial statements included in this Annual Report. These amounts do not reflect the actual economic value that may be realized by our NEOs upon the exercise of the options or the sale of the ordinary shares underlying such options.

(4) In addition to the options granted by the Company under the 2017 Omnibus Incentive plan, Dr. Huang was also granted an option to purchase ordinary shares of SEED with an aggregate grant date fair value of $30,000 (the "SEED Option") in 2024 under SEED's 2022 Share Incentive Plan. The aggregate grant date fair value of the SEED Option is included in this column for Dr. Huang for 2024.

(5) Amounts reported in this column reflect the annual incentive bonuses earned by our NEOs based on performance for the years of 2025 and 2024, and paid or scheduled to be paid in the following years, respectively. The annual incentive bonuses earned by each NEO are the products of (i) the NEO's target bonus for the year, expressed as a percentage of the NEO's then-effective base salary and (ii) a final performance rate. Refer to "—Elements of Compensation—Annual Incentive Bonuses" for a detailed description on the performance rate determination. As of the date of this Annual Report, the 2025 annual incentive bonuses earned by each of Dr. Huang and Dr. Lu have not been paid, and an amount of $165,890 of Dr. Huang's 2024 annual incentive bonuses remains unpaid. For Dr. Huang, her annual incentive bonuses include those earned from both the Company and SEED. Refer to section entitled "—Executive Employment Agreements" below for a more detailed description of Dr. Huang's employment arrangement.

(6) Amounts reported in this column for 2025 and 2024 reflect the 401(k) matching contributions made by the Company for Dr. Huang and Dr. Lu for each year..

Elements of Compensation

Our NEOs were provided with the following primary elements of compensation in 2025:

Base Salaries

Each of Dr. Huang and Dr. Lu received a fixed base salary from the Company in respect of 2025 (in respect of Dr. Huang, from both the Company and SEED). The 2025 base salaries for our NEOs were as follows: (a)
$452,920 for Dr. Lan Huang, and (b) $261,667 for Dr. June Lu. Dr. Lu's annual base salary rate was increased to

$280,000 effective as of December 1, 2025.

Annual Incentive Bonuses

Under the terms of Dr. Huang's employment agreement, Dr. Huang is eligible to participate in any bonus program sponsored by the Company on a basis consistent with that applicable to other senior management employees, in accordance with company policy. For 2025 and 2024, Dr. Huang's target annual incentive bonuses were 50% of her then-effective base salary. Under the terms of Dr. Lu's offer letter, Dr. Lu was eligible to receive an annual incentive bonus of up to 25% of her base salary, subject to the Company's performance and terms and conditions to be established by the Company.

The annual incentive bonuses that each of Dr. Huang and Dr. Lu earned for 2025 and 2024 were based on performance for 2025 and 2024, and paid or scheduled to be paid in the following years, respectively. The annual incentive bonuses earned by each of Dr. Huang and Dr. Lu for 2025 and 2024 are the products of (i) their respective target bonus for the applicable year, expressed as a percentage of their then-effective base salary; and (ii) a final performance rate determined as below. The final performance rate is the sum of: (i) a corporate performance rating determined by the Compensation Committee based on its evaluation of the Company's overall performance for the applicable year (weighted at 50% for 2025), (ii) a manager evaluation determined by our board of directors for Dr. Huang, and by Dr. Huang for Dr. Lu, based on an assessment of the NEO's individual performance for the applicable year (weighted at 25% for 2025), and (iii) the NEO's self-evaluation for the applicable year (weighted at 25% for 2025). As of the date of this Annual Report, the 2025 annual incentive bonuses earned by each of Dr. Huang and Dr. Lu have not been paid by the Company, and an amount of $165,890 of Dr. Huang's 2024 annual incentive bonuses remains unpaid. For Dr. Huang, her annual incentive bonuses include those earned from both the Company and SEED. Refer to section entitled "—Executive Employment Agreements" below for a more detailed description of Dr. Huang's employment arrangement.

Equity Awards

We granted the following options to our NEOs in fiscal year 2025:

- Dr. Huang: 43,630 options, granted on April 21, 2025, at an exercise price of $1.441 per share. These options will vest on April 21, 2026, subject to Dr. Huang's continuous service with us through the vesting date, and will expire on the fifth anniversary of the grant date. The aggregate grant date fair value of these options is $37,522, computed in accordance with ASC 718.

- Dr. Lu: 18,981 options, granted on April 21, 2025, at an exercise price of $1.31 per share. These options will vest on April 21, 2026, subject to Dr. Lu's continuous service with us through the vesting date, and will expire on the tenth anniversary of the grant date. The aggregate grant date fair value of these options is $21,449, computed in accordance with ASC 718.

Additional information regarding outstanding equity awards held by each of our NEOs is described in greater detail in the section entitled "—Outstanding Equity Awards at Fiscal Year End for 2025" below.

Retirement Benefit

We maintain a tax-qualified 401(k) savings plan for our employees in the U.S. Our NEOs are eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan provides for an employer match of 100% of employee deferrals up to 6% of the employee's compensation, capped at the statutory compensation limits. Company matching contributions are 100% vested after one year of service.

The Company does not maintain defined benefit plans or nonqualified deferred compensation plans.

Employee Benefits

Dr. Huang and Dr. Lu are eligible to participate in our other broad-based employee benefit plans, including our medical, dental, vision, disability and life insurance plans, in each case, on the same basis as our employees generally and subject to the terms and eligibility requirements of those plans.

Outstanding Equity Awards at Fiscal Year End for 2025

The following table sets forth information regarding outstanding equity awards held by our NEOs as of December 31, 2025.

Name	Date of Grant	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Lan Huang (1)	4/21/2025	-	43,630(2)	-	1.441	4/21/2030
	3/19/2024	33,663	-	-	3.168	3/19/2029
	5/8/2023	266,666	133,334(3)	-	0.9835	5/8/2033
	1/11/2022	90,343	-	-	4.69	1/11/2027
	8/1/2020	460,000	-	260,000(4)	11.03	8/1/2030
June Lu	4/21/2025	-	18,981(5)	-	1.31	4/21/2035
	4/1/2024	12,500	37,500(6)	-	3.57	4/1/2034
	3/1/2024	19,180	-	-	1.33	3/1/2034
	9/1/2023	5,000	-	-	0.90	9/1/2033
	1/11/2022	2,003	-	-	4.26	1/11/2032
	10/18/2021	10,000	-	-	16.55	10/18/2031

(1) In addition to the options listed above, Dr. Huang also holds a total of 750,000 outstanding options granted by SEED in 2022 and 2024 under the SEED Incentive Plan at an exercise price of $0.50 per share, of which, (i) 437,500 SEED options are unexercised options that were exercisable as of December 31, 2025, (ii) 312,500 SEED options are unexercised options that were not exercisable as of December 31, 2025. These unvested options granted by SEED will vest in five tranches as follows: 62,500 SEED options will vest on each of February 15, 2026, December 1, 2026, February 15, 2027, December 1, 2027 and February 15, 2028. The SEED options granted to Dr. Huang in 2022 have an expiration date of December 1, 2032, and those granted in 2024 have an expiration date of February 15, 2029.

(2) The options will vest on April 21, 2026.

(3) The options will vest on May 8, 2026.

(4) The options will vest upon satisfaction of certain performance conditions with respect to research and development progress prior to the expiration of the options on the 10-year anniversary of the date of grant, as provided under the option award agreements.

(5) The options will vest on April 21, 2026.

(6) The options will vest as follows: 12,500 options will vest on each of April 1, 2026, April 1, 2027, and April 1, 2028.

Executive Employment Agreements

The Company has entered into employment agreements with Dr. Huang and Dr. Lu. The key terms of the employment related agreements are described below.

Employment Agreement with Dr. Huang

Dr. Huang is party to an amended and restated employment agreement with BeyondSpring U.S. dated November 10, 2016, as amended on January 11, 2022 and further amended by those letter amendments dated January 13, 2022, March 23, 2023, October 11, 2023, August 7, 2024, and December 20, 2025. Dr. Huang's employment agreement provides for an annual base salary, which has been adjusted from time to time. Dr. Huang is also party to a separate employment agreement with a subsidiary of SEED, pursuant to which Dr. Huang has been assigned by the Company to SEED on a part-time basis and receives a base salary from SEED, which reduces her base salary from us. If Dr. Huang's employment with SEED terminates other than for cause, Dr. Huang will resume full time employment with us and her base salary from us will be restored.

Pursuant to Dr. Huang's employment agreement, Dr. Huang is eligible to participate in any bonus program sponsored by the Company on a basis consistent with that applicable to other employees at her level, in accordance with company policy, with a target annual merit bonus of 50% of base salary for 2024 and 2025. Dr. Huang's employment is at will, and can be terminated by us at any time or by Dr. Huang upon three months' notice. Dr. Huang's employment agreement contains a two year non-solicit of employees, a confidentiality provision and an assignment of intellectual property provision.

Dr. Huang's employment agreement also provides for severance payments and benefits in the event that Dr. Huang's employment is terminated by the Company without "cause" or by Dr. Huang with "good reason" (each as defined under Dr. Huang's employment agreement), subject to the terms and conditions thereof. Additional information regarding Dr. Huang's severance entitlements is described in greater detail in the section entitled "—Potential Payments Upon Termination or Change in Control" below.

Offer Letter with Dr. Lu

Dr. Lu is party to an offer letter with BeyondSpring U.S. dated September 17, 2021, as amended by those letter amendments effective as of April 1, 2024 and December 1, 2025. Dr. Lu's offer letter provides for an annual base salary, which has been adjusted from time to time, and her eligibility for an annual bonus of up to 25% of her base salary, subject to the Company's performance and terms and conditions to be established by the Company. Dr. Lu's employment is at will, and can be terminated by us or by Dr. Lu at any time and for any reason.

Potential Payments Upon Termination or Change in Control

Under Dr. Huang's employment agreement, in the event that Dr. Huang's employment is terminated by the Company without "cause" or by Dr. Huang with "good reason" (as each such term is defined in the employment agreement), Dr. Huang would become entitled (subject to her execution and non-revocation of a release of claims) to the payment of (i) her then base salary for the nine (9) month period commencing on the date of termination (the "Severance Period"), payable over the Severance Period in regular installments in accordance with the Company's normal payroll practices and (ii) a pro-rated portion of any bonus earned for the year in which the date of termination occurs, based on actual performance results, and paid at the same time as other senior executives.

Under the terms of the 2017 Omnibus Incentive Plan and option award agreements applicable to both Dr. Huang and Dr. Lu, (i) if the options are assumed or substituted for in the change in control, if the NEO's employment is terminated without cause within 12 months of such change in control, then any unvested options will become vested and will remain exercisable for the 90-day period following the termination date, and (ii) if the options are not assumed or substituted for in the change of control, then any unvested options will become vested upon such change of control and otherwise be treated as determined by the plan administrator. If the NEO's employment terminates due to death or disability, the next tranche of time-based options that would have vested had the NEO remained employed through the applicable vesting date will become fully vested on the termination date (and will remain exercisable for one year following such termination), and any remaining unvested time-based options will be forfeited. On a termination by us for cause, all vested and unvested options are forfeited. On a termination for any other reason, vested options remain exercisable for three months following such termination date. Upon any termination of employment, any unvested performance-based options as of the termination date will be forfeited.

Pay Versus Performance

As required by Item 402(v) of Regulation S-K, we are providing the following information regarding the relationship between executive compensation and our financial performance for each of the last three completed fiscal years. In determining the "compensation actually paid" to our CEO and the "average compensation actually paid" to our Non-CEO NEOs, we are required to make various adjustments to amounts that have been reported in the Summary Compensation Table for 2025 and in previous years, as the SEC's valuation methods for this section differ from those required in the Summary Compensation Table. The table below summarizes compensation values reported in our Summary Compensation Table for 2025 and in previous years, as well as the adjusted values required in this section for 2025, 2024 and 2023.

Year (1)	Summary Compensation Table Total for CEO ($)	Compensation Actually Paid to CEO (2) (3) ($)	Average Summary Compensation Table Total for Non-CEO NEOs ($)	Average Compensation Actually Paid to Non-CEO NEOs (2) (4) ($)	Value of Initial Fixed $100 Investment Based On Total Shareholder Return (5) ($)	Net Income (6) ($) (in thousands)
2025	702,182	744,044	351,082	352,502	86.70	(14,218)
2024	793,432	1,553,404	263,116	216,621	86.70	(16,693)
2023	1,046,852	700,831	187,833	156,300	47.87	(21,948)

(1) For years 2025, 2024 and 2023, Dr. Huang was our Chief Executive Officer. For 2025, Dr. Lu was our Non-CEO NEO. For 2024 and 2023, our Non-CEO NEOs were Dr. Lu and Dr. Lloyd.

(2) Adjustments to calculate "compensation actually paid" and "average compensation actually paid" include: (i) subtract the amounts reported in the Option Awards column of the Summary Compensation Table for each applicable year, (ii) add the fair value as of the end of the applicable year of outstanding and unvested equity awards granted in that year, (iii) add the fair value as of the vesting date of equity awards that were granted and vested in the applicable year, (iv) add the change in fair value (whether positive or negative) during the applicable year of equity awards granted in prior years that remained outstanding and unvested at the end of the year, (v) add the change in fair value (whether positive or negative) during the applicable year through the vesting date of equity awards granted in prior years that vested during that year, (vi) subtract the fair value at the end of the prior year of awards granted in prior years that failed to meet vesting conditions during the applicable year, and (vii) add the value of any dividends or other earnings paid during the applicable year on equity awards not otherwise reflected in the Summary Compensation Table for the applicable year. Equity fair value amounts are calculated using valuation assumptions and methodologies (including expected term, volatility, dividend yield and risk-free interest rates) that are generally consistent with those used to estimate the grant date fair value under U.S. GAAP. The valuation assumptions used to calculate the equity fair values as of each measurement date differed materially from those disclosed at the time of grant in the following ways: the expected term was updated to reflect the remaining life of the awards, adjusted for the passage of time since the grant date and the relationship between the share price and the option exercise price as of the measurement date.

(3) The following table shows the amounts deducted from and added to the Summary Compensation Table total for our CEO to calculate "compensation actually paid" to our PEO (in dollars):

	2025	2024	2023
Summary Compensation Table Total	702,182	793,432	1,046,852
(Minus): Grant Date Fair Value of Equity Awards Granted in Year	(37,522)	(108,435)	(320,000)
Plus: Fair Value at Fiscal Year End of Outstanding and Unvested Equity Awards Granted in the Year	39,935	292,337	293,238
Plus: Fair Value at Vesting Date of Equity Awards Granted and Vested in the Year	-	33,847	-
Plus (Minus): Change in Fair Value of Outstanding and Unvested Equity Awards Granted in Prior Years	37,029	349,040	(199,922)
Plus (Minus): Change in Fair Value as of the Vesting Date of Equity Awards Granted in Prior Years that Vested in the Year	2,420	193,184	(103,974)
(Minus): Fair Value as of the Prior Year End of Equity Awards Granted in Prior Years that Failed to Meet Vesting Conditions in the Year	-	-	(15,363)
Plus: Dividends or Other Earnings Paid in the Year	-	-	-
Compensation Actually Paid to CEO	744,044	1,553,404	700,831

(4) The following table shows the amounts deducted from and added to the average Summary Compensation Table total for our Non-CEO NEOs to calculate the "average compensation actually paid" to our Non-PEO NEOs (in dollars):

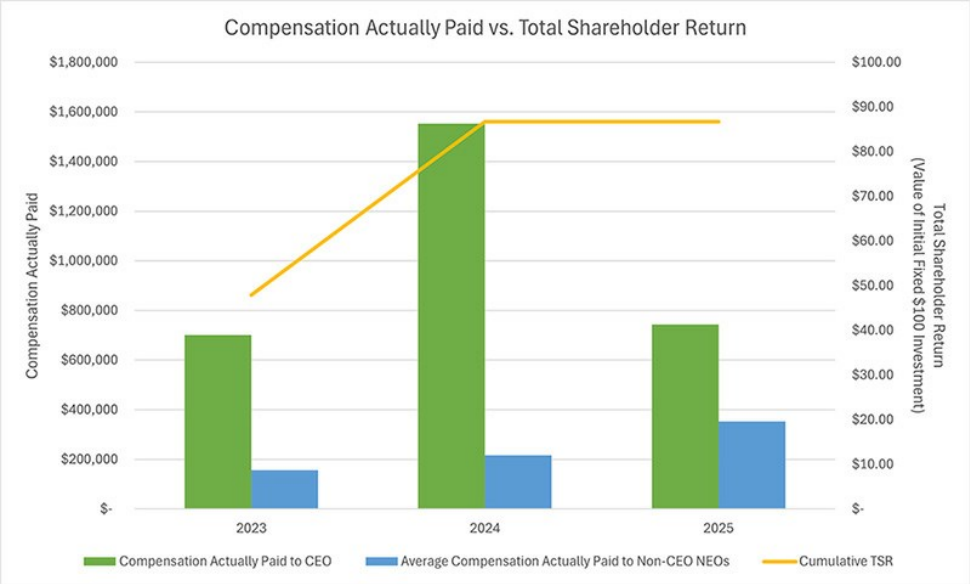
	2025 Average	2024 Average	2023 Average
Summary Compensation Table Total	351,082	263,116	187,833
(Minus): Grant Date Fair Value of Equity Awards Granted in Year	(21,449)	(93,118)	(21,925)
Plus: Fair Value at Fiscal Year End of Outstanding and Unvested Equity Awards Granted in the Year	23,110	39,308	19,542
Plus: Fair Value at Vesting Date of Equity Awards Granted and Vested in the Year	-	20,601	607
Plus (Minus): Change in Fair Value of Outstanding and Unvested Equity Awards Granted in Prior Years	(1,808)	606	(27,402)
Plus (Minus): Change in Fair Value as of the Vesting Date of Equity Awards Granted in Prior Years that Vested in the Year	1,567	12,359	(748)
(Minus): Fair Value as of the Prior Year End of Equity Awards Granted in Prior Years that Failed to Meet Vesting Conditions in the Year	-	(26,251)	(1,606)
Plus: Dividends or Other Earnings Paid in the Year	-	-	-
Average Compensation Actually Paid to Non-CEO NEOs	352,502	216,621	156,300

(5) Assumes $100 was invested for the period starting December 31, 2022, through the end of the listed year in the Company. For 2025, represents the three-year total shareholder return (2023-2025), for 2024, represents the two-year total shareholder return (2023-2024), and for 2023, represents the one-year total shareholder return (2023).

(6) The amounts reported represent the amount of net income (loss) reflected in our consolidated audited financial statements for the applicable year.

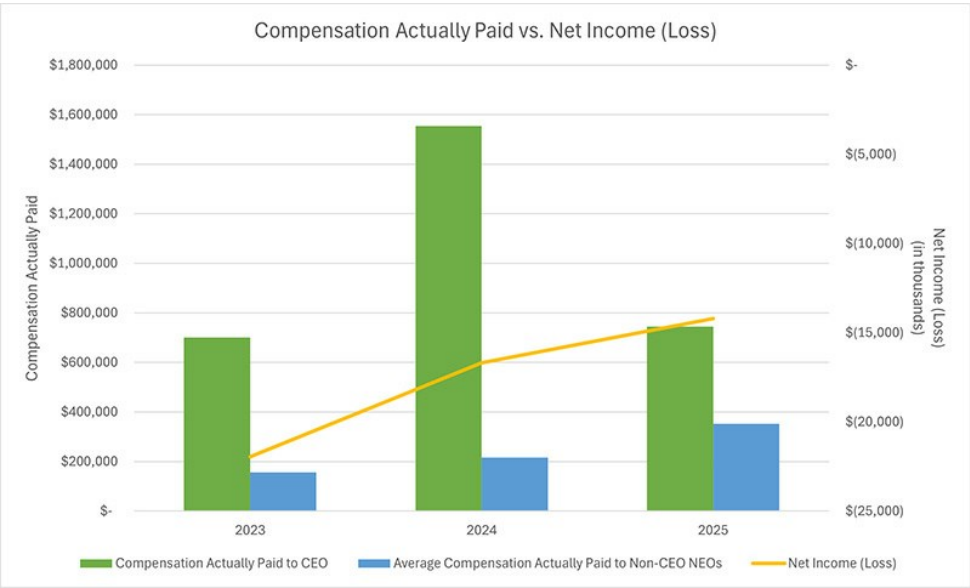
Relationships Between Compensation Actually Paid and Total Shareholder Return

The graph below reflects the relationship between "compensation actually paid" to the CEO, "average compensation actually paid" to the Non-CEO NEOs and the Company's cumulative total shareholder return ("TSR") for the years ended December 31, 2025, 2024 and 2023.



Relationships Between Compensation Actually Paid and Net Income (Loss)

The graph below reflects the relationship between "compensation actually paid" to the CEO, "average compensation actually paid" to the Non-CEO NEOs and the Company's net income (loss) for the years ended December 31, 2025, 2024 and 2023.



Director Compensation

We have entered into a director agreement (a "Director Agreement"), with each of our non-employee directors. Under the terms of each Director Agreement (as amended effective July 1, 2020), the compensation payable to our non-employee directors consists of:

- an annual cash retainer fee equal to $40,000 (pro-rated for any partial year of service);
- an additional cash retainer fee (pro-rated for any partial year of service) for service on a committee, as follows: Compensation Committee: $6,000 ($12,000 if chair); the Nominating and Corporate Governance Committee, $4,000 ($8,000 if chair); and the Audit Committee, $8,000 ($16,000 if chair);
- an initial grant of 20,000 options in respect of the director's first 12 months' of service; and
- an annual grant of 10,000 options at the start of each fiscal year.

Such options are granted under the 2017 Omnibus Incentive Plan, with a per share exercise price equal to the fair market value per share as of the date of grant. The initial option grant for a new director (made in respect of the director's first 12 months of service) is issued on or around the date of commencement of service, and vests in three equal installments on the first three anniversaries of the grant date, subject to the director's continued service as our director through the applicable vesting date. The annual director grants are made on a fiscal year basis at the start of the applicable fiscal year (with the annual grant made in respect of the first full fiscal year beginning during the director's term to be pro-rated for the length of service from the first anniversary of the director's start date through the end of such fiscal year), and vest on the first anniversary of the grant date, subject to the director's continued service as our director through the vesting date. All director option grants are subject to the terms and conditions of the 2017 Omnibus Incentive Plan and the applicable option award agreement memorializing such grant.

Director Compensation Table for 2025

The following table summarizes the total compensation earned by our non-employee directors in 2025.

Name	Fees Earned (1) (3) ($)	Option Awards (2) (3) ($)	Total ($)
Brendan Delaney	33,600	24,659	58,259
Patrick Fabbio	39,200	26,886	66,086
Matthew Kirkby	44,800	29,112	73,912
Jiangwen Majeti	37,800	26,329	64,129
Sihai Xu	28,000	22,433	50,433

(1) Amounts reported in this column reflect the cash retainer fees earned by each director for their services provided for the fiscal year 2025. On April 21, 2025, we elected to make the following option grants to our non-employee in substitution for 30% of their 2025 cash retainer fees: Mr. Delaney, 11,822 options; Mr. Fabbio, 13,793 options; Mr. Kirkby, 15,763 options; Dr. Majeti, 13,300 options; and Mr. Xu, 9,852 options.

(2) Amounts reported in this column reflect the aggregate grant date fair value of the options granted during 2025 (including those described in the preceding footnote), computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 for stock-based compensation transactions ("ASC 718"). Such grant date fair values do not take into account any estimated forfeitures related to service-based vesting conditions. Assumptions used in the calculation of these amounts are included in Note 7 to our consolidated financial statements included in this Annual Report. These amounts do not reflect the actual economic value that may be realized by the directors upon the exercise of the share options or the sale of the ordinary shares underlying such share options.

(3) As of December 31, 2025, (i) Mr. Delaney holds 121,728 unexercised options; (ii) Mr. Fabbio holds 108,793 unexercised options; (iii) Mr. Kirkby holds 130,638 unexercised options; (iv) Dr. Majeti holds 85,695 unexercised options; and (v) Mr. Xu holds 77,899 unexercised options.

Policies And Practices Related to The Grant of Certain Equity Awards

We grant equity awards on an annual basis and may grant equity awards on a discretionary basis in connection with certain events such as the commencement of employment, service or promotion. Although we do not have a formal policy regarding the timing of options , we do not grant options or any other form of equity compensation in anticipation of the release of material, non-public information. Similarly, we do not time the release of material, non-public information based on option or other equity award grant dates for the purpose of affecting the value of executive compensation. During the last completed fiscal year, we have not granted options to any of our NEOs during the period beginning four business days before and ending one business day after the filing of a periodic report on Form 10-Q or Form 10-K or the filing or furnishing of a current report on Form 8-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of February 27, 2026 by:

- each person known by us to be the beneficial owner of more than 5% of our outstanding ordinary shares;
- each of our executive officers and directors; and
- all our executive officers and directors as a group.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC and generally includes any shares over which a person exercises sole or shared voting or investment power, and includes the ordinary shares issuable pursuant to stock options that are exercisable within 60 days of February 27, 2026. Ordinary shares issuable pursuant to stock options are deemed outstanding for computing the percentage of the person holding such options but are not outstanding for computing the percentage of any other person. As of February 27, 2026, there were 1,501,892 ordinary shares issuable pursuant to stock options exercisable within 60 days thereof.

The calculation of percentage of ordinary shares beneficially owned in the table below is based on 41,119,820 ordinary shares outstanding as of February 27, 2026. Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such shares.

Unless otherwise noted below, each shareholder's address is c/o BeyondSpring Inc., 100 Campus Drive, West Side, 4th Floor, Suite 410, Florham Park, NJ 07932.

Name of Beneficial Owner	Number of Ordinary Shares Beneficially Owned	%
5% Shareholders		
Entities affiliated with Decheng Capital(1)	3,800,702	9.24
Executive Officers and Directors		
Lan Huang(2)	6,942,790	16.52
June Lu(3)	80,264	*
Brendan Delaney(4)	121,728	*
Patrick Fabbio(5)	133,385	*
Matthew Kirkby(6)	130,638	*
Jiangwen Majeti(7)	136,609	*
Sihai Xu(8)	77,899	*
All Directors and Executive Officers as a group (7 people)	7,623,313	18.17

* Amounts represent less than 1% of outstanding ordinary shares.

(1) Based on a Schedule 13G filed by Decheng Capital reporting persons, consisting of 1,448,293 ordinary shares owned by Decheng Capital China Life Sciences USD Fund III, L.P. ("Fund III"), 1,617,409 ordinary shares owned by Decheng Capital China Life Sciences USD Fund II, L.P. ("Fund II"), and 735,000 ordinary shares owned by Decheng Capital Global Healthcare Fund (Master), LP ("Healthcare"). Decheng Capital Management II (Cayman), LLC ("GP II") is the general partner of Fund II and shares voting and investment authority over the shares held by Fund II. Decheng Capital Management III (Cayman), LLC ("GP III") is the general partner of Fund III and shares voting and investment authority over the shares held by Fund III. Decheng Capital Global Healthcare GP, LLC ("Healthcare GP") is the general partner of Healthcare and shares voting and investment authority over the shares held by Healthcare. Dr. Xiangmin Cui ("Dr. Cui") is the sole manager of each of GP II and GP III and the indirect managing member and ultimate beneficial owner of Healthcare GP. Dr. Cui shares voting and investment authority over the shares held by each of Fund II, Fund III and Healthcare.

(2) Consisting of (i) two ordinary shares owned directly by Ever Regal Group Limited, (ii) one ordinary share owned directly by Fairy Eagle Investments Limited, (iii) one ordinary share owned directly by Rosy Time Holdings Limited, (iv) 253,465 Ordinary Shares directly held by Dr. Huang, (v) 260,582 ordinary shares owned directly by the Lan Huang 2022 Grantor Retained Annuity Trust ("2022 Trust"), (vi) 223,291 ordinary shares directly held by the 2024 SPIRIT GRAT, (vii) 494,462 ordinary shares held by Sincere Efforts Foundation Inc. ("Sincere Efforts"), (viii) 3,031,684 ordinary shares directly held by three irrevocable trusts for the benefit of Dr. Huang's children, over which Dr. Huang has been granted a proxy with voting power, (ix) 1,785,000 ordinary shares directly held by certain unaffiliated third-parties, over which Mr. Jia has been granted a proxy with voting power, and (x) share options to purchase 894,302 ordinary shares granted under the 2017 Omnibus Incentive Plan, of which 850,672 have been vested and 43,630 will vest on April 21, 2026. Dr. Huang is the sole owner of Ever Regal Group Limited. Mr. Jia, Dr. Huang's spouse, is the sole owner of Fairy Eagle Investments Limited and Rosy Time Holdings Limited. Dr. Huang is the sole trustee of 2022 Trust and the 2024 SPIRIT GRAT. Dr. Huang serves on the board of Sincere Efforts, a charitable foundation, and in such capacity may be deemed to exercise shared voting and dispositive power over such ordinary shares. Dr. Huang disclaims beneficial ownership of the ordinary shares held by Sincere Efforts and nothing herein shall be construed as an admission that Dr. Huang is the beneficial owner of such ordinary shares. Dr. Huang and Mr. Jia share voting and dispositive power for all of the foregoing shares, except for the shares over which they have been granted proxies with voting power. Dr. Huang and Mr. Jia share voting power over those shares.

(3) Consisting of (i) 100 ordinary shares purchased by Dr. June Lu before joining the Company and (ii) share options to purchase 80,164 ordinary shares granted under the 2017 Omnibus Incentive Plan, of which 48,683 have been vested and 31,481 will vest in April 2026.

(4) Consisting of share options to purchase 121,728 ordinary shares granted under the 2017 Omnibus Incentive Plan, of which 99,906 have been vested and 21,822 will vest on April 21, 2026.

(5) Consisting of (i) 19,592 restricted shares, 19,592 of which have been vested, held of record by Mr. Patrick Fabbio, granted under the 2017 Omnibus Incentive Plan, (ii) share options to purchase 108,793 ordinary shares granted under the 2017 Omnibus Incentive Plan, of which 85,000 have been vested and 23,793 will vest on April 21, 2026, and (iii) 5,000 ordinary shares purchased by Mr. Patrick Fabbio from the public market during the open window.

(6) Consisting of share options to purchase 130,638 ordinary shares granted under the 2017 Omnibus Incentive Plan, of which 104,875 have been vested and 25,763 will vest on April 21, 2026.

(7) Consisting of (i) 50,914 ordinary shares purchased by Dr. Majeti before joining our board of directors and (ii) share options to purchase 85,695 ordinary shares granted under the 2017 Omnibus Incentive Plan, of which 62,395 have been vested and 23,300 will vest on April 21, 2026.

(8) Consisting of share options to purchase 77,899 ordinary shares granted under the 2017 Omnibus Incentive Plan, of which 58,047 have been vested and 19,852 will vest on April 21, 2026.

We have one class of ordinary shares, and each holder of our ordinary shares is entitled to one vote per share. None of our shareholders has different voting rights from other shareholders.

We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Equity Compensation Plan Information

The following table presents information regarding securities authorized for issuance under equity compensation plans as of December 31, 2025:

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in (a))
Equity compensation plans approved by security holders	2,731,806	$ 5.01	1,464,288
Equity compensation plans not approved by security holders	—	—	—
Total	2,731,806	$ 5.01	1,464,288

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Since January 1, 2024, there has not been, nor is there currently proposed, any transaction to which we were or are a party to in which the amount involved exceeds the lesser of $120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years, and in which any director or executive officer, holder of more than 5% of ordinary shares, or any member of the immediate family of any of the foregoing persons, had or will have a direct or indirect material interest, other than the transactions we describe below.

Purchase of SEED's Preferred Shares

In September 2025, The JKNM Living Trust, dated November 27th, 2020 (the "JKNM Trust") purchased 117,647 shares of SEED's Series A-3 Preferred Shares, at $4.25 per share. The aggregate purchase price is $500,000. Jiangwen Majeti, one of the Company's directors, is the trustee of the JKNM Trust. The investment was made on the same terms as those offered to third-party investors.

Related Party Employees

Mr. Linqing Jia, the spouse of Dr. Huang and co-founder of the Company, is employed as the president of Wanchunbulin. Mr. Linqing Jia received compensation in the form of salary, bonus and benefits of more than
$120,000 in the aggregate in the year ended December 31, 2023.

The stepdaughter of Dr. Huang, our Chairperson and Chief Executive Officer, is employed as a vice president at BeyondSpring US, and her spouse is employed as a senior director at BeyondSpring US. Each of them received compensation in the form of salary, bonus, benefits and share options of more than $120,000 in the aggregate in each of the years ended December 31, 2025 and 2024, consistent with those provided to other employees with equivalent qualifications and responsibilities.

Employment Agreements

See "Item 11. Executive Compensation—Executive Employment Agreements."

Director Agreements

See "Item 11. Executive Compensation—Director Compensation."

2017 Omnibus Incentive Plan

See "Item 11. Executive Compensation—Outstanding Equity Awards at Fiscal Year End for 2024" and "Item 11. Executive Compensation—Director Compensation."

Indemnification Agreements

Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our amended and restated memorandum and articles of association require us to indemnify every director, alternate director, secretary, assistant secretary, or other officer for the time being and from time to time of our company (but not including our auditors) and the personal representatives of the same against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such indemnified person, other than by reason of such indemnified person's own dishonesty, willful default or fraud, in or about the conduct of our company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such indemnified person in defending (whether successfully or otherwise) any civil proceedings concerning us or our affairs in any court whether in the Cayman Islands or elsewhere. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation.

In addition, we have entered into indemnification agreements with each of our directors and executive officers that provide such persons with additional indemnification beyond that provided in our amended and restated memorandum and articles of association.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Director Independence

Our board of directors has determined that Brendan Delaney, Patrick Fabbio, Matthew Kirkby and Jiangwen Majeti are independent, as determined in accordance with the rules of the Nasdaq Capital Market. In making such independence determination, our board of directors considered the relationships that each such non-employee director has with us and all other facts and circumstances that the board of directors deemed relevant in determining their independence, including the beneficial ownership of our share capital by each non-employee director and the transactions involving them described in this Item 13.

Item 14. Principal Accounting Fees and Services.

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by CBIZ, our principal external accountant, and Marcum, our former principal external accountant, for the periods indicated.

	Year Ended December 31,	
	2025	2024
	(in thousands of U.S. Dollars ("$"))	
Audit Fees(1)	$ 562	$ 405
Audit-Related Fees(2)	-	-
Tax Fees(3)	-	-
All Other Fees(4)	-	-
Total	$ 561	$ 405

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(1) "Audit Fees" represents the aggregate fees for the interim reviews and annual audit of our financial statements for 2025 and 2024 as well as other assurance service.

(2) "Audit-Related Fees" represents the aggregate fees billed for each of the fiscal years listed for the assurance and related services rendered by our principal auditors that are reasonably related to the performance of the audit or review of our financial statements and not reported under "Audit Fees."

(3) "Tax Fees" represents the aggregate fees billed for each of the fiscal years listed for the professional tax services rendered by our principal auditors.

(4) "All Other Fees" represents the aggregate fees for services rendered by our principal auditors other than services reported under "Audit Fees," "Audit-related Fees" and "Tax Fees."

Policy on Board Pre-Approval of Audit and Permissible Non-Audit Services of the Independent Auditors

Our audit committee has adopted a policy pursuant to which we will not engage our auditors to perform any non-audit services unless the audit committee pre-approves the service. All of the non-audit services provided to us by the independent auditors as described above was pre-approved by the audit committee.

PART IV.

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K: Financial Statements: See "Item 8. Financial Statements and Supplementary Data—Index to Financial Statements and Supplementary Data" herein.

(b) Exhibits: The exhibits listed in the accompanying index to exhibits are filed or incorporated by reference as part of this Annual Report on Form 10-K.

No.	Description of Exhibit
3.1(1)	Amended and Restated Memorandum and Articles of Association of BeyondSpring Inc.
4.1(1)	Specimen Certificate for Ordinary Shares of BeyondSpring Inc.
4.2(2)	Description of Securities Registered under Section 12 of the Exchange Act
10.1(1)#	Amended and Restated Employment Agreement, dated as of November 10, 2016, between BeyondSpring U.S. and Lan Huang
10.2(1)#	Form of Director and Executive Officer Indemnification Agreement
10.3(1)#	BeyondSpring Inc. 2017 Omnibus Incentive Plan and related form agreements
10.4(6)#	Amendment to the BeyondSpring Inc. 2017 Omnibus Incentive Plan, effective September 18, 2020
10.5(7)#	Form of Director Agreement
10.6(7)#	Form of Amendment to Director Agreement
10.7(8)	English Translation of the Capital Increase Agreement, dated as of June 14, 2019, among Dalian Wanchunbulin Pharmaceuticals Ltd., Wanchun Biotech Ltd. and Shenzhen Efung 9th Venture Investment Center (Limited Partnership)
10.8(8)	English Translation of the Capital Increase Agreement, dated as of July 3, 2019, among Dalian Wanchunbulin Pharmaceuticals Ltd., Wanchun Biotech Ltd. and Nanjing TEEWIN Investment Partnership (Limited Partnership)
10.9(5)#	Second Amendment to Employment Agreement, dated as of January 11, 2022, between BeyondSpring U.S. and Lan Huang
10.10(5)#	Letter Agreement, dated as of January 13, 2022, between BeyondSpring U.S. and Lan Huang
10.11(3)#	Letter Agreement, dated as of March 23, 2023, between BeyondSpring U.S. and Lan Huang
10.12(4)#	Letter Agreement, dated as of October 11, 2023, between BeyondSpring U.S. and Lan Huang
10.13(11)#	Letter Agreement, dated as of August 7, 2024, between BeyondSpring U.S. and Lan Huang
10.14(2)#	Letter Agreement, dated as of December 20, 2025, between BeyondSpring U.S. and Lan Huang
10.15(4)#	Letter Agreement, dated as of September 17, 2021, between BeyondSpring U.S. and Yingjuan (June) Lu
10.16(4)#	Letter Agreement, dated as of March 20, 2024, between BeyondSpring U.S. and Yingjuan (June) Lu
10.17(2)#	Letter Agreement, dated as of November 12, 2025, between BeyondSpring U.S. and Yingjuan (June) Lu
10.18(9)	Purchase Agreement, dated January 24, 2025, between BeyondSpring Inc. and Winning View Investment Limited
10.19(9)	Purchase Agreement, dated January 24, 2025, between BeyondSpring Inc. and FULL TECH CORPORATE DEVELOPMENT LIMITED
10.20(9)	Purchase Agreement, dated January 24, 2025, between BeyondSpring Inc. and Mapfil Investment Limited
10.21(10)	First Amendment to Purchase Agreement, dated February 17, 2025, between BeyondSpring Inc. and Winning View Investment Limited
19.1(11)	Insider Trading Policy
21.1(2)	List of Subsidiaries of BeyondSpring Inc.
23.1(2)	Consent of CBIZ CPAs P.C.
23.2(2)	Consent of Marcum LLP
31.1(2)	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to Securities Exchange Act Rules 13a-14(a) and 15(d)-14(a), as adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1(12)	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1(4)	Clawback Policy of BeyondSpring Inc.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

(1) Previously filed with the Registration Statement on Form F-1 (File No. 333-214610), as amended, initially filed on November 15, 2016, and incorporated herein by reference.

(2) Filed with this annual report on Form 10-K.

(3) Incorporated by reference to the 2022 annual report on Form 20-F of BeyondSpring Inc. filed with the SEC on April 18, 2023.

(4) Incorporated by reference to the 2023 annual report on Form 20-F of BeyondSpring Inc. filed with the SEC on April 29, 2024.

(5) Incorporated by reference to the 2021 annual report on Form 20-F of BeyondSpring Inc. filed with the SEC on April 14, 2022.

(6) Incorporated by reference to the 2020 annual report on Form 20-F of BeyondSpring Inc. filed with the SEC on April 30, 2021.

(7) Previously filed with Form 6-K of BeyondSpring Inc., filed with the SEC on July 24, 2020, and incorporated by reference herein.

(8) Previously filed with Form 6-K of BeyondSpring Inc., filed with the SEC on July 10, 2019, and incorporated by reference herein.

(9) Previously filed with Form 8-K of BeyondSpring Inc., filed with the SEC on January 28, 2025, and incorporated by reference herein.

(10) Previously filed with Form 8-K of BeyondSpring Inc., filed with the SEC on February 25, 2025, and incorporated by reference herein.

(11) Incorporated by reference to the 2024 annual report on Form 10-K of BeyondSpring Inc. filed with the SEC on March 27, 2025.

(12) Furnished with this annual report on Form 10-K.

Management contract or compensatory plan, contract, or arrangement

In reviewing the agreements included as exhibits to this Annual Report on Form 10-K, please remember they are included to provide you with information regarding their terms and are not intended to provide any other factual or disclosure information about us or the other parties to the agreements.

The agreements may contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement and:

- should not in all instances be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;
- have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;
- may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and
- were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BeyondSpring Inc.

By: /s/ Lan Huang
Name: Lan Huang
Title: Chief Executive Officer

Date: March 25, 2026

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

/s/ Lan Huang

Name:	Lan Huang
Title:	Chief Executive Officer and Director (Principal Executive Officer and Principal Financial and Accounting Officer)
Date:	March 25, 2026

/s/ Brendan Delaney

Name:	Brendan Delaney
Title:	Director
Date:	March 25, 2026

/s/ Patrick Fabbio

Name:	Patrick Fabbio
Title:	Director
Date:	March 25, 2026

/s/ Matthew Kirkby

Name:	Matthew Kirkby
Title:	Director
Date:	March 25, 2026

/s/ Jiangwen Majeti

Name:	Jiangwen Majeti
Title:	Director
Date:	March 25, 2026

/s/ Sihai Xu

Name:	Sihai Xu
Title:	Director
Date:	March 25, 2026

Exhibit 4.2

DESCRIPTION OF SECURITIES

REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

As of December 31, 2025, BeyondSpring ("we," "us" or "our Company") had the following series of securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, par value $0.0001 per share	BYSI	The Nasdaq Stock Market

Ordinary Shares

General

All of our issued and outstanding ordinary shares are fully paid. Our ordinary shares are issued in registered form and are issued when registered in our register of members. Our shareholders who are non-residents of the Cayman Islands may freely hold and vote their shares.

Dividends

The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors. In addition, our shareholders may by ordinary resolution declare a dividend, but no dividend may exceed the amount recommended by our directors. Under Cayman Islands law, dividends may be declared and paid only out of funds legally available therefor, namely out of either profit or our share premium account, *provided* that in no circumstances may a dividend be paid if this would result in our Company being unable to pay its debts as they fall due in the ordinary course of business.

Voting Rights

Voting at any shareholders' meeting is by show of hands unless a poll is demanded. A poll may be demanded by the chairman of such meeting or any one or more shareholders who together hold not less than 10% of the voting share capital of our Company present in person or by proxy.

A quorum required for a meeting of shareholders consists of one or more shareholders present and holding not less than a majority of all voting share capital of our Company in issue. Shareholders may be present in person or by proxy or, if the shareholder is a legal entity, by its duly authorized representative. Shareholders' meetings may be convened by our board of directors on its own initiative or upon a request to the directors by shareholders holding at the date of deposit of the requisition not less than ten percent of our voting share capital in issue. Advance notice of at least seven calendar days is required for the convening of our annual general shareholders' meeting and any other general shareholders' meeting.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes attaching to the ordinary shares cast at a meeting. Both ordinary resolutions and special resolutions may also be passed by a unanimous written resolution signed by all the shareholders of our Company, as permitted by the Cayman Islands Companies Act (the "Companies Act") and our amended and restated memorandum and articles of association. A special resolution will be required for important matters such as a change of name or making changes to our amended and restated memorandum and articles of association. Holders of the ordinary shares may, among other things, divide or combine their shares by ordinary resolution.

Transfer of Ordinary Shares

Subject to the restrictions set out below, any of our shareholders may transfer all or any of his or her ordinary shares by an instrument of transfer in the usual or common form or any other form approved by our board of directors.

Our board of directors may, in its absolute discretion, decline to register any transfer of any ordinary share which is not fully paid up or on which we have a lien. Our board of directors may also decline to register any transfer of any ordinary share unless:

- the instrument of transfer is lodged with us, accompanied by the certificate for the ordinary shares to which it relates and such other evidence as our board of directors may reasonably require to show the right of the transferor to make the transfer;
- the instrument of transfer is in respect of only one class of shares;
- the instrument of transfer is properly stamped, if required;
- in the case of a transfer to joint holders, the number of joint holders to whom the ordinary share is to be transferred does not exceed four; and
- a fee of such maximum sum as the Nasdaq Capital Market may determine to be payable or such lesser sum as our directors may from time to time require is paid to us in respect thereof.

If our board of directors refuse to register a transfer they shall, within two months after the date on which the instrument of transfer was lodged, send to each of the transferor and the transferee notice of such refusal.

The registration of transfers may, after compliance with any notice required of the Nasdaq Capital Market, be suspended and the register closed at such times and for such periods as our board of directors may from time to time determine, *provided, however*, that the registration of transfers shall not be suspended nor the register closed for more than 30 days in any year as our board of directors may determine.

Liquidation

On a return of capital on winding up or otherwise (other than on conversion, redemption or purchase of shares), assets available for distribution among the holders of ordinary shares shall be distributed among the holders of our ordinary shares on a pro rata basis. If our assets available for distribution are insufficient to repay all of the paid-up capital, the assets will be distributed so that the losses are borne by our shareholders proportionately.

Calls on Shares and Forfeiture of Shares

Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their shares in a notice served to such shareholders at least 14 calendar days prior to the specified time or times of payment. The shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption, Repurchase and Surrender of Ordinary Shares

We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders thereof, on such terms and in such manner as may be determined, before the issue of such shares, by our board of directors. Our Company may also repurchase any of our shares (including any redeemable shares) provided that the manner and terms of such purchase have been approved by our board of directors or by ordinary resolution of our shareholders, or are otherwise authorized by our amended and restated memorandum and articles of association. Under the Companies Act, the redemption or repurchase of any share may be paid out of the company's profits or out of the proceeds of a fresh issue of shares made for the purpose of such redemption or repurchase, or out of capital (including share premium account and capital redemption reserve) if the company can, immediately following such payment, pay its debts as they fall due in the ordinary course of business. In addition, under the Companies Act no such share may be redeemed or repurchased (a) unless it is fully paid up, (b) if such redemption or repurchase would result in there being no shares outstanding, or (c) if the company has commenced liquidation. In addition, our Company may accept the surrender of any fully paid share for no consideration.

Variations of Rights of Shares

The rights attached to any class or series of shares (unless otherwise provided by the terms of issue of the shares of that class or series) may, subject to our amended and restated memorandum and articles of association, be varied with the consent in writing of the holders of not less than two thirds of the issued shares of that class or series or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking pari passu with such existing class of shares.

Issuance of Additional Shares

Our amended and restated memorandum and articles of association authorize our board of directors to issue additional ordinary shares from time to time as our board of directors shall determine, to the extent of available authorized but unissued shares.

Our amended and restated memorandum and articles of association also authorize our board of directors to establish from time to time one or more series of preferred shares and to determine, with respect to any series of preferred shares, the terms and rights of that series, including:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights, voting rights; and
- the rights and terms of redemption and liquidation preferences.

Our board of directors may issue preferred shares without action by our shareholders to the extent authorized but unissued. Issuance of these shares may dilute the voting power of holders of ordinary shares.

Inspection of Books and Records

Holders of our ordinary shares will have no general right under Cayman Islands law to inspect or obtain copies of our register of members or our corporate records (other than the memorandum and articles of association, our register of mortgages and charges and special resolutions passed by our shareholders). However, we will provide our shareholders with annual audited financial statements. Under Cayman Islands law, the names of current directors can be obtained from a search conducted at the Registrar of Companies in the Cayman Islands.

Anti-Takeover Provisions

Some provisions of our amended and restated memorandum and articles of association may discourage, delay or prevent a change of control of our Company or management that shareholders may consider favorable, including provisions that:

- authorize our board of directors to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our shareholders; and
- limit the ability of shareholders to requisition and convene general meetings of shareholders.

However, under Cayman Islands law, our directors may only exercise the rights and powers granted to them under our memorandum and articles of association for a proper purpose and for what they believe in good faith to be in the best interests of our Company.

General Meetings of Shareholders and Shareholder Proposals

Our shareholders' general meetings may be held in such place within or outside the Cayman Islands as our board of directors considers appropriate.

As a Cayman Islands exempted company, we are not obliged by the Companies Act to call shareholders' annual general meetings. Our amended and restated memorandum and articles of association provide that we may (but are not obliged to) hold a general meeting in each year as our annual general meeting.

Shareholders' annual general meetings and any other general meetings of our shareholders may be convened by a majority of our board of directors. Our board of directors shall give not less than seven calendar days' written notice of a shareholders' meeting to those persons whose names appear as members in our register of members on the date the notice is given (or on any other date determined by our directors to be the record date for such meeting) and who are entitled to vote at the meeting.

Cayman Islands law provides shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in a company's articles of association. Our amended and restated memorandum and articles of association allow our shareholders holding shares representing in aggregate not less than ten percent of our voting share capital in issue, to requisition an extraordinary general meeting of our shareholders, in which case our directors are obliged to call such meeting and to put the resolutions so requisitioned to a vote at such meeting; however, our amended and restated memorandum and articles of association do not provide our shareholders with any right to put any proposals before annual general meetings or extraordinary general meetings not called by such shareholders.

Exempted Company

We are an exempted company with limited liability under the Companies Act. The Companies Act distinguishes between ordinary resident companies and exempted companies. Any company that is registered in the Cayman Islands but conducts business mainly outside of the Cayman Islands may apply to be registered as an exempted company. The requirements for an exempted company are essentially the same as for an ordinary company except that an exempted company:

- does not have to file an annual return of its shareholders with the Registrar of Companies;
- is not required to open its register of members for inspection;
- does not have to hold an annual general meeting;
- may issue negotiable or bearer shares or shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 30 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as a limited duration company; and
- may register as a segregated portfolio company.

"Limited liability" means that the liability of each shareholder is limited to the amount unpaid by the shareholder on the shares of the company (except in exceptional circumstances, such as involving fraud, the establishment of an agency relationship or an illegal or improper purpose or other circumstances in which a court may be prepared to pierce or lift the corporate veil).

Register of Members

Under Cayman Islands law, we must keep a register of members and there should be entered therein:

- the names and addresses of the members, a statement of the shares held by each member, and of the amount paid or agreed to be considered as paid, on the shares of each member;
- the date on which the name of any person was entered on the register as a member; and
- the date on which any person ceased to be a member.

Under Cayman Islands law, the register of members of our Company is prima facie evidence of the matters set out therein (i.e., the register of members will raise a presumption of fact on the matters referred to above unless rebutted) and a member registered in the register of members should be deemed as a matter of Cayman Islands law to have legal title to the shares as set against its name in the register of members. Once our register of members has been updated, the shareholders recorded in the register of members should be deemed to have legal title to the shares set against their name.

If the name of any person is incorrectly entered in, or omitted from, our register of members, or if there is any default or unnecessary delay in entering on the register the fact of any person having ceased to be a member of our company, the person or member aggrieved (or any member of our Company or our Company itself) may apply to the Cayman Islands Grand Court for an order that the register be rectified, and the Court may either refuse such application or it may, if satisfied of the justice of the case, make an order for the rectification of the register.

Differences in Corporate Law

The Companies Act is derived, to a large extent, from the older Companies Acts of England but does not follow recent United Kingdom statutory enactments, and accordingly there are significant differences between the Companies Act and the current Companies Act of England. In addition, the Companies Act differs from laws applicable to United States corporations and their shareholders. Set forth below is a summary of the significant differences between the provisions of the Companies Act applicable to us and the laws applicable to companies incorporated in the United States and their shareholders.

Mergers and Similar Arrangements

The Companies Act permits mergers and consolidations between Cayman Islands companies and between Cayman Islands companies and non-Cayman Islands companies. For these purposes, (a) "merger" means the merging of two or more constituent companies and the vesting of their undertaking, property and liabilities in one of such companies as the surviving company and (b) a "consolidation" means the combination of two or more constituent companies into a combined company and the vesting of the undertaking, property and liabilities of such companies to the consolidated company. In order to effect such a merger or consolidation, the directors of each constituent company must approve a written plan of merger or consolidation, which must then be authorized by (a) a special resolution of the shareholders of each constituent company and (b) such other authorization, if any, as may be specified in such constituent company's articles of association. The written plan of merger or consolidation must be filed with the Registrar of Companies together with a declaration as to the solvency of the consolidated or surviving company, a declaration as to the assets and liabilities of each constituent company and an undertaking that a copy of the certificate of merger or consolidation will be given to the members and creditors of each constituent company and that notification of the merger or consolidation will be published in the Cayman Islands Gazette. Dissenting shareholders have the right to be paid the fair value of their shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) if they follow the required procedures, subject to certain exceptions. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

In addition, there are statutory provisions that facilitate the reconstruction and amalgamation of companies, *provided* that the arrangement is approved by a majority in number of each class of shareholders or creditors with whom the arrangement is to be made, and who must in addition represent three-fourths in value of each such class of shareholders or creditors, as the case may be, that are present and voting either in person or by proxy at a meeting, or meetings, convened for that purpose. The convening of the meetings and subsequently the arrangement must be sanctioned by the Grand Court of the Cayman Islands. While a dissenting shareholder has the right to express to the court the view that the transaction ought not to be approved, the Grand Court can be expected to approve the arrangement if it determines that:

- the statutory provisions as to the required majority vote have been met;
- the shareholders have been fairly represented at the meeting in question and the statutory majority are acting bona fide without coercion of the minority to promote interests adverse to those of the class;

- the arrangement is such that may be reasonably approved by an intelligent and honest man of that class acting in respect of his interest; and
- the arrangement is not one that would more properly be sanctioned under some other provision of the Companies Act.

When a takeover offer is made and accepted by holders of 90% of the shares affected within four months, the offeror may, within a two-month period commencing on the expiration of such four-month period, require the holders of the remaining shares to transfer such shares on the terms of the offer. An objection can be made to the Grand Court of the Cayman Islands, but this is unlikely to succeed in the case of an offer which has been so approved unless there is evidence of fraud, bad faith or collusion.

If an arrangement and reconstruction is thus approved, the dissenting shareholder would have no rights comparable to appraisal rights, which would otherwise ordinarily be available to dissenting shareholders of Delaware corporations, providing rights to receive payment in cash for the judicially determined value of the shares.

Shareholders' Suits

In principle, we will normally be the proper plaintiff to sue for a wrong done to us as a company and a derivative action may ordinarily not be brought by a minority shareholder. However, based on English authority, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands courts can be expected (and have had occasion) to follow and apply the common law principles (namely the rule in Foss v. Harbottle and the exceptions thereto) so that a minority shareholder may be permitted to commence a representative action against, or derivative actions in the name of, our Company to challenge:

- an act which is ultra vires the company or illegal and is therefore incapable of ratification by the shareholders,
- an act which constitutes a fraud against the minority where the wrongdoers are themselves in control of the company, or
- an act which requires a resolution with a qualified (or special) majority (i.e., more than a simple majority) which has not been obtained.

Indemnification of Directors and Executive Officers and Limitation of Liability

Cayman Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the Cayman Islands courts to be contrary to public policy, such as to provide indemnification against civil fraud or the consequences of committing a crime. Our amended and restated memorandum and articles of association require us to indemnify every director, alternate director, secretary, assistant secretary, or other officer for the time being and from time to time of our Company (but not including our auditors) and the personal representatives of the same against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such indemnified person, other than by reason of such indemnified person's own dishonesty, willful default or fraud, in or about the conduct of our Company's business or affairs (including as a result of any mistake of judgment) or in the execution or discharge of his duties, powers, authorities or discretions, including without prejudice to the generality of the foregoing, any costs, expenses, losses or liabilities incurred by such indemnified person in defending (whether successfully or otherwise) any civil proceedings concerning us or our affairs in any court whether in the Cayman Islands or elsewhere. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation.

In addition, we have entered into indemnification agreements with each of our directors and executive officers that provide such persons with additional indemnification beyond that provided in our amended and restated memorandum and articles of association.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Securities Act") may be permitted to our directors, officers or persons controlling us under the foregoing provisions, we have been informed that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Directors' Fiduciary Duties

Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director acts in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, the director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

As a matter of Cayman Islands law, a director of a Cayman Islands company is in the position of a fiduciary with respect to the company and therefore it is considered that he owes the following duties to the company — a duty to act in good faith in the best interests of the company, a duty not to make a personal profit based on his position as director (unless the company permits him to do so), a duty not to put himself in a position where the interests of the company conflict with his personal interest or his duty to a third party and a duty to exercise powers for the purpose for which such powers were intended. A director of a Cayman Islands company owes to the company a duty to act with skill and care. It was previously considered that a director need not exhibit in the performance of his duties a greater degree of skill than may reasonably be expected from a person of his knowledge and experience. However, English and Commonwealth courts have moved towards an objective standard with regard to the required skill and care and these authorities are likely to be followed in the Cayman Islands.

Shareholder Action by Written Consent

Under the Delaware General Corporation Law, a corporation may eliminate the right of shareholders to act by written consent by amendment to its certificate of incorporation. Cayman Islands law and our amended and restated articles of association provide that shareholders may approve corporate matters by way of a unanimous written resolution signed by or on behalf of each shareholder who would have been entitled to vote on such matter at a general meeting without a meeting being held.

Shareholder Proposals

Under the Delaware General Corporation Law, a shareholder has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.

Cayman Islands law provides shareholders with only limited rights to requisition a general meeting, and does not provide shareholders with any right to put any proposal before a general meeting. However, these rights may be provided in articles of association. Our amended and restated articles of association allow our shareholders holding not less than ten percent of all voting power of our share capital in issue to requisition a shareholder's meeting, in which case our board of directors is obliged to call such meeting and to put the resolutions so requisitioned to a vote at such meeting. Other than this right to requisition a shareholders' meeting, our amended and restated articles of association do not provide our shareholders other right to put proposal before a meeting. As an exempted Cayman Islands company, we are not obliged by law to call shareholders' annual general meetings.

Cumulative Voting

Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation specifically provides for it. Cumulative voting potentially facilitates the representation of minority shareholders on a board of directors since it permits the minority shareholder to cast all the votes to which the shareholder is entitled on a single director, which increases the shareholder's voting power with respect to electing such director. There are no prohibitions in relation to cumulative voting under the laws of the Cayman Islands but our amended and restated articles of association do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

Removal of Directors

Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under our amended and restated articles of association, directors may be removed with or without cause, by an ordinary resolution of our shareholders.

Transactions with Interested Shareholders

The Delaware General Corporation Law contains a business combination statute applicable to Delaware corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder, generally, is a person who, or a group which, owns or owned 15% or more of the target's outstanding voting share within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

Cayman Islands law has no comparable statute. As a result, we cannot avail ourselves of the types of protections afforded by the Delaware business combination statute. However, although Cayman Islands law does not regulate transactions between a company and its significant shareholders, it does provide that such transactions must be entered into bona fide in the best interests of the company and for a proper purpose and not with the effect of constituting a fraud on the minority shareholders.

Dissolution; Winding up

Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board.

Under Cayman Islands law, a company may be wound up by either an order of the courts of the Cayman Islands or by a special resolution of its members or, if the company is unable to pay its debts as they fall due, by an ordinary resolution of its members. The court has authority to order winding up in a number of specified circumstances including where it is, in the opinion of the court, just and equitable to do so. Under the Companies Act and our amended and restated articles of association, our Company may be dissolved, liquidated or wound up by a special resolution of our shareholders, or by an ordinary resolution on the basis that our Company is unable to pay its debts as they fall due.

Variation of Rights of Shares

Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. Under Cayman Islands law and our amended and restated articles of association, if our share capital is divided into more than one class of shares, we may vary the rights attached to any class with the written consent of the holders of not less than two thirds of the issued shares of that class or with the sanction of a special resolution passed at a general meeting of the holders of the shares of that class.

Amendment of Governing Documents

Under the Delaware General Corporation Law, a corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under Cayman Islands law, our amended and restated memorandum and articles of association may only be amended with a special resolution of our shareholders.

Rights of Non-resident or Foreign Shareholders

There are no limitations imposed by our amended and restated memorandum and articles of association on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in our amended and restated memorandum and articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

Exhibit 10.14

December 20, 2025

Lan Huang

Re: Salary adjustment

Dear Lan:

Hope this letter finds you well. Per our discussion, this letter is to inform you about your salary adjustment.

Following a careful assessment of our current financial situation and operations, we have approved your request for a salary reduction. Effective from January 1, 2026, your new salary rate will be $37,000 until further notice.

Thank you for your continued commitment to the company.

/s/ Matthew Kirkby

Matthew Kirkby, Board Member,
Chair, Compensation Committee
BeyondSpring Pharmaceuticals, Inc.
BeyondSpring Inc.

Acknowledgement:

/s/ Lan Huang
Lan Huang

December 22, 2025
Date

Exhibit 10.17

November 12, 2025

Dear June(Yingjuan Lu),

I am pleased to inform you that effective December 1, 2025, your new annual base salary at BeyondSpring will be $280,000. The Company may change your position, duties, and work location from time to time at its discretion.

Congratulations on this well-deserved increase!

We understand that your contributions to our organization have been invaluable, and we are committed to recognizing and rewarding your hard work and dedication. This adjustment reflects the value that we place on your contributions and our commitment to providing competitive compensation to our employees.

We appreciate your continued commitment to our company's success and your dedication to your role. Your contributions are an important part of our ongoing growth, and we are thrilled to have you on our team.

Once again, congratulations on your salary adjustment, and we look forward to your continued success and leadership at BeyondSpring.

Sincerely,

/s/ Lan Huang
Lan Huang
CEO & Co-Founder
BeyondSpring Pharmaceuticals, Inc

Exhibit 21.1

List of Subsidiaries

Name of Subsidiary	**Jurisdiction of Incorporation**
BeyondSpring Pharmaceuticals, Inc.	Delaware, United States
BeyondSpring Ltd.	British Virgin Islands
BeyondSpring (HK) Limited	Hong Kong
Wanchun Biotechnology Limited	British Virgin Islands
Wanchun Biotechnology (Dalian) Ltd.	China
Dalian Wanchunbulin Pharmaceuticals Ltd.	China
SEED Therapeutics Inc.	British Virgin Islands
SEED Technology Limited	British Virgin Islands
Beijing Wanchun Pharmaceutical Technology Ltd.	China
SEED Therapeutics US, Inc.	Delaware, United States
Wanchun Hongji (Dalian) Pharmaceuticals Ltd.	China
SEED LH Inc.	British Virgin Islands
SEED LH MG Inc.	Delaware, United States

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-280153) and Form S-8 (No. 333-216639 and No. 333-240082) of our report dated March 25, 2026, with respect to the consolidated financial statements of BeyondSpring Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

Costa Mesa, CA
March 25, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-280153) and Form S-8 (No. 333-216639 and No. 333-240082) of our report dated March 27, 2025, with respect to the consolidated financial statements of BeyondSpring Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

Costa Mesa, CA
March 25, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lan Huang, certify that:

1. I have reviewed this annual report on Form 10-K of BeyondSpring Inc. (the "Company");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

(c) Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: March 25, 2026

By: /s/ Lan Huang
Name: Lan Huang
Title: Chief Executive Officer (Principal Executive Officer and Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Lan Huang, Chief Executive Officer of BeyondSpring Inc. (the "Company"), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Company's annual report on Form 10-K for the year ended December 31, 2025 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 25, 2026

By: /s/ Lan Huang
Name: Lan Huang
Title: Chief Executive Officer (Principal Executive Officer and Principal Financial and Accounting Officer)