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

FORM 20-F

(Mark One)

☐ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR 12(g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

☒ 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_____

OR

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

Date of event requiring this shell company report:_____

For the transition period from_____to_____

Commission file number: 001-42445

Jyong Biotech Ltd.
(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

Cayman Islands
(Jurisdiction of incorporation or organization)

23F-3, No. 95, Section 1, Xintai 5th Road,
Xizhi District, New Taipei City,
Taiwan, 221
Tel: +886-2-2732-5205
(Address of principal executive offices)

Wei Zhang, Chief Financial Officer
Telephone: +886-2-2732-5205
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23F-3, No. 95, Section 1, Xintai 5th Road,
Xizhi District, New Taipei City, Taiwan, 221
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be 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 US$0.00001 per share	MENS	The Nasdaq Stock Market LLC

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

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report:

As of December 31, 2025, there were 76,027,667 ordinary shares issued and outstanding, par value US$0.00001 per share.

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 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, or an emerging growth company. See definition of "large accelerated filer, "accelerated filer" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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 which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒	International Financial Reporting Standards as issued by the International Accounting Standards Board ☐	Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow: Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. ☐ Yes ☐ No

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INTRODUCTION

In this annual report on Form 20-F, unless the context otherwise requires, references to:

- "CAGR" refers to compound average growth rate;
- "China" or the "PRC", in each case, refers to the People's Republic of China, excluding, for the purpose of this annual report only, Hong Kong, Macau and Taiwan. The term "Chinese" has a correlative meaning for the purpose of this annual report. When used in the case of laws and regulations, of "China" or "the PRC", it refers to only such laws and regulations of mainland China;
- "EIT" refers to enterprise income tax;
- "Hong Kong" refers to Hong Kong Special Administrative Region in the PRC;
- "HKD" refers to the legal currency of Hong Kong;
- "mu" refers to a Chinese unit of area, which equals to approximately 666.7 square meters;
- "NTD" refers to the legal currency of Taiwan;
- "ordinary shares" or "shares" prior to the completion of our IPO refer to our ordinary shares of par value US$0.00001 per share, and upon and after the completion of our IPO are to our ordinary shares;
- "P value" refers to a statistical measurement used to validate a hypothesis against observed data. The lower the P value, the greater the statistical significance of the observed difference. A P value of 0.05 or lower is generally considered statistically significant;
- "R&D" refers to research and development;
- "RMB" and "Renminbi" refer to the legal currency of China;
- "R value" refers to the ratio of intrinsic clearance values of a probe substrate for an enzymatic pathway in the absence of the potential inducing drug versus in the presence of the potential inducing drug in vitro drug-drug interaction study and was calculated using the following equation:

$$R = \frac{1}{1 + \frac{d \times E_{max} \times [I]}{w_D \times EC_{50} + [I]}},$$

where d is a scaling factor that is assumed as 1; EC_{50} is the concentration causing half maximal effect; E_{max} is the maximum induction effect; $[I]$ is the concentration of BDS component D in serum; w_D is the percentage of component D in BDS.

- "SEC" refers to the Securities and Exchange Commission;
- "Taiwan" refers to Taiwan, Republic of China.
- "TFDA" refers to the Food and Drug Administration, Ministry of Health and Welfare, the Republic of China;
- "US$" and "U.S. dollars" refer to the legal currency of the United States;
- "U.S. FDA" refers to the U.S. Food and Drug Administration;
- "U.S. GAAP" refers to generally accepted accounting principles in the United States; and
- "we," "us," and "our" refer to Jyong Biotech Ltd., a Cayman Islands company and its subsidiaries.

This annual report on Form 20-F includes our audited consolidated financial statements for the fiscal years ended December 31, 2025, 2024, and 2023. In this annual report, we refer to assets, obligations, commitments, and liabilities in our consolidated financial statements in U.S. dollars. Certain dollar references are based on the exchange rate of NTD to U.S. dollars, determined as of a specific date or for a specific period. Changes in the exchange rate will affect the amount of our obligations and the value of our assets in terms of U.S. dollars which may result in an increase or decrease in the amount of our obligations (expressed in dollars) and the value of our assets, including accounts receivable (expressed in dollars).

This annual report contains translations of certain NTD into U.S. dollars at specified rates. Unless otherwise stated, the following exchange rates are used in this annual report:

	December 31,		
US$ Exchange Rate	**2025**	**2024**	**2023**
At the end of the year - NTD	NTD 31.3700 to $1.00	NTD 32.7900 to $1.00	NTD30.6200 to $1.00
Average rate for the year - NTD	NTD31.1663 to $1.00	NTD32.1064 to $1.00	NTD31.1525 to $1.00

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This annual report contains forward-looking statements that reflect our current expectations and views of future events. These forward-looking statements are made under the "safe-harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Known and unknown risks, uncertainties and other factors, including those listed under "Item 3. Key Information — D. Risk Factors," may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements.

You can identify some of these forward-looking statements by words or phrases such as "may," "will," "expect," "anticipate," "aim," "estimate," "intend," "plan," "believe," "is/are likely to," "potential," "continue" or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events that we believe may affect our financial condition, results of operations, business strategy and financial needs. These forward-looking statements include statements relating to:

- our goals and strategies;
- our future business development, financial condition and results of operations;
- the expected growth of the pharmaceutical industry;
- our expectations regarding demand for and market acceptance of our products and services;
- our expectations regarding our bases of customers;
- our plans to invest in our products and services;
- competition in our industry; and
- relevant government policies and regulations relating to our industry.

These forward-looking statements involve various risks and uncertainties. Although we believe that our expectations expressed in these forward-looking statements are reasonable, our expectations may later be found to be incorrect. The forward-looking statements made in this annual report relate only to events or information as of the date on which the statements are made in this annual report. Except as required by law, we undertake no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, after the date on which the statements are made or to reflect the occurrence of unanticipated events. You should thoroughly read this annual report and the documents that we refer to herein with the understanding that our actual future results may be materially different from and worse than what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This annual report contains certain data and information that we obtained from various government and private publications. Statistical data in these publications also include projections based on a number of assumptions. The pharmaceutical industry may not grow at the rate projected by market data, or at all. Failure of this industry to grow at the projected rate may have a material and adverse effect on our business and the market price of our ordinary shares. In addition, the competitive and rapidly changing nature of the pharmaceutical industry results in significant uncertainties for any projections or estimates relating to the growth prospects or future condition of our industry. Furthermore, if any one or more of the assumptions underlying the market data are later found to be incorrect, actual results may differ from the projections based on these assumptions. You should not place undue reliance on these forward-looking statements.

Part I

Item 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not Applicable.

Item 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not Applicable.

Item 3. KEY INFORMATION

A. [Reserved]

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

RISK FACTORS SUMMARY

You should carefully consider the risks and uncertainties summarized below, the risks described under "Item 3. Key Information — D. Risk Factors" beginning on page 1. The risks described in "Risk Factors" in this annual report may cause us to not realize the full benefits of our strengths or may cause us to be unable to successfully execute all or part of our growth strategy. Some of the more significant risks include the following:

- Our business is highly dependent on the success of our core drug candidate, Botreso®. If we are unable to obtain marketing approval for or successfully commercialize Botreso®, or if we experience significant delays in doing so, our business would expect to be materially and adversely affected. (page 3)
- We may allocate our limited resources to pursue a particular drug candidate, indication, or technology and fail to capitalize on existing or future drug candidates, indications or technologies that may later prove to be more profitable, or for which there is a greater likelihood of success. (page 4)
- The U.S. FDA has rarely approved botanical drug products. If we are unable to obtain the U.S. FDA's approval for marketing our drug candidates, or if we experience significant delays in doing so, our business could be materially and adversely affected. (page 5)
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results. (page 5)
- All of our key drug candidates are in preclinical or clinical development. If we are unable to complete clinical development and obtain regulatory approval to ultimately commercialize our key drug candidates, or if we experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially harmed. (page 6)
- If we encounter delays or difficulties enrolling and retaining patients in our clinical trials, our clinical development progress and our receipt of necessary regulatory approvals could be delayed or otherwise adversely affected. (page 7)
- The U.S. FDA has concluded that one of our four Phase III trials failed to demonstrate a statistically significant difference between Botreso® with API-1 and placebo in the primary efficacy endpoint in the Botreso®-US-a study. If our future clinical trials of our key drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development, regulatory approval, and commercialization of our drug candidates. (page 8)
- Our drug candidates may cause serious adverse, undesirable or unacceptable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, and/or result in significant negative consequences following regulatory approval, if any. (page 10)

- The manufacture of our drug products is a complex process which requires significant expertise and capital investment, and if we encounter problems in establishing our manufacturing capabilities for clinical or commercial scale or in the manufacture of our future products, our business could suffer. (page 11)

- Changes in our drug candidates' manufacturing or formulation may result in additional costs or delay. (page 12)

- We have not yet obtained marketing approval for a drug candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for our drug candidates. (page 12)

- Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not mean that we will be successful in obtaining or maintaining regulatory approval of our drug candidates in other jurisdictions. (page 12)

- If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, or to conduct other additional clinical trials as may be required by the U.S. FDA, which would significantly delay our product development and increase our costs. (page 15)

- Even if any of our drug candidates receives marketing approval, we or others may later discover that the product is less effective than previously believed or causes rare undesirable side effects that were not previously identified, which could compromise our ability, or that of any future collaborators, to market the product. (page 15)

- Our drug candidates may fail to achieve the degree of market acceptance by physicians, patients, patient advocacy groups, third-party payors and others in the medical community necessary for commercial success. (page 16)

- We face substantial competition, rapid technological change and the possibility that our competitors may discover, develop or commercialize drugs before we do or more successfully than we do, or develop therapies that are similar, more advanced or more effective than ours, each of which may adversely affect our financial condition and our ability to successfully market or commercialize our drug candidate. (page 16)

- Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or unavailable in certain market segments for our drug candidates, and we may be subject to unfavorable pricing regulations, which could harm our business. (page 17)

- The data and information that we gather in our research and development process could be inaccurate or incomplete, which may have negative influence on our business, reputation, financial condition and results of operations. (page 18)

- The incidence and prevalence for target patient populations of our drug candidates are based on estimates and third-party sources. The market opportunities for our drug candidates, if approved, may be smaller than we anticipate. (page 19)

- We have been involved in legal proceedings in the ordinary course of our business, and are currently involved in active legal proceedings. Any adverse outcome of these legal proceedings could have a material adverse effect on our business, results of operations and financial condition. (page 21)

- We face economic and political risks associated with doing business in Taiwan, particularly due to the geopolitical tension between Taiwan and PRC that could negatively affect our business and hence the value of your investment. (page 24)

- We are required to comply with extensive regulations and hold a number of permits and licenses to carry on our business in Taiwan. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our drug candidates. (page 26)

- Our future success depends on our ability to attract, retain and motivate senior management and qualified scientific employees. (page 27)

- If we do not achieve our projected development and commercialization goals in the timeframes we announced and expected, the commercialization of any of our drug candidates may be delayed and our business will be negatively influenced. (page 27)

- Certain of our facilities are mortgaged. If the mortgagees enforce the mortgage, our business could be materially and adversely affected. (page 28)

- As we rely on third parties to conduct our clinical trials and provide other important services related to research and development, regulatory submissions, and commercialization, if we fail to maintain our relationships with these third parties or if they do not successfully carry out their contractual duties, comply with applicable laws, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed. (page 42)

- If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected. (page 45)

- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. (page 47)

- If the TFDA, the U.S. FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of data exclusivity before approving generic versions of our products, the sales of our products could be materially and adversely affected. (page 47)

RISKS RELATED TO THE DISCOVERY, DEVELOPMENT, AND COMMERCIALIZATION OF OUR DRUG CANDIDATES

Our business is highly dependent on the success of our core drug candidate, Botreso®. If we are unable to obtain marketing approval for or successfully commercialize Botreso®, or if we experience significant delays in doing so, our business would expect to be materially and adversely affected.

We currently have no drug products that are approved for commercial sale. Compared with other companies that have multiple drug candidates in active development, our business and future success depends, in large parts, on our ability to obtain regulatory approval for, and then successfully commercialize our core drug candidate, Botreso®. If we cannot obtain approval for Botreso®, which is the initial indication that we are currently exploring, we will have spent substantial time and financial resources without receiving a return on investment.

The success of Botreso® will depend on several factors, including the following:

- the successful completion of Phase I PK study and Phase III clinical trial to support marketing approval by the U.S. FDA and successfully addressing the deficiencies the U.S. FDA identified in our previous submissions;

- timely receipt of marketing approvals from applicable regulatory authorities;

- the performance of our future collaborators, if any;

- the extent of any required post-marketing approval commitments to applicable regulatory authorities;

- establishment of supply arrangements with third-party raw materials suppliers;

- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in Taiwan, the U.S. and internationally;

- protection of our rights in our intellectual property portfolio;

- successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval, and meeting all applicable post-market commitments, obligations, and requirements;
- commercial acceptance of our products, if approved, by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

If we do not achieve one or more of these factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays or an inability to obtain regulatory approvals or commercialize Botreso®. Even if regulatory approvals are obtained, we may not be able to successfully commercialize Botreso® due to various factors beyond our control. Accordingly, we may not be able to generate sufficient revenue through the sale of Botreso® to sustain our operations.

We may allocate our limited resources to pursue a particular drug candidate, indication, or technology and fail to capitalize on existing or future drug candidates, indications or technologies that may later prove to be more profitable, or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing drug candidates for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forgo or delay pursuit of opportunities with other drug candidates or for other indications or technologies that later may 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. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable drug candidates. In addition, if we do not accurately evaluate the commercial potential or target market for a particular drug candidate or technology, we may relinquish valuable rights to that drug candidate or technology through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate or technology. For example, we are developing our core drug candidate, Botreso®, to initially treat BPH/LUTS. We are also considering a number of additional indications for Botreso®, including the potential to prevent prostate cancer. We cannot guarantee that the treatment of BPH/LUTS will be the most profitable indication for Botreso® as opposed to other contemplated indications. This could result in us failing to capitalize on the true market potential of our core drug candidate in a timely manner or at all.

Although a substantial amount of our efforts will focus on the continued clinical testing, potential approval, manufacturing and commercialization of our existing drug candidates, the success of our business depends, in part, upon our ability to identify, license, discover, develop, and commercialize additional drug candidates or new technologies. Research efforts to identify new drug candidates and technologies require substantial technical, financial, and human resources. Although we do not currently engage in such activities, we may in the future seek to expand our drug pipeline through in-licensing arrangements. We may end up focusing our efforts and resources on potential drug candidates and technologies that ultimately prove to be unsuccessful. Our research and any future licensing efforts may fail to identify, discover or in-license new drug candidates and technologies suitable for clinical development and commercialization for a number of reasons, including, but not limited to, the following:

- our research or business development methodology or search criteria and process may be unsuccessful in identifying potential drug candidates and technologies, or potential drug candidates and technologies that are within our resources to license or acquire and develop;
- our potential drug candidates and technologies may be shown to have adverse effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; and
- it may take greater human, financial and/or research resources to identify additional therapeutic opportunities for our drug candidates or to develop more suitable potential drug candidates and technologies than what we possess, thereby limiting our ability to diversify and expand our drug portfolio.

Accordingly, there can be no assurance that we will successfully identify and develop new drug candidates or technologies, or additional therapeutic opportunities for our drug candidates, whether through internal research or future licensing efforts, which could materially and adversely affect our future growth and prospects.

The U.S. FDA has rarely approved botanical drug products. If we are unable to obtain the U.S. FDA's approval for marketing our drug candidates, or if we experience significant delays in doing so, our business could be materially and adversely affected.

As of the date of this annual report, only four botanical drug products have received the U.S. FDA's approval for marketing as prescription drugs: (i) Veregen which contains the drug substance sinecatechins, which is a partially purified fraction of the water extract of green tea leaves from *Camellia sinensis (L.) O Kuntze* and is indicated for the treatment of genital and perianal warts, (ii) Mytesi which is a proanthocyanidin oligomer indicated to relieve symptoms of diarrhea in HIV/AIDS patients taking antiretroviral therapy and is derived from the red latex of *Croton lechleri Müll. Arg*., (iii) NexoBrid which is a topically administered, biological orphan drug for the enzymatic removal of eschar in patients with deep partial- and full-thickness thermal burns, and (iv) Filsuvez which is a prescription medicine used on the skin to treat wounds that may happen with dystrophic and junctional epidermolysis bullosa (EB) in adults and children 6 months of age and older.

The quality control of botanical drug products is very complex due to the variability of botanical raw material and the need to ensure that the therapeutic effect for botanical drug product batches is consistent. It is challenging to ensure batch-to-batch consistency, which must be demonstrated to obtain U.S. FDA approval. Minor changes in API source or the manufacturing process can result in meaningful difference in clinical effects and may mean that earlier developed pharmacological, nonclinical and clinical data no longer apply to the changed product.

We cannot predict the time required to secure all appropriate regulatory approvals or the extent of testing and documentation that may be required by governmental authorities, in particular, to obtain the approval for a botanical drug product from the U.S. FDA. Any delays in obtaining, or failure to obtain, regulatory approvals would significantly delay the development of markets and products and would have a material adverse effect on our business, results of operations and financial condition.

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

There is a risk of failure for every drug candidate. Clinical testing is expensive, difficult to design and implement and can take many years to complete, so its outcome is inherently uncertain. It is difficult to predict when or if any of our drug candidates will prove effective and safe in humans or will receive regulatory approval, and failure can occur at any time during the preclinical and clinical development process. Before obtaining regulatory approval from regulatory authorities for the commercialization of any drug candidate, our drug candidates must complete preclinical studies and then be subjected to extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans.

The results of preclinical studies and clinical trials of our drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates during later stages of clinical trials may fail to show the desired results in safety and efficacy despite having progressed through preclinical studies and initial to advanced clinical trials and despite the level of scientific rigor in the study, design and adequacy of execution. In some instances, there can be significant variability in safety and/or efficacy results among different studies of the same drug candidate due to numerous factors, including, but not limited to, differences in individual patient conditions, including genetic differences, and other compounding factors, such as other medications or pre-existing medical conditions. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval of their drug candidates.

In the case of any studies we conduct, results may differ from earlier studies due to the larger number of clinical trial sites, foreign subjects and different languages involved in such studies. Clinical practices vary globally, and there is a lack of harmonization among the guidance provided by various regulatory bodies of different regions and countries with respect to the data that is required to receive marketing approval, which makes designing global studies increasingly complex. Differing regulatory approval requirements in different countries could make it more difficult for us to conduct unified global studies, which can lead to increased development costs and marketing delays or non-viability of our clinical trials. In addition, regulatory authorities may determine that clinical trial results obtained in foreign subjects do not adequately represent the results that would be obtained in local patients and are thus not supportive of relevant approvals.

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

Investigation and development of botanical drug products is very complex due to the variability of botanical raw material and the need to ensure that the therapeutic effect for botanical drug product batches is consistent. Minor changes in API source or the manufacturing process can result in meaningful difference in clinical effects and may mean that earlier developed pharmacological, nonclinical and clinical data no longer apply to the changed product.

All of our key drug candidates are in preclinical or clinical development. If we are unable to complete clinical development and obtain regulatory approval to ultimately commercialize our key drug candidates, or if we experience significant delays in doing so, our business, financial condition, results of operations and prospects will be materially harmed.

All of our key drug candidates are still in development. Our ability to generate revenue from our key drug candidates is dependent on receipt of regulatory approval and successful commercialization of such products. We cannot guarantee that we will be able to obtain regulatory approvals for our existing drug candidates in a timely manner, or at all, and we may be unable to obtain successful commercialization of our key drug candidates even if we receive regulatory approval. Each of our key drug candidates will require additional preclinical and/or clinical development, regulatory approvals in multiple jurisdictions, development of commercial manufacturing supply and capacity, substantial investment and significant marketing efforts before we generate any revenue from product sales.

The success of our key drug candidates will depend on several factors, including, but not limited to, the following:

- hiring and maintaining sufficient experts and employees to oversee all development and regulatory activities and meeting of safety requirements;
- for our botanical drug product candidates, the ability to obtain and maintain an adequate supply of the botanical raw material from which the drug products are derived and manufactured;
- successful completion of preclinical studies and clinical trials, including the successful enrollment in such clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities for planned and future clinical trials, drug registration, manufacturing and commercialization;
- successful completion of all studies required to obtain regulatory approval in the United States, Taiwan, China, Europe and any other jurisdictions where we intend to market our key drug candidates;
- our ability to establish manufacturing capabilities and capacities, whether internally or through third-party cooperators, to the specifications of our key drug candidates for clinical supply;
- obtaining and maintaining patent, trade secret and other intellectual property protection and/or regulatory exclusivity for our key drug candidates;
- launching commercial sales of our key drug candidates, if and when approved, whether alone or in collaboration with others;

- acceptance of the drug candidates, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining healthcare coverage and adequate reimbursement;
- effectively competing with other therapies and alternative drugs;
- successfully enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of the drug candidates following regulatory approval, and meeting all applicable post-market commitments, obligations, and requirements.

Any significant delays in, or an inability to, obtain regulatory approval and ultimately achieve commercial success for our existing and future drug candidates in one or more jurisdictions would materially harm our business and we may not be able to generate enough revenues and cash flows to continue our operations could further materially harm our business. As a result, our financial condition, results of operations and prospects will be materially and adversely harmed.

If we encounter delays or difficulties enrolling and retaining patients in our clinical trials, our clinical development progress and our receipt of necessary regulatory approvals 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 that will remain in the study until its conclusion. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these studies as required by the TFDA, the U.S. FDA, and any other applicable similar regulatory authorities, or if there are delays in the enrollment of eligible patients as a result of the competitive clinical enrollment environment. Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. The inability to enroll a sufficient number of patients who meet the applicable criteria for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. If patients are unwilling to enroll in our clinical trials because of restrictions on travel or healthcare institution policies, negative publicity from adverse events related to the pharmaceutical industry or for other reasons, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of our drug candidates may be delayed. As of the date of this annual report, we have not encountered any delays or difficulties enrolling and retaining patients in our clinical trials, however, we cannot predict or guarantee that we will be successful at enrolling subjects in future clinical trials. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment could result in increased development costs, delays in advancing our drug candidates, delays in testing the effectiveness of our drug candidates or termination of clinical trials altogether.

Patient enrollment for our clinical trials may be affected by other factors, including, but not limited to, the following:

- severity of the disease under investigation;
- total size and nature of the relevant patient population;
- design and eligibility criteria for the clinical trial in question;
- perceived risks and benefits of the drug candidate under study;
- our resources to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- availability of competing therapies also undergoing clinical trials;
- our investigators' or clinical trial sites' efforts to screen and recruit eligible patients;
- our ability to maintain patients' consents;
- ability to monitor patients adequately during and after treatment;

- proximity and availability of clinical trial sites for prospective patients; and

- the occurrence of any pandemic, epidemic or any other public health crises, including from the COVID-19 pandemic, the monkeypox outbreak, natural catastrophe or other disasters that may cause a delay in enrollment of patients in clinical trials.

Additionally, our ability to successfully initiate, enroll and complete clinical trials in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with our cooperators, including but not limited to research institutions, hospitals and physicians;

- different standards for the conduct of clinical trials;

- absence in some countries of established groups with sufficient regulatory expertise for review of clinical trial protocols;

- inability to locate qualified local consultants, physicians and cooperators; and

- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements.

In addition, our clinical trials may compete with other clinical trials for drug candidates that are in the same therapeutic areas as our drug candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. For example, although we have not encountered any delays or difficulties in enrolling or retaining patients for our clinical trials in the past, we may in the future experience such delays or difficulties due to government orders and site policies on account of health epidemics, and some patients may be unwilling or unable to travel to study sites, enroll in our studies or comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. If we have difficulty enrolling a sufficient number of patients or finding additional clinical trial sites to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which could have an adverse effect on our business, financial condition, results of operations and prospects. In addition, it is possible that health pandemics may have an impact on the workforce of the third parties on which we rely, which could adversely impact our ability to conduct preclinical studies, enroll and retain patients in our clinical trials and conduct the clinical trials of our drug candidates on expected timeframes or to complete such studies, and our ability to ultimately obtain regulatory approval. As a result, the value of our Company could decline and our ability to obtain additional financing may be impaired.

The U.S. FDA has concluded that one of our four Phase III trials failed to demonstrate a statistically significant difference between Botreso® with API-1 and placebo in the primary efficacy endpoint in the Botreso®-US-a study. If our future clinical trials of our key drug candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development, regulatory approval, and commercialization of our drug candidates.

Before obtaining regulatory approval for the sale of our drug candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. We may experience numerous unexpected events during, or as a result of clinical trials that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates, including, but not limited to, the following:

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

- delay in reaching, or failure to reach, agreements on acceptable terms with prospective CROs and study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;

- manufacturing issues, including problems with manufacturing, supply quality, compliance with current good manufacturing practices, or obtaining sufficient quantities of a drug candidate from third parties for use in a clinical trial;

- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide to conduct additional clinical trials or abandon the development of such drug candidates, or regulators may require us to do so;

- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment may be insufficient or slower than we anticipate, or patients may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;

- our third-party contractors used in our clinical trials, including any clinical investigators, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from clinical trial protocol or dropout of clinical trials, which may require that we add new clinical trial sites or clinical investigators;

- we might have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding of a lack of clinical response, serious adverse, undesirable or unacceptable side effects or other unexpected characteristics or a finding that participants are being exposed to unacceptable health risks;

- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research or not rely on the results of clinical research for various reasons, including non-compliance with regulatory requirements;

- the cost of clinical trials of our drug candidates may be greater than we anticipate; and

- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently plan, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these studies or tests are not positive or are only modestly positive, or if they raise safety concerns, we may (i) be delayed in obtaining regulatory approval for our drug candidates; (ii) obtain approval for indications or patient populations that are not as broad as intended or desired; (iii) not obtain regulatory approval at all; (iv) have the drug removed from the market after obtaining regulatory approval; (v) be subject to additional post-marketing testing requirements; (vi) be subject to restrictions on how the drug is distributed or used; or (vii) be unable to obtain reimbursement for use of the drug. Many of the factors that cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Further, the TFDA, the U.S. FDA or other regulatory authorities may disagree with our clinical trial design or our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials.

We used one supplier for API-1, which formed the basis for the NDA that has since been withdrawn by the Company. The supplier of API-1 sold a parcel of its land and is currently in the process of relocating and reconstructing its manufacturing facility. Consequently, API-1 is presently unavailable to us, and the supplier of API-1 withdrew its consent for us to reference their DMF on file with the U.S. FDA.

The U.S. FDA has determined that one of our four Phase III trials failed to demonstrate a statistically significant difference between Botreso® with API-1 and placebo in the primary efficacy endpoint in the MCS-2-US-a study. Given the current unavailability of API-1, we requested a Type D meeting on December 12, 2023, to propose conducting a new Phase III trial and Phase I PK study using API-2. The U.S. FDA provided written responses on February 23, 2024, with their comments on the Phase III trial and Phase I PK study design and requested that we provide the Statistical Analysis Plan for the Phase III study. We are currently finalizing the Phase III protocol and the Phase I PK study protocol from the synopsis to comply with the U.S. FDA requirements. If the CMC comparability between API-1 and API-2 is approved, we will request a Type B meeting (WRO) with the U.S. FDA to discuss our revised Phase III protocol, Statistical Analysis Plan, and PK study protocol.

We intend to conduct the two studies in the US following the completion of our second round of financing, with the completion targeted within one to two years. The study budget cannot be determined at present and will need to be estimated after further comments from the U.S. FDA. The aforementioned completion timeline and study budget are additional to the originally allocated resources, necessitated by the lack of access to API-1 supplies.

Our drug candidates may cause serious adverse, undesirable or unacceptable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, and/or result in significant negative consequences following regulatory approval, if any.

As is the case with pharmaceuticals generally, it is likely that there may be serious adverse, undesirable or unacceptable side effects caused by our drug candidates that could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive label, a delay or denial of regulatory approval by the TFDA, the U.S. FDA or other comparable regulatory authorities, or a significant change in our clinical trial protocols or even our development plan. Results of our future preclinical studies and clinical trials could reveal a high and unacceptable severity or prevalence of adverse events. In such an event, our studies could be suspended or terminated and the TFDA, the U.S. FDA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates for any or all targeted indications. Adverse events related to our drug candidates may affect patient recruitment or the ability of enrolled subjects to complete the study and could result in potential liability claims. Serious or life-threatening adverse events associated with any of our drug candidates or of a botanical constituent could be so rare in occurrence as to not be statistically likely to arise during clinical trials and may only arise after regulatory approval and marketing. Any of these occurrences may significantly influence our reputation, business, financial condition and prospects.

All identified serious adverse events have been determined to be “not related” to Botreso®, with the exception of a pancreatitis event observed in the MCS-2-US-c trial. In this instance, the pancreatitis lasted only three days, and the causality was assessed as “possibly related” but not “definitely related,” as the event was most likely attributable to Metformin, a medication used to treat diabetes mellitus.

Additionally, the identification of serious adverse, undesirable or unacceptable side effects caused by any of our future approved drug candidates may lead to potentially significant negative consequences, which include, but are not limited to, the following:

- suspension of our marketing of the drug candidate;
- withdrawal or revocation by regulatory authorities of their approvals of or the licenses for the drug candidate;
- the requirement by regulatory authorities to conduct additional clinical trials, add additional warnings to, or otherwise change the label of the drug candidate, such as recommending or requiring additional pre-screening testing prior to prescribing or administering the drug candidate or requiring a “black box” warning or contraindication, or to create a medication guide outlining the risks of such side effects for distribution to patients;

- restriction on the distribution of the drug candidate or imposition of burdensome implementation requirements on us through the establishment of a Risk Evaluation and Mitigation Strategy, or REMS, or similar strategy as may be required by the U.S. FDA or a comparable regulatory authority;
- the requirement by regulatory authorities to conduct specific post-marketing studies of the drug candidate;
- the requirement to change the way the drug candidate is distributed or administered;
- becoming subjected to regulatory investigations, government enforcement actions or litigation proceedings, and being held liable for harm caused to subjects or patients;
- the product becoming less competitive;
- removal of drug candidates from the marketplace; and
- harm to our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of any particular drug candidate that is approved and could significantly harm our business, results of operations and prospects.

Further, the use of our drug candidates in conjunction with other therapies, may result in unique adverse events that could be exacerbated compared with adverse events from the use of our drug candidates alone. Results of our studies could reveal a high and unacceptable severity or prevalence of adverse events. These types of adverse events could be caused by our drug candidates and could cause us or regulatory authorities to interrupt, delay or halt clinical trials and may result in a more restrictive indication or the delay or denial of regulatory approval by the TFDA, the U.S. FDA or other comparable regulatory authority.

The manufacture of our drug products is a complex process which requires significant expertise and capital investment, and if we encounter problems in establishing our manufacturing capabilities for clinical or commercial scale or in the manufacture of our future products, our business could suffer.

As of the date of this annual report, only four botanical drug products have received the U.S. FDA's approval for marketing as prescription drugs. The quality control of botanical drug products is very complex due to the variability of botanical raw material and the need to demonstrate that the therapeutic effect for the tested botanical drug product batches is the targeted constituent (or constituents in the aggregate). It is challenging to ensure batch-to-batch consistency, which must be demonstrated to obtain U.S. FDA approval. Minor changes in geographical location of the API source or the manufacturing process can result in meaningful differences in clinical effects and may mean that earlier developed pharmacological, nonclinical and clinical data no longer apply to the changed product. If we are unable to obtain the U.S. FDA's approval for marketing our drug candidates, or if we experience significant delays in doing so, our business could be materially and adversely affected.

The manufacture of our drug products is a complex process, in part due to strict regulatory requirements and the inherent variability and sensitivities of the botanical nature of our drug products' raw materials. If we are unable to identify an appropriate geographical location for growing our botanical raw materials to ensure consistency in the concentration of target constituents or if we are unable to identify an appropriate production site or suitable collaborators to develop our manufacturing infrastructure, or if we fail to do so in a timely manner, any of these may lead to significant delays in the clinical supply of our drug candidates as well as the commercial manufacturing of our drug candidates once regulatory and marketing approvals have been obtained. In turn, this could delay our clinical trials, negatively impact our ability to ultimately obtain regulatory approval and materially harm any future commercialization plans.

In addition, problems may arise during the manufacturing process for a variety of reasons, including, but not limited to, required consistency of botanical raw materials, equipment malfunction, failure to follow specific protocols and procedures, problems with (including shortage of) raw materials, global supply chain issues, delays related to the construction of new facilities or expansion of any future growing or manufacturing facilities, including changes in growing or manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in the types of products produced, increases in the prices of raw materials, physical limitations that could inhibit continuous supply, man-made or natural disasters and environmental factors. For example, although we have not experienced material supply disruptions due to the COVID-19 pandemic, we cannot guarantee that we will not experience supply disruptions in the future due to the COVID-19 pandemic or any other pandemics, epidemics or other public health crises, natural catastrophes or other disasters." If problems arise during the production of a batch of future products, that batch of future products may have to be discarded and we may experience product shortages or incur added expenses. This, as well as problems that may arise during the manufacturing process, could, among other things, lead to significant additional costs and/or delays, lost revenue, damage to customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other batches or products. If problems are not discovered before such product is released to the market, recall and product liability costs may also be incurred.

Changes in our drug candidates' manufacturing or formulation may result in additional costs or delay.

As our drug candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as raw materials testing and release, manufacturing methods and formulation, are altered in an effort to optimize processes, which may not pass regulatory inspections. If we engage in the scale-up of manufacturing, we may encounter unexpected issues relating to the manufacturing process or the quality, purity and stability of the product, and we may be required to refine or alter our manufacturing processes to address these issues. Such changes may not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of preclinical studies and clinical trials. Such changes may also require additional testing, notification or approval by relevant regulatory authorities, including additional pharmacokinetics or pharmacodynamics trials. This could delay completion of preclinical studies and clinical trials; require us to conduct bridging clinical trials or studies, or to repeat one or more clinical trials; increase study or clinical trial costs; or delay approval of our product candidates and jeopardize our ability to commence product sales and generate revenue.

We have not yet obtained marketing approval for a drug candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for our drug candidates.

We have not yet obtained marketing approval for a drug candidate. It is possible that the TFDA, the U.S. FDA or other comparable regulatory authority may refuse to accept for review any NDAs that we submit for our drug candidates. It is also possible that the U.S. FDA may conclude, after review of our data, that our application for Botreso® is insufficient or the data fails to achieve clinical endpoints to statistical significance when compared with placebo, and thus may delay the U.S. FDA's issuance of marketing approval of Botreso®. If the TFDA, the U.S. FDA or other comparable regulatory authority does not accept or approve our NDAs for any of our drug candidates, it may require that we conduct additional clinical trials, preclinical studies or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other required trials or studies, approval of any NDA or application that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional trials or studies, if performed and completed, may not be considered sufficient by the TFDA, the U.S. FDA or other comparable regulatory authority to approve our NDAs. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our drug candidates, generating revenues and achieving and sustaining profitability.

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not mean that we will be successful in obtaining or maintaining regulatory approval of our drug candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our drug candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the U.S. FDA grants marketing approval of a drug candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the drug candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in Taiwan or the U.S., including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities have requirements for approval of drug candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be harmed.

Potential Non-Acceptance by the U.S. FDA of API-1 and API-2 Comparability could materially and adversely affect our business, financial condition, and results of operations.

Active pharmaceutical ingredient-1(API-1), the raw material we used in the previous clinical trials for Botreso®, is currently unavailable due to the supplier's relocation and withdrawal of their consent to reference their Drug Master File on file with the U.S. FDA. We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2 and submitted it to the U.S. FDA on October 16, 2024, and are awaiting feedback from the U.S. FDA. As of the date of this annual report, the Company has not yet successfully demonstrated the comparability of API-1 and API-2.

We are currently in the process of providing the U.S. Food and Drug Administration (FDA) with the necessary information to demonstrate the comparability of API-1 and API-2 and are awaiting a response. However, there is a risk that the FDA may determine that API-1 and API-2 are not sufficiently comparable and we would have to perform more clinical trials.

The FDA's concerns primarily relate to potential differences in the sources and methods of producing API-1 and API-2, including, but not limited to, changes in agricultural sites, agricultural and collection practices, processing methods, and manufacturing techniques. Each of these factors could impact the quality, safety, and efficacy of the active pharmaceutical ingredients, leading to a requirement for additional data or even new clinical trials to establish comparability.

If the FDA does not agree that API-1 and API-2 are sufficiently comparable, we could face significant consequences, including, but not limited to, regulatory delays and increased costs. We will be required to repeat the Botreso® and PCP clinical trials using API-2, or to conduct other additional clinical trials as may be required by the U.S. FDA. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

The approval process for our drug candidates could be delayed significantly, as we may be required to conduct additional studies or provide further data to address the FDA's concerns. The need for additional studies or data submissions could result in substantial, unanticipated costs, which could adversely affect our financial condition and operational results.

Our ability to obtain FDA approval for our new drug application (NDA) may be delayed or denied due to concerns raised by the FDA regarding our clinical trial data and comparability of our active pharmaceutical ingredients.

The U.S. FDA has reviewed our proposed Phase III protocol and Phase I pharmacokinetic (PK) synopsis, as reflected in their written response dated February 23, 2024. The U.S. FDA raised several concerns in this response that could impact our ability to obtain approval for our new drug application (NDA):

(i) The U.S. FDA questioned whether one new Phase III study with API-2 would be sufficient, as they believe results from two positive Phase III efficacy studies provide more convincing evidence of effectiveness than results from a single trial. Additionally, a single Phase III efficacy study could make it challenging to collect the amount of safety information required for a new molecular entity.

(ii) The U.S. FDA noted its concern that Study MCS-2-US-a did not demonstrate a statistically significant difference between the drug and placebo in the primary efficacy endpoint. They also expressed concerns regarding the treatment effect of questionable significance in Study MCS-2-TWN-a.

(iii) The U.S. FDA was concerned that our study plan had not specified either the quantity or quality of the confirmatory evidence, and did not state a specific clinical circumstance, ethical or practical consideration, or unmet medical need that would preclude the conduct of a second adequate and well-controlled efficacy study.

(iv) Additionally, regarding the comparability of API-1 and API-2, the U.S. FDA commented that it will need more information on how we would demonstrate comparability between API-1 and API-2. They noted that their determination of whether our original Phase III studies with API-1 would be useful depends on the quality of support for a convincing link between products containing these APIs.

In response to these concerns and upon U.S. FDA's recommendation, we are developing a comparability plan to provide the U.S. FDA with convincing link and data between products containing API-1 and API-2. As of the date of this annual report, the Company is still in the process of providing the information required by the U.S. FDA and has not yet successfully demonstrated the comparability of API-1 and API-2.

After our submission of our comparability plan and, if U.S. FDA agrees our data demonstrates comparability between API-1 and API-2, we will be able to rely on trials that were previously conducted using API-1, and we then will initiate the Botreso® Phase III study and the PK study using API-2 simultaneously. As mentioned earlier, for Botreso® (API-1), we have conducted four Phase III clinical trials in the U.S. and Taiwan, including two pivotal trials (one in each location) and two open-label extension studies (also one in each location) using API-1. The U.S. FDA raised concerns about one pivotal Phase III trial in the U.S., which failed to demonstrate a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population. Additionally, the FDA expressed concerns regarding the reproducibility of some reported efficacy results for Study MCS-2-TWN-a. However, the U.S. FDA had no further comments on the two open-label extension studies in the U.S. and Taiwan using API-1. Therefore, if the FDA agrees that our data demonstrates comparability between API-1 and API-2, we will also need to conduct another pivotal Phase III study using API-2, and we will work with the FDA to address the reproducibility issue.

To address the U.S. FDA's concern that Study MCS-2-US-a did not demonstrate a statistically significant difference between the drug and placebo in the primary efficacy endpoint, we plan to conduct an additional Phase III study, MCS-2-US-b, using API-2.

Regarding the U.S. FDA's concerns about the reproducibility of the reported efficacy results for Study MCS-2-TWN-a, we propose to re-analyze the statistical results of the MCS-2-TWN-a study data using Clinical Data Interchange Standards Consortium (CDISC) data sets that match the FDA's requested data format. Then, we will submit the reanalysis for further discussions with U.S. FDA about its concerns.

On May 14, 2024, we asked U.S. FDA to provide a written response to our questions about obtaining U.S. FDA's review and comments on a newly proposed Phase III clinical trial protocol for Botreso® with API-2 and a pharmacokinetic (PK) study. On May 23, 2024, we received a denial notice from the U.S. FDA, stating that it was premature to provide such a written response at this stage of drug development, however, the U.S. FDA would continue its review of the study design of PK study and Phase III clinical trial using API-2. The U.S. FDA decided that until the company provides complete Chemistry, Manufacturing, and Controls (CMC) information on API-2 and a plan to establish comparability between API-1 and API-2, the U.S. FDA is not in a position to reach any agreement on protocols designed to establish the safety and efficacy of Botreso®. We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2 and submitted it to the U.S. FDA on October 16, 2024, and are awaiting feedback from the U.S. FDA. If the U.S. FDA does not agree that API-1 and API-2 are comparable, we will continue to research additional API sources based on our own patent, to pursue additional outsourcing API vendors, and to follow U.S. FDA's guidance for demonstrating comparability between API-1 and API-2 to the U.S. FDA's satisfaction. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the Botreso® and PCP clinical trials using API-2, or to conduct other additional clinical trials as may be required by the U.S. FDA. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

There can be no assurance that the U.S. FDA will agree with our comparability plan or that our additional studies will satisfactorily address the U.S. FDA's concerns. Any failure to adequately address these concerns could significantly delay or prevent the approval of our NDA, which would materially and adversely affect our business, financial condition, and results of operations.

If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, or to conduct other additional clinical trials as may be required by the U.S. FDA, which would significantly delay our product development and increase our costs.

Our clinical trials for Botreso® and PCP have thus far utilized API-1, an active pharmaceutical ingredient (API) produced by a supplier that is no longer available. We have transitioned to using API-2, a new API produced by an alternative supplier, and are in the process of establishing comparability between API-1 and API-2. The U.S. FDA requires that we demonstrate that API-2 is sufficiently comparable to API-1 to rely on the results of our previous clinical trials using API-1.

If we are unable to successfully demonstrate this comparability, or if we are unable to identify another supplier capable of producing an API that meets the required standards, we may be required to repeat the clinical trials that we conducted using API-1 for both Botreso® and PCP. This would encompass phases I, II, and III studies for Botreso® using. API-2, and phases I and II studies for PCP using API-2, or to conduct other additional clinical trials as may be required by the U.S. FDA.

This could result in significant delays in our product development timelines, increased costs, and could adversely affect our business, financial condition, and results of operations. Furthermore, we cannot guarantee that any future clinical trials using API-2 or any alternative API would yield results similar to those previously obtained using API-1, which could further hinder our ability to obtain regulatory approval and bring our products to market.

Even if any of our drug candidates receives marketing approval, we or others may later discover that the product is less effective than previously believed or causes rare undesirable side effects that were not previously identified, which could compromise our ability, or that of any future collaborators, to market the product.

Clinical trials of our drug candidates are conducted in carefully defined sets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a drug candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a drug candidate, we, or others, discover that the product is less effective than previously believed or causes rare undesirable side effects that were not previously identified, any of the following adverse events could occur and may have material negative influence on our business and operations:

- regulatory authorities may withdraw their approval of our drug products;
- we, or any future collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as recommending or requiring additional pre-screening testing prior to prescribing or administering the drug candidate or requiring a “black box” warning or a contraindication;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- damages to our reputation.

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

Even if our drug candidates receive regulatory approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, patient advocacy groups and others in the medical community. Efforts to educate physicians, patients, patient advocacy groups and third-party payors on the benefits of our drug candidates may require significant resources and may not be successful, and physicians and patients may prefer other drugs or drug candidates to ours. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue from sales of our drugs or drug candidates and may not become profitable.

The degree of market acceptance of our drug candidates, if and only when they are approved for commercial sale, will depend on a number of factors, including, but not limited to, the following:

- the clinical indications for which our drug candidates are approved;
- the degree to which physicians, hospitals, patient advocacy groups and patients consider our drug candidates as safe and effective treatments;
- whether our drug candidates have achieved the perceived advantages of our drug candidates over alternative treatments;
- the prevalence and severity of any adverse effects;
- product labeling or package insert requirements of the TFDA, the U.S. FDA or other comparable regulatory authorities;
- limitations or warnings or contraindications contained in the labeling approved by the TFDA, the U.S. FDA or other comparable regulatory authorities;
- timing of market introduction of our drug candidates as well as competitive drugs;
- cost of treatment in relation to alternative treatments;
- availability of adequate coverage and reimbursement from third-party payors and government authorities in the United States, Taiwan and/or any other jurisdictions;
- willingness of patients to pay any out-of-pocket expenses in the absence of coverage and reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared with alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

We face substantial competition, rapid technological change and the possibility that our competitors may discover, develop or commercialize drugs before we do or more successfully than we do, or develop therapies that are similar, more advanced or more effective than ours, each of which may adversely affect our financial condition and our ability to successfully market or commercialize our drug candidate.

The development and commercialization of new drugs are highly competitive and the pharmaceutical industry is subject to rapid and significant technological change. We face competition with respect to our drug candidates and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from companies of all sizes around the world, including major and specialty pharmaceutical companies and generic drug companies. Potential competitors further include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Our competitors may have significantly greater financial, technical, human and other resources, such as larger research and development staff and experienced marketing and manufacturing departments, and more experience in the development and regulatory approval process than we have. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated on our competitors. As a result, these companies may obtain regulatory approval from the TFDA, the U.S. FDA or other comparable regulatory authorities more rapidly than we are able to and may be more effective in selling and marketing their products as well. This may lead to potential increased competition from drugs that have already obtained approval in other jurisdictions. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Our competitors also may also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our drug development programs.

Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are more effective, safer or less costly than any drug candidate that we may develop, or may achieve earlier patent protection, regulatory approval, product commercialization, and market penetration than we do. Additionally, technologies developed by our competitors may render our potential drug candidates uneconomical or obsolete, and we may not be successful in marketing our drug candidates against competitors. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any drug candidates that we may develop and commercialize.

While certain of our employees have experience in launching and marketing drug candidates, we may not be able to effectively build and manage a sales network or benefit from the sales network of third-party collaborators.

We are actively establishing a team for sales, marketing and distribution, which requires significant capital expenditures, management resources and time. We will have to compete with other biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable to establish internal sales, marketing and commercial distribution capabilities for any or all of the drugs we develop or in particular regions or markets, we may pursue third-party collaborative arrangements regarding the sales and marketing of our drug products into such regions or markets. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or, if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend on the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties, and our revenue from product sales may be lower than if we had commercialized our drug candidates ourselves. We will also face competition in our search for third parties to assist us with the sales and marketing efforts of our drug candidates, which may result in collaborative arrangements with less-than-optimal terms.

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

Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or unavailable in certain market segments for our drug candidates, and we may be subject to unfavorable pricing regulations, which could harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or licensing approval is granted. In some non-U.S. markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a drug product in a particular country, but then be subject to price regulations that delay our commercial launch of the drug and negatively impact the revenues we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain regulatory approval.

Our ability to commercialize any drugs successfully also will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the global healthcare industry is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any drug that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any drug for which we obtain regulatory approval. Obtaining reimbursement for certain of our drugs may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate that we successfully develop.

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

Preliminary interim or "top-line" data that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish preliminary interim or "top-line" data from clinical trials. Positive preliminary data from such interim analyses may not be predictive of such trial's subsequent or overall results. Preliminary data are subject to the risk that one or more of the outcomes may materially change as more data become available. Additionally, preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Therefore, positive preliminary results in any ongoing clinical trial may not be predictive of such results in the completed trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, preliminary data that we report may differ from future results from the same clinical trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to preliminary data could significantly harm our business prospects.

The data and information that we gather in our research and development process could be inaccurate or incomplete, which may have negative influence on our business, reputation, financial condition and results of operations.

We collect, aggregate, process, and analyze data and information from our preclinical studies and clinical trials. We also engage in substantial information gathering following the identification of a promising drug candidate. Because data in the healthcare industry is fragmented in origin, inconsistent in format, often incomplete and rapidly evolving, the overall quality of data collected or accessed in the healthcare industry is often subject to challenge, the degree or amount of data which is knowingly or unknowingly absent or omitted can be material, and we often discover data issues and errors when monitoring and auditing the quality of our data. If we make mistakes in the capture, input, or analysis of these data, our ability to advance the development of our drug candidates may be materially harmed and our business, prospects and reputation may suffer.

We also engage in the procurement of regulatory approvals necessary for the development and commercialization of our drug candidates, for which we manage and submit data to governmental entities. These processes and submissions are governed by complex data processing and validation policies and regulations. Notwithstanding such policies and regulations, interim, top-line or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data, in which case we may be exposed to liability to a customer, court or government agency that concludes that our storage, handling, submission, delivery or display of health information or other data was wrongful or erroneous. Although we maintain insurance coverage for clinical trials this coverage may prove to be inadequate or could cease to be available to us on acceptable terms, if at all. Even unsuccessful claims could result in substantial costs and diversion of management time, attention, and resources. A claim brought against us that is uninsured or under-insured could harm our business, financial condition and results of operations.

In addition, we rely on CROs and other third parties to monitor and manage data for some of our ongoing preclinical studies and clinical trials and control only certain aspects of their activities. If any of our CROs or other third parties do not perform to our standards in terms of data accuracy or completeness, data from those preclinical studies and clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For a detailed discussion, see "— Risks Related to Our Dependence on Third Parties — As we rely on third parties to conduct our clinical trials and provide other important services related to research and development, regulatory submissions, and commercialization, if we fail to maintain our relationships with these third parties or if they do not successfully carry out their contractual duties, comply with applicable laws, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed."

The incidence and prevalence for target patient populations of our drug candidates are based on estimates and third-party sources. The market opportunities for our drug candidates, if approved, may be smaller than we anticipate.

We expect to initially seek approval of Botreso® for the treatment of BPH/LUTS. Our projections of the number of patients with BPH/LUTS and the portion of those patients that would benefit from treatment with Botreso® are based on our beliefs and estimates, including the report by Frost & Sullivan, data published by third parties, including scientific literature, patient foundations and publicly available databases, and on internally generated data and assumptions. While we believe our market size information is generally reliable, such information is inherently imprecise, and relies on our and third parties' projections, assumptions and estimates within our target market, which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors. For more details, please refer to "Risks Related to the Discovery, Development, and Commercialization of Our Drug Candidates — Even if we are able to commercialize any approved drug candidates, reimbursement may be limited or unavailable in certain market segments for our drug candidates, and we may be subject to unfavorable pricing regulations, which could harm our business." If such third-party or internally generated data prove to be inaccurate or we make errors in our projections, assumptions or estimates based on that data, our addressable target market opportunity and/or our future growth rate may be less than we currently estimate. Further, new sources may reveal a change in the estimated number of patients, and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our current programs or future drug candidates may be limited. Accordingly, the information regarding the size of our addressable market opportunity included in this annual report should not be taken as indicative of our future growth.

The ultimate market opportunity for our drug candidates will depend on, among other things, the final labeling for such drug candidates as agreed with the TFDA, the U.S. FDA and any other applicable comparable foreign regulatory authorities, acceptance by the medical community and patient access, potential competition and drug pricing and reimbursement. Even if we obtain significant market share for any drug candidate, if the potential target populations deviate from our estimation, our business, financial condition, results of operations and prospects may be harmed.

Potential product liability claims or lawsuits could divert our resources, incur substantial liabilities and limit the commercialization of any drug products that we may develop.

We face an inherent risk of product liability claims as a result of the clinical testing of our drug candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we or any future collaborators commercially sell any product that we or they may develop. For example, we may be sued if any product we develop allegedly causes injury or is 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 product, 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 the commercialization of our drug candidates.

Regardless of the merits or eventual outcome, liability claims may result in significant negative consequences to our business and prospects, including, but not limited to:

- significant negative media attention and reputational damage;
- withdrawal of clinical trial participants or clinical trial sites or investigators and inability to continue clinical trials;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- the inability to commercialize any drug candidates that we may develop;
- initiation of investigations by regulators;
- loss of revenue;
- diversion of management's time and our resources; and
- a decline in the price of our ordinary shares.

We currently maintain liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or which is in excess of the limits of our insurance coverage. Our insurance policies also contain various exclusions, and we may be subject to particular liability claims for which we have no coverage. We will have to pay any amount awarded by a court or negotiated in a settlement that exceeds our coverage limitations or that is not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. In addition, if we cannot successfully defend ourselves against such claims, we may incur substantial liabilities and be required to suspend or delay our ongoing clinical trials.

Illegal and/or parallel imports and counterfeit pharmaceutical products may reduce demand for our future approved drug candidates and could have a negative impact on our reputation and business.

The illegal importation of competing products from countries where government price controls or other market dynamics result in lower prices may adversely affect the demand for our future approved drug candidates, if any, and, in turn, may adversely affect our sales and profitability in countries and regions where we plan to commercialize our products. Unapproved foreign imports of prescription drugs are illegal in most of the territories all over the world. However, illegal imports may continue to occur or even increase as the ability of patients and other customers to obtain these lower priced imports continues to grow. Furthermore, cross-border imports from lower-priced markets (which are known as parallel imports) into higher-priced markets could harm sales of our future drug products and exert commercial pressure on pricing within one or more markets. In addition, government authorities may expand consumers' ability to import lower priced versions of our future approved products or competing products from outside Taiwan, the U.S., China or other countries where we operate or expect to operate. Any future legislation or regulations that increase consumer access to lower priced medicines from outside Taiwan, the United States, China or other countries where we may operate could have a material adverse effect on our business.

Certain products distributed or sold in the pharmaceutical market may be manufactured without proper licenses or approvals, or be fraudulently mislabeled with respect to their content or manufacturers. These products are generally referred to as counterfeit pharmaceutical products. The counterfeit pharmaceutical product control and enforcement system, particularly in developing markets may be inadequate to discourage or eliminate the manufacturing and sale of counterfeit pharmaceutical products imitating our products. Since counterfeit pharmaceutical products in many cases have very similar appearances compared with the authentic pharmaceutical products but are generally sold at lower prices, counterfeits of our products could quickly erode the demand for our future approved drug candidates.

In addition, counterfeit pharmaceutical products are not expected to meet our rigorous manufacturing and testing standards. A patient who receives a counterfeit pharmaceutical product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit pharmaceutical products sold under our brand name. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

We have been involved in legal proceedings in the ordinary course of our business, and are currently involved in active legal proceedings. Any adverse outcome of these legal proceedings could have a material adverse effect on our business, results of operations and financial condition.

As of the date of this annual report, we are a party to a legal dispute against one of our shareholders, the Taizhou City Optimization and Upgrade Investment Partnership (Limited Partnership), or the Plaintiff, concerning a claim of redemption. The dispute arose out of a share purchase agreement entered into in May 2019 among (i) the Plaintiff, (ii) Medi-life Co., Limited and Sira View Corp. (collectively, the "Transferring Shareholders"), (iii) Jyong Biotech Ltd., or "Jyong," (iv) Health Ever Bio-Tech Co., Ltd., our Taiwan subsidiary, and (iv) our CEO, Ms. Fu Feng Kuo, under which the Plaintiff purchased 1,794,258 shares of Jyong from the Transferring Shareholders at an aggregate price of RMB112,500,000. The Plaintiff filed a complaint to the Taizhou Intermediate People's Court and primarily claimed for a redemption of all shares of Jyong held by it, as well as confirmation of the Plaintiff's right to liquidate all equity interests in our PRC subsidiary, Innovative Biotech Co., Ltd., which was pledged to the Plaintiff by our Hong Kong subsidiary, Top ShunXing Bio-Tech Co., Limited on July 22, 2019. This dispute went on trial on March 16, 2023 and November 29, 2023, respectively. On March 25, 2024, the Taizhou Court entered into a judgement partially in favor of the Plaintiff, ordering, among other things, the Transferring Shareholders to pay the Redemption price of RMB112,500,000 and corresponding interests, and Jyong, HEB, and Ms. Fu Feng Kuo to be jointly liable for such obligation. The Taizhou Court also ruled that the Plaintiff is entitled to liquidate all equity interest in Innovative Biotech pledged to it in order to realize the payment of the aforementioned obligations. We filed an appeal against this judgement on April 29, 2024 to the High People's Court of Zhejiang Province (the "High Court"). The High Court held a hearing for this case on August 9, 2024, and later issued a judgement against us to sustain the ruling of the Taizhou Court. As of December 31, 2024, our total potential liability under this judgement is USD 19,378,364. The judgment is final and not appealable, and the settlement agreement becomes legally binding upon execution by the parties. Under applicable Chinese law, Taizhou is entitled to initiate enforcement proceedings to recover the approximately RMB 134.5 million (USD 19.4 million) in cash, with Jyong, HEB, and Ms. Fu Feng Kuo jointly liable for such obligations. As of the date of this annual report, the Plaintiff has initiated enforcement procedure before competent courts respectively in Taiwan, Hong Kong and Cayman Islands, however, the concerned parties are actively engaged in negotiation to reach a settlement and thus postpone or suspend the enforcement procedure. Under PRC's civil procedure, after a judgement from civil litigation enters into effect, the parties may, at any time before and during the enforcement procedure, and until such enforcement procedure is completed, choose to enter into a settlement agreement and file to the competent court to perform such agreement in lieu of enforcing the judgement. In the opinion of our legal counsel for this lawsuit, should we eventually fail to reach a settlement with the Plaintiff, this case is likely to result in an outcome unfavorable to us. We estimated the fair value of guarantee liabilities at the fair value of the shares at the inception of this guarantee and recorded guarantee liabilities of US$19.4 million and accrued liabilities – guarantee obligation of US$21.6 million as of December 31, 2024 and 2025, respectively. For more details about the legal dispute, please see "Item 4. Information on the Company — B. Business Overview — Legal Proceedings — Taizhou Investment Dispute." There are no insurance policies to cover related payment liabilities. The dispute may incur substantial costs of settlement or litigation and may result in an outcome adverse to our interests, which may in turn result in the loss of our PRC subsidiary and materially and adversely affect our business, financial conditions and results of operations.

In addition to the right of requesting redemption of the shares purchased, certain provisions of the share purchase agreement also stipulate that the Plaintiff shall enjoy various preferential rights and management authorities as a shareholder of Jyong. Specifically, section 7 of the share purchase agreement states that the Plaintiff shall be entitled to, among other things: (i) the right of anti-dilution should Jyong engage in financing activities at a lower price per share; (ii) the right of first refusal when Jyong issues new shares or any existing shareholder transfers shares to a third party before "Qualified Issuance and Listing" (defined as Jyong's potential public filing of shares and listing on the main board of The Stock Exchange of Hong Kong Limited, or the HKEx, which never occurred); and (iii) the right to take prior to other shareholders in case of liquidation events. Section 8 stipulates that should Jyong fails to get listed on the HKEx by June 30, 2020, then the execution of certain matters shall obtain a written consent from the Plaintiff, including but not limited to: (i) approving any plans for initial public offering or merger/acquisition of Jyong; (ii) amending Jyong's registered capital or issuing any securities that may increase Jyong's registered capital or dilute Plaintiff's shareholding; (iii) selling, transferring or licensing any important intellectual property rights of the group companies; and (iv) determining plan for issuing dividends or offsetting losses for Jyong.

On November 23, 2022, the Bureau of Natural Resources and Planning in Taizhou ("Taizhou Resources Bureau") issued a formal notice of reminder of default, requiring Innovative Biotech Co., Ltd. to pay liquidated damages of RMB13,080,170, with the amount of damages accruing from November 24, 2022 to the date of actual construction to be calculated separately, due to its failure to commence and complete construction on a parcel of land which it acquired the use right in December 2019. This claim arose out of a land use right agreement entered into on November 29, 2019 between Innovative Biotech Co., Ltd. and Taizhou Resources Bureau, under which the land use right for a parcel of state-owned land, with an aggregated area of 26,680 square meters, was transferred to Innovative Biotech Co., Ltd. (the "Land Use Right Agreement") for the construction of a pharmaceutical factory project (the "Factory Project"). According to the Land Use Right Agreement, the construction of the Factory Project shall commence on May 28, 2020 and complete on November 28, 2022. However, Innovative Biotech Co., Ltd. failed to commence and complete the construction on agreed schedule. As of the date of this annual report, we have not paid the liquidated damages of RMB13,080,170 yet and we are currently in litigation with Taizhou Resources Bureau and awaiting the judgment. Under the Land Use Right Agreement, in addition to the liquidated damages, Innovative Biotech Co., Ltd. is obliged to pay land idling fee if the land is left idle for more than one year but less than two years, and Taizhou Resources Bureau has the right to take back the land use right if the land is left idle for more than two years. On September 26, 2024, the Taizhou Resources Bureau issued a notice regarding taking back the land use right without compensation, giving Innovative Biotech Co., Ltd. the right to file for an administrative hearing within five business days of receipt of notice. While the Company initially applied for the administrative hearing, it subsequently decided to relinquish the land use rights to the Taizhou Resources Bureau in accordance with the notice. As a result, the Company will no longer proceed with the hearing process. On February 8, 2025, the Bureau issued a formal Decision Letter confirming the reclamation of IB's land use rights without compensation. IB timely filed an application for administrative reconsideration with the Taizhou Municipal People's Government. On June 26, 2025, the Municipal Government issued its decision upholding the Bureau's reclamation order. Dissatisfied with the outcome, IB initiated an administrative lawsuit with the Taizhou Intermediate People's Court of Zhejiang Province on July 23, 2025. On January 19, 2026, the Court rendered a judgment dismissing IB's claims and ordering IB to bear the litigation costs of RMB 50. Although IB filed an appeal against this judgment on February 2, 2026, management, based on the advice of our local legal counsel, assesses that there is a high probability that the unfavorable judgment will be upheld on appeal. As of the date of this annual report, the appellate process remains ongoing. The claims and proceedings discussed above, and other potential claims or proceedings relating to this issue, could result in substantial costs and materially and adversely affect our business, financial conditions and results of operations. For details about the legal dispute, please also see "Item 4. Information on the Company — B. Business Overview — Legal Proceedings — Taizhou Administrative Penalty" and "Item 4. Information on the Company — B. Business Overview — License and Collaboration Agreements — Taizhou Collaboration Framework Agreement."

Moreover, we are exposed to risks related to potential legal disputes arising from agreements and contracts entered into from time to time in our ordinary course of business. For instance, on December 21, 2018, we entered into a collaboration framework agreement, or the 2018 Taizhou Agreement, with Taizhou High-tech Industrial Park Management Committee, or the "Taizhou High-tech Committee," and Taizhou Infrastructure Investment Group Co., Ltd., pursuant to which Taizhou High-tech Committee agreed to grant up to 40 mu (approximate 26,666.66 sq.m.) industrial land to us for the Factory Project with a favorable price of RMB400,000 per mu and 1,500 mu industry land to us subject to further negotiation. On September 12, 2019, based on the 2018 Taizhou Agreement, we entered into an investment cooperation agreement with the Taizhou Circular Economic Industrial Concentration District Administrative Committee (the "Taizhou Industry District Committee"), the successor of the Taizhou High-tech Committee, or the "2019 Taizhou Agreement," which further specified details relating to the Factory Project with no material deviation from the 2018 Taizhou Agreement. According to the 2018 Taizhou Agreement and 2019 Taizhou Agreement, we are obligated to complete the construction of the Factory Project by 2022, which shall be ready for production by 2023. As of the date of this annual report, the construction of the Factory Project has been suspended. In addition, RMB30 million of Innovative Biotech Co., Ltd.'s registered capital shall be actually paid within one year of its registration. As of the date of this annual report, only RMB16,562,000 of Innovative Biotech Co., Ltd.'s registered capital has been paid. Furthermore, our PRC subsidiary shall pay a cash deposit of RMB 10,000 per mu after signing the "standard parcel" development and construction agreement, or the Construction Agreement, with the Taizhou Industry District Committee. As of the date of this annual report, both the deposit and the final balance for the land have already been paid in full regarding the "Standard Land" deposit. There are liquidated penalties for failing to commence construction on schedule. However, we have not received any relevant payment demand notices as of the date of this annual report. According to the 2018 Taizhou Agreement, failure to commence and conclude the construction of the Factory Project on schedule as agreed may entitle the Taizhou Municipality with the rights to replace the granted parcel, adjust or withdraw the preferential policies available under such agreement (including but not limited to the government subsidy of RMB12.0 million innovative Biotech Co., Ltd. has already received), and take back the parcel with the original purchase price of RMB400,000 per mu. See also "Item 4. Information on the Company — B. Business Overview — License and Collaboration Agreements — Taizhou Collaboration Framework Agreement."

On November 29, 2019, our PRC subsidiary, Innovative Biotech Co. ("IB") entered into the Construction Agreement with the Taizhou Industry District Committee. The Construction Agreement provided specifics regarding the Factory Project IB was required to meet, including but not limited to the period of construction, plot ratio, amount of investment and tax income per mu. The Construction Agreement stipulates that before the Factory Project meets the requirements of amount of investment and plot ratio under the Construction Agreement, IB and its shareholder shall not transfer the acquired parcel, directly or via transfer or pledge of equity, to a third party. Should IB breaches this agreement and causes the purpose of the Construction Agreement unable to be realized, the Taizhou Industry District Committee shall have the right to terminate the Construction Agreement and claim corresponding damages. The Taizhou Industry District Committee did not explicitly consent to the pledging of IB's shares to the Taizhou City Optimization and Upgrade Investment Partnership (Limited Partnership). However, as of the date of this annual report, the Taizhou Industry District Committee has yet to raise any claims against IB based on the event discussed above. As of December 31, 2024 and 2025, IB classified the liquidated damages and accrued interests of US$2.9 million and US$3.0 million as other current liabilities, respectively.

On November 29, 2022, the Taizhou Bay New District Administrative Committee (the "Plaintiff"), successor of the Taizhou Industry District Committee, filed a civil complaint to the Taizhou Intermediate People's Court ("the Taizhou Court") against our PRC subsidiary, IB, claiming that IB has materially breached the 2019 Taizhou Agreement by failing to initiate and conclude the construction of the Factory Project in accordance with the schedule stipulated by the 2019 Taizhou Agreement and the Land Use Right Agreement. The Plaintiff requested the Taizhou Court to terminate the 2019 Taizhou Agreement, and to order IB to return the government subsidy of RMB 12.0 million IB previously received under the 2019 Taizhou Agreement, and to pay corresponding interests calculated at the Loan Prime Rate published by the National Inter-bank Funding Center. On December 1, 2022, the Court issued an order of preliminary asset preservation, freezing the RMB 10.7 million deposit in IB's bank account. This dispute went on trial on February 13, 2023, and two hearings were held on May 6, 2023 and August 17, 2023 respectively. On September 8, 2023, the Court entered into a judgement in favor of the Plaintiff, terminating the 2019 Taizhou Agreement and ordering IB to return the government subsidy of RMB12.0 million and corresponding interest and expenses to the Plaintiff. On September 14, 2023, we filed an appeal with the High People's Court of Zhejiang Province (the "High Court") regarding each of the Court's rulings described above. The High Court held a hearing for this case on October 24, 2023. On December 12, 2023, the High Court issued a judgment against IB to affirm the Taizhou Court's ruling in its entirety. On January 5, 2024, the Taizhou Court issued an order of enforcement, stipulating, among other things, freezing and assignment of IB's deposit in its bank account or withholding of IB's income up to RMB 12.0 million and corresponding interests, and the seizure, attachment and freezing of IB's property valued at RMB 12.0 million and corresponding interests, and restrictions on making certain high expenses by IB and related personnel. As of the date of this annual report, the 40 mu (approximate 26,666.66 sq.m.) industrial land we acquired for the Factory Project have been seized by the Taizhou Court, and IB's RMB 11.1 million deposit in its bank account has been transferred to the Plaintiff. On December 27, 2023, we filed a petition for retrial to the Supreme People's Court of the People's Republic of China (the "Supreme Court"). The Supreme Court issued a decision to reject our petition for retrial on August 21, 2024. As of December 31, 2024, and 2025, IB accrued US$0.4 million and US$0.4 million of other current liabilities for the loss contingencies for this dispute, respectively. For more details about the legal dispute, please see "Item 4. Information on the Company — B. Business Overview— Legal Proceedings — Taizhou Government Subsidy Dispute." There are no insurance policies to cover related payment liabilities. This dispute has resulted in an outcome adverse to our interests, which may in turn result in financial loss and adversely affect our business, financial conditions and results of operations.

We initially planned to use approximately 10% of the net proceeds of Jyong Biotech Ltd.'s initial public offering (the "IPO") for (i) a possible settlement of the litigation with Taizhou Bay New District Administrative Committee, including the return of government subsidy, litigation expenses and interest expenses, and (ii) commitments with Taizhou Resources Bureau, including liquidated damages and land idling fee. However, due to the significant increase in our total potential liabilities, including the judgment in the Taizhou Investment Dispute of approximately USD 21.6 million, our current liabilities now substantially exceed the originally anticipated amount. As a result, a significantly greater portion of the net proceeds from the IPO, or potentially all of such proceeds, may be required to satisfy our outstanding liabilities and legal obligations rather than being deployed for research and development or other business purposes. We may, in the future, be subject to allegations, claims and legal actions arising in the ordinary course of our business, which may include claims by shareholders and claims by third parties, including customers, suppliers, product consumers, business partners, or regulators. If any of these proceedings is determined adversely against us, or results in judgments, fines or settlements involving a payment of a material sum of money, it could materially and adversely affect our business, financial condition, and results of operations. In addition, negative publicity could adversely affect the reputation and brand of the operating entities. Even the successful defense of these proceedings may cause the operating entities to incur substantial legal costs and may divert management's attention and resources.

We face economic and political risks associated with doing business in Taiwan, particularly due to the geopolitical tension between Taiwan and PRC that could negatively affect our business and hence the value of your investment.

Our performance is affected by global economic conditions as well as geopolitical issues and other conditions with global reach. Macroeconomic weakness and uncertainty make it more difficult for us to manage our operations and accurately forecast financial result. As a result of the invasion of Ukraine by Russia, the United States, the European Union, the United Kingdom and other jurisdictions have imposed sanctions on certain Russian and Ukrainian persons and entities, including certain Russian banks, energy companies and defense companies, and have imposed restrictions on exports of various items to Russian and certain regions of Ukraine (including the self-proclaimed Donetsk People's Republic and Luhansk People's Republic and Crimea). Moreover, on February 22, 2022, the Office of Foreign Assets Control of the United States issued sanctions aimed at limiting Russia's ability to raise funds through sovereign debt. Such ongoing events between Ukraine and Russia could also increase China/Taiwan political tensions and U.S./China trade and other relations. These geopolitical issues have resulted in increasing global tensions and create uncertainty for global commerce. Any or all of these factors could negatively affect demand for our products and our business, financial condition and result of operations. In addition, new requirements or restrictions could come into effect which might increase the scrutiny on our business or result in one or more of our business activities being deemed to have violated sanctions. Our business and reputation could be adversely affected if the authorities of the United Nations, the United States, the European Union, Taiwan or other jurisdictions were to determine that any of our activities constitutes a violation of the sanctions they impose or provides a basis for a sanction's designation of us.

Further, our headquarters, R&D center and material laboratory are located in Taiwan. Accordingly, our business, financial condition and results of operations and the market price of our ordinary shares may be affected by changes in governmental policies, taxation, growth rate, inflation rate or interest rates and by social instability and diplomatic and social developments in or affecting Taiwan. In particular, the unique political status of Taiwan and its internal political movement cause sustained tension between PRC and Taiwan. Past developments related to the interactions between PRC and Taiwan, especially in relation to trade activities such as bans on exports of goods from time to time, have on occasions depressed the transactions and business operations of certain Taiwanese companies and overall economic environment. We cannot predict whether there will be an escalation of the tensions between PRC and Taiwan which would lead to new bans or tariffs on exports or even conflict. Any conflict which threatens the military, political or economic stability in Taiwan could have a material adverse effect on our current or future business and financial condition and results of operations.

We have engaged in transactions with related parties, and such transactions present possible conflicts of interest that could have an adverse effect on our business and results of operations.

We have entered into a number of transactions with related parties, including our significant stockholders, directors and executive officers, and their relatives. For example, we have entered into several transactions with our Co-Founder and Chief Executive Officer, Fu-Feng Kuo, including leases with landlord entities in which Ms. Kuo has or had a significant ownership interest. Also, From February 2021 to November 2021, the Company entered into several loan agreements with Nobel Consumer Corporation, which is managed by a related party of the Company. In addition, on June 24, 2025, we entered into a loan agreement with Linkage Gladden Enterprise Ltd., one of our shareholders. See "Item 7. Major Shareholders and Related Party Transactions — B. Related Party Transactions" on page 144. We may in the future enter into additional transactions with entities in which members of our board of directors and other related parties hold ownership interests.

Transactions such as loans and leases in which related parties hold ownership interests present potential conflicts of interest. The interests of the landlord entity and lender, along with their shareholders, may not align with the interests of our stockholders regarding the negotiation and certain other matters related to our lease or loan terms with that landlord entity or lender. We may have achieved more favorable terms if such transactions had not been entered into with related parties, and these transactions, individually or in the aggregate, may have an adverse effect on our business and results of operations, or may result in government enforcement actions or other litigation.

We will need to obtain substantial additional financing for our outstanding liabilities due to legal proceedings and commitment, and bank loans, and if we fail to obtain additional financing, we may not be able to continue as a going concern.

The accompanying consolidated financial statements in this annual report have been prepared in accordance with accounting principles generally accepted in the United States of America on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the consolidated financial statements do not include any adjustments relating to the recoverability of assets and classification of liabilities that might be necessary should we be unable to continue as a going concern. We concluded that there is substantial doubt about our ability to continue as a going concern for a period of one year from the date that the unaudited interim consolidated financial statements included in this registration statement were issued. In addition, our independent registered public accounting firm has issued a report that included an explanatory paragraph referring to our significant net losses, working capital deficit and need to raise additional funds, which also raised substantial doubt about our ability to continue as a going concern as it noted.

As of the date of this annual report, we have not generated revenue and we had a net working capital deficit of approximately US$11.9 million and US$11.2 million as of December 31, 2024 and 2025, respectively. This deficit included accrued expenses of approximately US$1.2 million and US$1.0 million, accounts payable of approximately US$3,000 and US$2,000, short-term and long-term loan from banks of approximately US$7.3 million and US$8.3 million which will be due within the next twelve months, other current liabilities of approximately US$3.3million and US$3.4 million due to litigation with Taizhou Bay New District Administrative Committee and commitments with Taizhou Resources Bureau, and accrued interest owed under the loan agreement with related parties of approximately US$0.1 million and US$0.3 million, as of December 31, 2024 and 2025, respectively. As of the date of this annual report, the Company's total potential liability under the judgment in the Taizhou Investment Dispute is approximately USD 21.6 million. The judgment is final and non-appealable. Under applicable Chinese law, Taizhou is entitled to initiate enforcement proceedings to recover approximately RMB 149.1 million (USD 21.6 million) in cash, with Jyong, HEB, and Ms. Fu Feng Kuo jointly and severally liable for such obligations. As of the date of this annual report, the Plaintiff has initiated enforcement procedure before competent courts respectively in Taiwan, Hong Kong and Cayman Islands, however, the concerned parties are actively engaged in negotiation to reach a settlement and thus postpone or suspend the enforcement procedure. The Company is engaged in ongoing discussions with the counterparty to reach a settlement; however, there can be no assurance that a settlement will be reached. In the event that a settlement is not concluded, Jyong, HEB, and Ms. Fu Feng Kuo may be required to jointly pay the full amount of approximately RMB 149.1 million (USD 21.6 million) in cash. Due to the significant increase in our total potential liabilities, a significantly greater portion of the net proceeds from our IPO, or potentially all of such proceeds, may be required to satisfy our outstanding liabilities and legal obligations. We will seek future funding based on the requirements of our business operations until we obtain regulatory approvals to market and commercialize our drug candidates and generate sufficient revenue from them. We have the ability to exercise discretion and flexibility to deploy our capital resources used in research and development activities according to the amount and timing of our financing activities.

Given that our significant current liabilities as described above exceed US$20 million, there is a substantial risk that all or substantially all of the net proceeds from our IPO may be required to satisfy these liabilities. In such event, we would have limited funds available from the IPO proceeds to fund our research and development activities, clinical trials, or other business operations, and we would need to seek additional financing to continue our operations. There can be no assurance that such additional financing will be available on acceptable terms, or at all. If we are unable to obtain sufficient funding, we may be forced to delay, reduce, or eliminate our research and development programs, which could have a material adverse effect on our business, financial condition, and results of operations.

We cannot guarantee that we are able to obtain future financing in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for our product candidates when we would otherwise develop our product candidates on our own, or at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail or cease operations.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material and adverse effect on our business, operating results and prospects which could result in a loss of your investment.

We are required to comply with extensive regulations and hold a number of permits and licenses to carry on our business in Taiwan. Our ability to obtain and maintain these regulatory approvals is uncertain, and future government regulation may place additional burdens on our efforts to commercialize our drug candidates.

We are a Taiwan-based biotechnology company which is subject to extensive government regulation and supervision in Taiwan. The regulatory framework addresses all aspects of operating in the pharmaceutical industry, including product development activities, clinical trials, registration, production, distribution, packaging, labelling, storage and shipment, advertising, licensing and post-approval pharmacovigilance certification requirements and procedures, periodic renewal and reassessment processes, data security and data privacy protection requirements and compliance and environmental protection. Violation of applicable laws and regulations may materially and adversely affect our business. In particular, if we and our cooperators are unable to obtain or renew permits or licenses required for our operations, they will not be able to manufacture or distribute our drug candidates and we will not be able to engage in the commercialization and distribution of our drug candidates and our business may be adversely affected.

The regulatory framework governing the pharmaceutical industry in Taiwan is subject to change and amendment from time to time. Any such change or amendment could materially and adversely impact our business, financial condition and prospects. The Taiwan government has introduced pharmaceutical laws and regulations in recent years, especially imposing further obligations on the pharmaceutical manufacturers with respect to the management of drug safety surveillance. In addition, in order to align Taiwan laws and regulations with the global practice, the Taiwan government also requires the pharmaceutical manufacturers to comply with several global practice rules. In addition, the Taiwan government has also introduced reforms to the health care system in recent years and may continue to do so, with an overall objective to expand basic medical insurance coverage and improve the quality and reliability of healthcare services. The specific regulatory changes under the various reform initiatives remain uncertain. The implementing measures to be issued may not be sufficiently effective to achieve the stated goals, and as a result, we may not be able to benefit from such reform to the extent we expect, if at all. Moreover, the various reform initiatives could give rise to regulatory developments, such as more burdensome administrative procedures, which may have an adverse effect on our business, financial condition and prospects.

For further information regarding government regulation in Taiwan and other jurisdictions, see "Item 4. Information on the Company — B. Business Overview — Regulations" for more details.

Even if we receive regulatory approval for any of our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense, and if we fail to comply with ongoing regulatory requirements or experience any unanticipated problems with any of our drug candidates, we may be subject to penalties.

If the TFDA, the U.S. FDA or a comparable regulatory authority approves any of our drug candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and record keeping for any such drug will be subject to extensive and ongoing regulatory requirements. These requirements may include submissions of safety and other post-marketing information and reports, facility registration and drug listing requirements, and continued compliance with current good laboratory practices, or cGLPs and current good clinical practice, or GCPs. Any regulatory approvals that we receive for our drug candidates may also 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.

Once a drug is approved by the TFDA, the U.S. FDA or a comparable regulatory authority for marketing, it is possible that there could be a subsequent discovery of previously unknown problems with the drug, including problems with manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs with respect to our drug products, it may result in, among other things:

- restrictions on the marketing or manufacturing of the drug, withdrawal of the drug from the market or voluntary or mandatory drug recalls;
- manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring mediation;
- revisions to the labeling, including limitation on approved uses or the addition of additional warnings, contraindications or other safety information, such as boxed warnings;
- imposition of a risk mitigation plan, or RMP, which may include distribution or use restrictions;

- requirements to conduct additional post-market clinical trials to assess the safety of the product;
- fines, warning letters or holds on clinical trials;
- refusal by the TFDA, the U.S. FDA or comparable regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil, administrative or criminal penalties; and
- revocation of approval of such drug.

Any government investigation of alleged violations of law could require us to expend significant time and resources and could generate negative publicity. Moreover, regulatory policies may change or additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are not able to maintain regulatory compliance, regulatory approval that has been obtained may be lost and we may not achieve or sustain profitability, which may harm our business, financial condition and prospects significantly.

Our future success depends on our ability to attract, retain and motivate senior management and qualified scientific employees.

We are highly dependent on the expertise of the members of our research and development team, as well as the principal members of our management. We have entered into employment agreements with our executive officers, but each of them may terminate their employment with us at any time with or without prior written notice. In addition, we currently do not have "key-man" insurance for any of our executive officers or other key personnel.

Recruiting, retaining and motivating qualified management, scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Further, replacing executive officers and key employees 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 drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, our management are required to devote significant time to compliance initiatives as we are a public company, which may require us to recruit more management personnel.

Competition for skilled personnel is intense, particularly in the pharmaceutical industry. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. This competition may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous biotechnology companies for similar personnel. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed or may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

If we do not achieve our projected development and commercialization goals in the timeframes we announced and expected, the commercialization of any of our drug candidates may be delayed and our business will be negatively influenced.

For planning purposes, we generally estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the regulatory submissions or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical trials, receipt of regulatory approval or the commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;

- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the TFDA, the U.S. FDA and comparable regulatory authorities in other jurisdictions, and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our drug candidates;
- our ability to manufacture and supply clinical trial materials to our clinical sites on a timely basis;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, commercial product manufacturing as well as sales and marketing activities.
- If we fail to achieve announced milestones in the timeframes we expected, the commercialization of any of our drug candidates may be delayed, and our business, results of operations, financial condition and prospects may be adversely affected.

Certain of our facilities are mortgaged. If the mortgagees enforce the mortgage, our business could be materially and adversely affected.

Some of our properties are mortgaged to commercial banks. We currently mortgage our titles of one construction and two land parcels in Yilan County to Taiwan Cooperative Bank Suao Branch ("Taiwan Cooperative Bank") to secure our long terms borrowings with a total amount of NTD88.2 million. The construction and two land parcels in Yilan County are currently used as our research and development center.

Taiwan Cooperative Bank may, at any time, reduce the loan amount or shorten the term of the loan to the Company, or deem it to be fully due, if any of the following circumstances apply to any of the debts owed by our Company to Taiwan Cooperative Bank, without prior notice or reminder from Taiwan Cooperative Bank: (1) when any debt is not paid off as agreed or when the principal is to be paid ; (2) when filing for settlement in accordance with the Bankruptcy Law, filing for declaration of bankruptcy, filing for company reorganization, being notified by the clearing house to refuse transactions, cessation of business, liquidation of debts; (3) when the original obligation to provide guarantee is not provided according to the agreement; (4) when an heir is declared to have abandoned the inheritance after the person's death; (5) when the main property is confiscated due to criminal offenses; and (6) in addition to the above items, it is necessary for your bank to preserve its creditor's rights and the matters specifically stipulated in the contract.

In case the mortgagees enforce the mortgage, we may not be able to continue using our properties. Our business may be interrupted, and additional relocation costs may be incurred if we are required to relocate operations. Even if the mortgage is not enforced, such third-party security rights may also limit our use of the collateral assets and adversely affect our operational efficiency. It could result in diversion of management attention and cause us to incur extra costs associated with addressing relevant issues. However, as of the date of this annual report, we are not aware of any action, claim or investigation being conducted or threatened by mortgagees to enforce the mortgage.

We are subject to risks relating to our leased properties.

We lease certain real properties in Taiwan and China from third parties primarily as office space and operation facilities. We may become involved in disputes with the property owners or third parties who otherwise have rights to or interests in our leased properties. We can provide no assurance that we will be able to find suitable replacement sites on terms acceptable to us on a timely basis, or at all, or that we will not be subject to material liability resulting from third parties' challenges on our use of such properties. As a result, our business, financial condition and results of operations may be materially and adversely affected.

Furthermore, we have not registered any of our leasehold interests with the relevant Chinese governmental authorities as required by PRC law, which may expose us to potential fines if we fail to remediate after receiving any notice from the relevant Chinese governmental authorities. Failure to complete the lease registration will not affect the legal effectiveness of the lease agreements according to PRC law, but the real estate administrative authorities may require the parties to the lease agreements to complete lease registration within a prescribed period of time, and failure to do so may subject the parties to fines from RMB1,000 ($US137) to RMB10,000 ($US1,370) for each of such lease agreements. In addition, there may be tax consequences, including stamp duty and other applicable taxes, in connection with such lease agreements.

As of the date of this annual report, we are current on our mortgage payments, no defaults have occurred, and we had not been subject to any actions, claims or investigations threatened against us or our lessors with respect to the defects in our leasehold interests which may have a material adverse impact on our business, financial condition and results of operation. However, if any of our leases is terminated as a result of challenges by third parties or governmental authorities for lack of title certificates or proof of authorization to lease, we do not expect to be subject to any fines or penalties, but we may be forced to relocate the affected offices, stores or warehouses and incur additional expenses relating to such relocation. We cannot guarantee that suitable alternative locations are readily available on commercially reasonable terms, or at all, and if we fail to relocate our operations in a timely manner, our operations may be interrupted.

Our employees, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, consultants, collaborators and contract research organizations may engage in fraud or other misconduct, including intentional failures to comply with the TFDA and the U.S. FDA regulations or similar regulations of comparable regulatory authorities, to provide accurate information to the TFDA, the U.S. FDA or comparable regulatory authorities, to comply with manufacturing standards we have established, to comply with healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, 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 be in compliance with such laws, standards 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, financial condition and results of operations, including the imposition of significant fines or other sanctions.

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 insurance policies that are required under applicable laws and regulations as well as insurance based on our assessment of our operational needs and industry practice. We also maintain liability insurance covering our clinical trials as well as certain other types of insurance. Our insurance coverage may be insufficient to cover any claim for product liability, 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.

Operating as a public company has made it more expensive for us to obtain director and officer liability insurance, since we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, our board committees or as our executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may result in a substantial amount of payments, which would adversely affect our cash position and results of operations.

Our future success depends on our ability to promote our brand and protect our reputation. If we are unable to effectively promote our brand, our business may be materially and adversely affected.

We believe that enhancing and maintaining awareness of our "HEB" brand is critical to achieving widespread acceptance of our drug candidates, especially Botreso®, and attracting new customers. Successful promotion of our brand depends largely on the quality of the products we offer and the effectiveness of our branding and marketing efforts. We expect that our branding and marketing efforts will require us to incur significant expenses and devote substantial resources. We cannot guarantee that our sales and marketing efforts will be successful. Brand promotion activities may not lead to increased revenue in the near term, and, even if they do, any revenue increases may not offset the expenses we incur to promote our brand. Our failure to establish and promote our brand and any damage to our reputation will hinder our growth. In addition, our reputation may be undermined as a result of the negative publicity about our company or our industry in general. If our drug candidates do not perform to customers' expectations, it may result in lower confidence in our products in general, which may in turn impair our operating results and our reputation.

The tax laws of the jurisdictions in which we operate may adversely affect our business and our tax results.

The tax laws applicable to our business activities are subject to change and uncertain interpretation. Our tax position could be adversely impacted by changes in tax rates, laws, practices, treaties or regulations or changes in the interpretation thereof by the authorities in jurisdictions in which we do business.

Moreover, we conduct operations through our subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any jurisdiction in which we operate were to successfully challenge our transfer prices as not reflecting arms' length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. Furthermore, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions. Such circumstances could adversely affect our financial condition, results of operations and cash flows.

If we, our CROs, consultants or any other collaborators fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and third parties, such as our CROs and consultants or any other collaborators, 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 wastes. Our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. 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 resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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

Although the audit report included in this annual report is issued by an independent registered public accounting firm that is subject to inspections by the Public Company Accounting Oversight Board, or the PCAOB, and has been inspected by the PCAOB on a regular basis, there is no guarantee that future audit reports will be prepared by auditors or their international affiliates in jurisdictions where the PCAOB is able to fully inspect their work, and as such, future investors may be deprived of such inspections, which could result in limitations or restrictions to our access of the U.S. capital markets.

On April 21, 2020, SEC Chairman Jay Clayton and PCAOB Chairman William D. Duhnke III, along with other senior SEC staff, released a joint statement highlighting the risks associated with investing in companies based in or having substantial operations in emerging markets including China. The joint statement emphasized the risks associated with lack of access for the PCAOB to inspect auditors and audit work papers in China and higher risks of fraud in emerging markets.

On May 18, 2020, Nasdaq filed three proposals with the SEC to (i) apply minimum offering size requirement for companies primarily operating in "Restrictive Market," (ii) adopt a new requirement relating to the qualification of management or board of director for Restrictive Market companies, and (iii) apply additional and more stringent criteria to an applicant or listed company based on the qualifications of the company's auditors.

On May 20, 2020, the U.S. Senate passed the HFCAA requiring a foreign company to certify it is not owned or controlled by a foreign government if the PCAOB is unable to audit specified reports because the company uses a foreign auditor not subject to PCAOB inspection. If the PCAOB is unable to inspect the company's auditors for three consecutive years, the issuer's securities are prohibited from trading on a national exchange. On December 2, 2020, the U.S. House of Representatives approved the HFCAA. On December 18, 2020, the HFCAA was signed into law. On March 28, 2021, the SEC issued interim measures implementing the HFCAA which became effective on May 5, 2021. On December 2, 2021, the SEC adopted final amendments implementing congressionally mandated submission and disclosure requirements of the HFCAA, which sent into effect on January 10, 2022. On June 22, 2021, the U.S. Senate passed the Accelerating Holding Foreign Companies Accountable Act. The bill, which was enacted, shortened the three-consecutive-year compliance period under the HFCAA to two consecutive years. As a result, the time period before our ordinary shares may be prohibited from trading or delisted will be reduced. On September 22, 2021, the PCAOB adopted a final rule implementing the HFCAA, which provides a framework for the PCAOB to use when determining, as contemplated under the HFCAA, whether the PCAOB is unable to inspect or investigate completely registered public accounting firms located in a foreign jurisdiction because of a position taken by one or more authorities in that jurisdiction.

Inspections of an independent registered public accounting firm conducted by the PCAOB outside China have at times identified deficiencies in those auditors' audit procedures and quality control procedures, which may be addressed as part of the inspection process to improve future audit quality. The recent joint statement by the SEC and PCAOB, proposed rule changes submitted by Nasdaq, and the Holding Foreign Companies Accountable Act, or HFCAA, all call for additional and more stringent criteria to be applied to emerging market companies, including companies based in China, upon assessing the qualification of their auditors, especially the non-U.S. auditors who are not inspected by the PCAOB. On August 26, 2022, the PCAOB signed a Statement of Protocol with the China Securities Regulatory Commission and the PRC Ministry of Finance, which was the first step toward opening access for the PCAOB to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong completely, consistent with U.S. Law. On December 15, 2022, the PCAOB determined that it was able to secure complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong and vacated its previous determinations to the contrary. However, should PRC authorities obstruct or otherwise fail to facilitate the PCAOB's access in the future, the PCAOB may consider the need to issue a new determination. On December 29, 2022, the Accelerating HFCAA was signed into law, which amended the HFCAA by requiring the SEC to prohibit an issuer's securities from trading on any U.S. stock exchanges if its auditor is not subject to PCAOB inspections for two consecutive years instead of three.

Our auditor, WWC, P.C., headquartered in San Mateo, California, is independent registered public accounting firms with the PCAOB, are required under the laws of the United States to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and professional standards. Therefore, it is not subject to the determinations announced by the PCAOB on December 16, 2021 as it is not on the list published by the PCAOB. Although we have a subsidiary within the PRC, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Chinese government authorities, our auditor, WWC, P.C., headquartered in San Mateo, California, has been inspected by the PCAOB on a regular basis. However, due to the recent developments in connection with the implementation of the HFCAA, we still cannot assure you whether the SEC, Nasdaq or other regulatory authorities would apply additional and more stringent criteria to us after considering the effectiveness of our auditor's audit procedures and quality control procedures, adequacy of personnel and training, or sufficiency of resources, geographic reach or experience as it relates to the audit of our consolidated financial statements. The requirement in the Accelerating HFCAA that the PCAOB be permitted to inspect the issuer's public accounting firm within two years, may result in our delisting in the future if the PCAOB is unable to inspect our accounting firm at such future time.

Our internal computer systems, or those used by our consultants or any other third-party cooperators may fail or suffer breakdowns, cyberattacks or information security breaches that could compromise the confidentiality, integrity and availability of such systems and data, result in material disruptions of our development programs and business operations, risk disclosure of confidential, financial or proprietary information, and affect our reputation.

Despite the implementation of security measures, our internal computer systems or those used by our consultants or any other third-party cooperators, may be vulnerable to damage from computer viruses and unauthorized access. As the cyber-threat landscape evolves, attacks are growing in frequency, sophistication, and intensity, and are becoming increasingly difficult to detect. These risks are increased given the recent work from home arrangements because of the monkeypox outbreak and the threat of Russian cyberattacks in response to the war in Ukraine. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering, and/or other means. If a breakdown, cyberattack, or other information security breach were to occur and cause interruptions in our operations, it could result in a misappropriation of confidential information, including our intellectual property or financial information, and a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing, 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 rely on our third-party research institution collaborators for research and development of our drug candidates and other third parties for the manufacture of our drug 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 systems, or inappropriate disclosure of confidential, financial, or proprietary information, including data related to our personnel, we could incur liability or risk disclosure of confidential, financial, or proprietary information, and the further development and commercialization of our drug candidates could be delayed. There can be no assurance that we and our business counterparties will be successful in efforts to detect, prevent, or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive data, which could result in financial, legal, business, or reputational harm to us.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions, which could include civil or criminal fines or penalties, private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Regulatory authorities in virtually every jurisdiction in which we operate have implemented and are considering a number of legislative and regulatory proposals concerning personal data protection. Additionally, the interpretation and application of data protection laws in jurisdictions applicable to us are often uncertain and in flux. We therefore face uncertainty as to the exact interpretation of any such requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of new laws.

Since we are conducting clinical trials in the U.S., we are subject to laws and regulations that address privacy, personal information protection and data security at both the federal and state levels, including federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology and Clinical Health Act, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. 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 are also subject to laws and regulations that address personal information protection and data security in Taiwan, primarily including the Personal Data Protection Act ("PDPA"), under which we are generally required to give notice to and obtain consent from an individual before collecting, processing, or using any of the said individual's personal information, subject to certain exceptions, and are restricted from providing personal information beyond the authorized scope to third parties without an individual's prior consent. Personal data pertaining to a natural person's medical records, healthcare, genetics, sex life, physical examination and criminal records are classified as sensitive personal data, which shall be subject to certain stricter obligations. Any violation may lead to a fine ranging from NTD20,000 to NTD500,000, in some cases up to NTD1,000,000 depending on the violating scenario and be liable for any damages caused. Moreover, in the event that the violation is with the intention of obtaining unlawful gains, or with the intention of impairing other person's interests, thereby causing damage to others, such violation may lead to the imprisonment for no more than five years.

Regulatory authorities in Europe have implemented and are considering a number of legislative and regulatory proposals concerning data protection. For example, the General Data Protection Regulation (EU) 2016/ 679, or the GDPR, which became effective in May 2018, imposes a broad range of strict requirements on companies subject to the GDPR, such as us, including, but not limited to, requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the European Economic Area (including to the U.S.), providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals and recordkeeping. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to €10.0 million or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to €20.0 million or up to 4% of our total worldwide annual turnover for more serious offenses. Given the new law, we face uncertainty as to the exact interpretation of the new requirements, and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law. National laws of member states of the European Union are in the process of being adapted to the requirements under the GDPR. Because the GDPR specifically gives member states flexibility with respect to certain matters, national laws may partially deviate from the GDPR and impose different obligations from country to country, leading to additional complexity and uncertainty.

We expect that we will continue to face uncertainty as to whether our efforts to comply with evolving obligations under global data protection, privacy and security laws will be sufficient. Any failure or perceived failure by us to comply with applicable laws and regulations could result in reputational damage or proceedings or actions against us by governmental entities, individuals or others. These proceedings or actions could subject us to significant civil or criminal penalties, damages, injunctive relief and negative publicity, result in the delayed or halted transfer or confiscation of certain personal information, require us to change our business practices, increase our costs and otherwise materially harm our business, prospects, financial condition and results of operations. In addition, our current and future relationships with customers, vendors, pharmaceutical collaborators and other third parties could be negatively affected by any proceedings or actions against us, or current or future data protection obligations imposed on them under applicable law. In addition, 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 significant legal and financial exposure and reputational damage that could potentially have an adverse effect on the development of our drug candidates and our business.

Our Taiwan subsidiaries are subject to restrictions on paying dividend or making other payments to us, which may restrict our ability to satisfy its liquidity requirements.

As an exempted company with limited liability incorporated under the laws of the Cayman Islands structured as a holding company, we may need dividends and other distributions on equity from our Taiwan subsidiaries to satisfy our liquidity requirements. Current Taiwan regulations permit our Taiwan subsidiaries to pay dividends to their respective shareholders only out of their accumulated profits, if any, which shall first make up previous losses and set aside at least 10% of its accumulated profits each year. These reserves are not distributable as cash dividends. Furthermore, if our Taiwan subsidiaries incur debt on their own behalf in the future, the instruments governing the debt may restrict their ability to pay dividends or make other payments to us. Any limitation on the ability of our Taiwan subsidiaries to distribute dividends or to make payments to us may restrict our ability to satisfy our liquidity requirements. In addition, the dividend payments by our Taiwan subsidiaries to us shall be subject to the withholding tax of 21% since January 1, 2018.

Taiwan laws and regulations of loans to and direct investment in Taiwan entities by offshore holding companies may delay or prevent us from using the proceeds of our IPO to make loans or additional contributions to our Taiwan subsidiaries, which could materially and adversely affect our ability to fund and expand our business.

We are an offshore holding company conducting our operations substantially in Taiwan through our Taiwan subsidiaries. We may make loans to our Taiwan subsidiaries, or we may make additional capital contributions to our Taiwan subsidiaries, or we may establish new Taiwan subsidiaries and make capital contributions to these new Taiwan subsidiaries, or we may acquire offshore entities with business operations in Taiwan in an offshore transaction.

Most of these ways are subject to Taiwan regulations and approvals or registration. For example, investment, including lending long-term loans, in Taiwan entities require Foreign Investment Approved from the Investment Commission, Ministry of Economic Affairs. Furthermore, foreign entities are prohibited from investing in some industries which are relating to national security and environmental protection, as specified in the negative list provided by Taiwan authority.

Our Taiwan subsidiaries are subject to foreign exchange control imposed by Taiwan authorities, which may affect the paying dividends, repatriating the interest or making other payments to us.

Currently Taiwan regulates only those foreign exchange transactions that involve the conversion of the NTD into foreign currencies. Pursuant to the relevant provisions of Taiwan Foreign Exchange Control Act, foreign exchange transactions by a company shall be submitted and such remittance shall be subject to the approval of the Central Bank of Taiwan where the annual accumulated settlement amount of foreign exchange purchased or sold has exceeded USD50 million. Nevertheless, Taiwan government may impose further foreign exchange restrictions in certain emergency situations, where Taiwan government experiences extreme difficulty in stabilizing the balance of payments or where there are substantial disturbances in the financial and capital markets in Taiwan. If the dividend payments or other payments by our Taiwan subsidiaries and branches to us involves the currency conversion from NTD to US Dollar, such conversion would be subject to the foregoing foreign exchange control imposed by Taiwan authority.

We are subject to changing laws and regulations regarding regulatory matters, corporate governance and public disclosure that have increased both our costs and the risk of non-compliance.

We are subject to rules and regulations by various governing bodies, including, for example, as a public company, the SEC, which is charged with the protection of investors and the oversight of companies whose securities are publicly traded as well as Nasdaq, and the various regulatory authorities in the Cayman Islands and Taiwan, and to new and evolving regulatory measures under applicable law. Our efforts to comply with new and changing laws and regulations have resulted in and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Further, there could be unanticipated changes in existing regulatory requirements. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our drug candidates. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our Company and our operating results will be adversely affected.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or the FCPA, and similar anti-corruption and anti-bribery laws of Taiwan and other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and any determination that we have violated these laws could have a material adverse effect on our business or our reputation.

Our operations are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of Taiwan and other countries in which we operate. The FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from, directly or indirectly, offering, authorizing or making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business or other advantage. We may engage third parties for preclinical studies or clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. As our business expands, the applicability of the FCPA and other anti-bribery laws to our operations will increase. If our procedures and controls to monitor anti-bribery compliance fail to protect us from reckless or criminal acts committed by our employees or agents or if we, or our employees, agents, contractors or other collaborators, 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.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international or domestic sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Our operations are subject to the effects of a rising rate of inflation.

Taiwan has recently experienced historically high levels of inflation. The inflation rate of Taiwan inched up to 2.7% in December of 2022 from 2.4% in the previous month. The inflation rate in June 2022 was 3.6%, highest inflation rate since August of 2008. As of December 2024 and 2025, the inflation rate in Taiwan stood at 2.10%. and 1.31%, respectively. If the inflation rate increases, for example due to increases in the costs of labor and supplies, it will affect our expenses, such as employee compensation and research and development charges. Research and development expenses account for a significant portion of our operating expenses. Such increased charges may not be readily recoverable during the period of time that we are bringing the drug candidates to market. Additionally, Taiwan is experiencing an acute workforce shortage, which in turn, has created a very competitive wage environment that may increase our operating costs. To the extent inflation results in rising interest rates and has other adverse effects on the market, it may adversely affect our consolidated financial condition and results of operations.

Our business may be exposed to foreign exchange risks.

We conduct clinical trials in multiple jurisdictions and thus we have expenses denominated in local currencies in multiple jurisdictions in connection with, among other things, our sponsored clinical trials, purchase of drug product for our clinical trials, process development and the prosecution and maintenance of our intellectual property portfolio. 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. In accordance with our business decisions, our exposure to this type of risk could change depending on:

- the currencies chosen when agreements are signed, such as licensing agreements, or co-marketing or co-development agreements;
- the location of clinical trials on drug candidates; and
- our policy for insurance coverage.

Should any of these risks materialize, this could have a material adverse effect on our business, prospects, financial condition and results of operations.

In addition, our business is conducted in Taiwan, and our books and records are maintained in NTD. The consolidated financial statements that we file with the SEC and provide to our shareholders are presented in U.S. dollars. Changes in the exchange rates between NTD and U.S. dollars affect the value of our assets and the results of our operations, when presented in U.S. dollars. The value of NTD against the U.S. dollar and other currencies may fluctuate and is affected by, among other things, changes in the Taiwan's political and economic conditions and perceived changes in the economy of Taiwan and the United States. Any significant revaluation of NTD may materially and adversely affect our cash flows, revenue, and financial condition. Further, our ordinary shares offered by this annual report are offered in U.S. dollars, we will need to convert the net proceeds we receive into NTD or other currencies in order to use the funds for our business. Changes in the conversion rate among the U.S. dollar, NTD and other currencies will affect the amount of proceeds we will have available for our business.

As of the date of this annual report, we have not entered into any hedging transactions in an effort to reduce our exposure to foreign currency exchange risk. While we may decide to enter into more hedging transactions in the future, the availability and effectiveness of these hedges may be limited and we may not be able to adequately hedge our exposure or at all. In addition, our currency exchange losses may be magnified by local exchange control regulations that restrict our ability to convert NTD into foreign currencies. See "— Our Taiwan subsidiaries are subject to restrictions on paying dividend or making other payments to us, which may restrict our ability to satisfy its liquidity requirements." As a result, fluctuations in exchange rates may have a material adverse effect on your investment.

We have recorded net cash outflow from operating activities since our inception and we expect to need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our drug candidates.

Since our inception, our operations have consumed substantial amounts of cash. The expenses used in our research and development activities were approximately US$0.9 million and US$0.8 million for the years ended December 31, 2024 and 2025, respectively.

We expect our expenses to increase in connection with our ongoing activities, particularly as we initiate new clinical trials of, initiate new research and preclinical development efforts for and seek marketing approval for, our drug candidates. In addition, if we obtain marketing approval for any of our drug candidates, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator. Furthermore, following the completion of our IPO, we have incurred significant additional costs associated with operating as a public company. Accordingly, we expect to need to obtain substantial additional funding in connection with our continuing operations. Our financing to fund our operations may be adversely affected, delayed or fail to raise because of capital market environment, valuation of our company or the progress of our competitors. If we are unable to raise capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Given that our significant current liabilities exceed US$20 million, there is a substantial risk that all or substantially all of the net proceeds from our IPO may be required to satisfy these liabilities. In such event, we would have limited funds available from the IPO proceeds to fund our research and development activities, clinical trials, or other business operations, and we would need to seek additional financing to continue our operations. We do not have any committed external source of funds. Accordingly, we may have to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. The incurrence of indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in our undertaking 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. However, adequate additional financing may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a holder of our ordinary shares.

Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Our existing cash on hand will not be sufficient to enable us to meet our short-term obligations or long-term plans, including commercialization of clinical pipeline products, if approved, or initiation or completion of future clinical trials. Our future funding requirements, both short-term and long-term, will depend on many factors, including:

- the number of future drug candidates that we pursue and their development requirements;
- the scope, progress, timing, results and costs of discovering, researching and developing drug candidates, and conducting preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the cost of manufacturing our drug candidates and any products we commercialize, including costs associated with expanding our supply chain;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive regulatory approval;
- the cash received, if any, from commercial sales of any drug candidates for which we receive regulatory approval;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such collaborations and arrangements;
- the extent to which we acquire or in-license other drug candidates and technologies;
- our headcount growth and associated costs;
- the costs, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- costs required to ensure that our and any of our partners' business arrangements with third parties comply with applicable healthcare laws and regulations; and
- the costs of operating as a public company.

We have no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

We have no history of commercializing pharmaceutical products. Our operations, to date, have been limited to financing and staffing our company, developing our biotechnology and conducting preclinical research and clinical trials for our drug candidates. We have not yet demonstrated an ability to successfully obtain marketing approvals for or commercialize our drug candidates or manufacture our drug candidates on a scale sufficient to supply the commercial markets. We currently have no drug candidates approved for commercial sale and have not generated any revenue from such sales. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history and/or approved products on the market.

Due to the fact that we have yet to commercialize a drug product, particularly in light of the rapidly evolving drug research and development industry in which we operate and the changing regulatory and market environments we encounter, may make it difficult to evaluate our prospects for future performance. As a result, any assessment of our future performance or viability is 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.

As we continue to build our business, we expect our financial condition and operating results may fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any particular quarterly or annual period as indications of future operating performance.

We have incurred net losses since our inception and anticipate that we will continue to incur net losses for the foreseeable future and may not generate revenue that is significant or large enough to achieve profitability.

We have incurred significant annual net operating losses in every year since our inception. We may continue to incur net operating losses for at least the next several years. Our net losses were approximately US$3.0 million and US$4.7 million for the years ended December 31, 2024 and 2025, respectively. As of December 31, 2024 and 2025, we had an accumulated deficit of approximately US$33.0 million and US$37.8 million, respectively. In addition, we incurred negative cash flows in operating activities for the approximate amount of US$3.6 million and US$3.0 million for the years ended December 31, 2024 and 2025, respectively. We have not generated any revenues from product sales and may never have a drug candidate approved for commercialization. We have financed our operations to date primarily through bank loans. We have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We anticipate that our expenses will increase substantially if and as we:

- continue to develop and conduct clinical trials with respect to our key drug candidates, PCP and IC;
- initiate and continue research, preclinical and clinical development efforts for any future drug candidates;
- seek regulatory approvals for our drug candidates;
- commercialize our drug candidates once we have obtained marketing approval;
- establish sales, marketing, distribution and other commercial infrastructure in the future to commercialize various products for which we may obtain marketing approval, if any;
- hire additional clinical, operational, financial and administrative, quality control and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and help us comply with our obligations as a public company;
- require the manufacture of larger quantities of drug candidates for clinical development and, potentially, commercialization;
- seek to identify additional drug candidates and technologies;
- obtain, maintain, expand and protect our intellectual property portfolio;
- enforce and defend any intellectual property-related claims;
- acquire or in-license other drug candidates, intellectual property and technologies;
- enter into out-licensing and co-development collaborations consistent with our global strategy;
- add equipment and physical infrastructure to support our research and development
- incur setbacks or delays to the initiation or completion of preclinical studies, drug development and/or clinical trials due to any pandemic; and
- incur any disruption or delays to the supply of our drug candidates due to any pandemic.

We will likely need to increase the size and capabilities of our organization, and we may experience difficulties in managing our growth.

In order to execute our business plans, we expect that we will need to significantly increase the number of our employees and consultants and the scope of our operations, particularly in the areas of research and development, regulatory affairs and business development. Our future financial performance and our ability to commercialize our drug candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To manage our anticipated future growth, we will need to continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations and have a material adverse effect on our business.

In addition, we currently rely, and for the foreseeable future may continue to rely, in substantial part on certain academic organizations, advisors and consultants to provide certain services. There can be no assurance that the services of these academic organizations, advisors and consultants will continue to be available to us on a timely basis when needed or that we can find qualified replacements. Furthermore, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by academic organizations, advisors or 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 drug candidates or otherwise advance our business. There can be no assurance that we will be able to maintain our existing relationships with these academic organizations, advisors and consultants or find other competent academic organizations, advisors and consultants on economically reasonable terms, if at all.

If we fail to implement and maintain an effective system of internal controls, we may be unable to accurately report our results of operations, meet our reporting obligations or prevent fraud, and investor confidence and the market price of our shares may be materially and adversely affected.

We are subject to the reporting requirements of the Exchange Act of 1934, or Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the Nasdaq. Our independent registered public accounting firm has not conducted an audit of our internal control over financial reporting, as we are not required to provide a report of management's assessment on our internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

In connection with the audits of our consolidated financial statements as of December 31, 2024 and 2025, we and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting as well as other control deficiencies for the above mentioned periods. The material weakness identified is a lack of sufficient financial reporting and accounting personnel with appropriate knowledge of U.S. GAAP and SEC reporting requirements to formalize key controls over financial reporting and to prepare consolidated financial statements and related disclosures.

We intend to implement measures designed to improve our internal control over financial reporting to address the underlying causes of the material weakness, including (i) hiring more qualified staff to fill up the key roles in the operations; (ii) setting up a financial and system control framework with formal documentation of polices and controls in place; and (iii) strengthening corporate governance.

In response to the material weaknesses identified prior to our IPO, we will implement a number of measures to address the material weakness identified, including but not limited to (i) working closely with external highly qualified accountants with relevant U.S. GAAP and SEC reporting experience and qualifications to strengthen the financial reporting function, establish a financial and system control framework, and arrange regular training programs on U.S. GAAP accounting for our accounting and financial reporting personnel; (ii) strengthening and improving the overall internal control function by employing an external consulting firm to assist us in assessing the compliance requirements of the Sarbanes Oxley Act; (iii) strengthen corporate governance; and (iv) making an internal control report to the Audit Committee every quarter to report the progress and improvement in internal control, which is well monitored by the Audit Committee.

However, we cannot assure you that all these measures will be sufficient to address all the potential internal control issues for the financial reporting, and we cannot assure you that we will not identify additional material weaknesses or significant deficiencies in the future. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, our ordinary shares may not be able to remain listed on the Nasdaq Global Market.

Section 404 of the Sarbanes-Oxley Act of 2002 requires that we include a report of management on our internal control over financial reporting in our annual report on Form 20-F beginning with our annual report beginning with our second annual report on Form 20-F. In addition, once we cease to be an "emerging growth company" as such term is defined under the JOBS Act, our independent registered public accounting firm must attest to and report on the effectiveness of our internal control over financial reporting. Our management may conclude that our internal control over financial reporting is not effective. Moreover, even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm, after conducting its own independent testing, may issue a report that is qualified if it is not satisfied with our internal controls or the level at which our controls are documented, designed, operated or reviewed, or if it interprets the relevant requirements differently from us. In addition, as we are a public company, our reporting obligations may place a significant strain on our management, operational and financial resources and systems for the foreseeable future. We may be unable to timely complete our evaluation testing and any required remediation.

During the course of documenting and testing our internal control procedures, in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act of 2002, we may identify other weaknesses and deficiencies in our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal control over financial reporting, as these standards are modified, supplemented or amended from time to time, we may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting. If we fail to achieve and maintain an effective internal control environment, we could suffer material misstatements in our financial statements and fail to meet our reporting obligations, which would likely cause investors to lose confidence in our reported financial information. This could in turn limit our access to capital markets, harm our results of operations and lead to a decline in the trading price of our shares. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange on which we list, regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements from prior periods.

We currently have no operations in China although we have established a subsidiary in each of Hong Kong and China. However, due to the extraterritorial reach (the so-called "long arm provisions") under the current PRC laws and regulations, the Chinese government may exert substantial oversight and influence over the manner in which we must conduct our business and may intervene in or influence our operations at any time, which could result in a material change in our operations and significantly and adversely impact the value of our ordinary shares. We endeavor to operate our business in compliance with applicable laws and regulations in all material respects.

We currently have no operations in China although we have established a subsidiary in each of Hong Kong and China. However, we may in the future expand our operations into China. The Chinese government has significant oversight and discretion over the conduct of our business and may intervene or influence our operations as the government deems appropriate to further regulatory, political and societal goals. The Chinese government has recently published new policies that significantly affected certain industries such as the education and internet industries, and we cannot rule out the possibility that it will in the future release regulations or policies regarding our industry that could require us to seek permission from Chinese authorities to continue to operate our business which adversely affect our business, financial condition and results of operations. Furthermore, recent statements made by the 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, as well as foreign investment in China-based issuers. On February 17, 2023, the CSRC issued the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies, or the Trial Measures, which became effective on March 31, 2023. We reasonably believed that the Trial Measures do not apply to us, and as of the date of this annual report, we have not received any inquiry, notice, warning or sanctions regarding our planned overseas listing from the CSRC and any other PRC governmental authorities. Although as of the date of this annual report, we do not expect to be materially affected by the foregoing statements or the Trial Measures, any such action, once taken by the Chinese government, could significantly limit or completely hinder our ability to offer or continue to offer ordinary shares to our investors, and could cause the value of our ordinary shares to significantly decline or become worthless.

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.

If we, in the future, expand our operations into China, our financial condition and results of operations may be affected by economic, political and legal developments in China. The PRC economy differs from the economies of most developed countries in many respects, including the extent of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. Although the PRC government has implemented measures emphasizing the utilization of market forces for economic reform, the reduction of state ownership of productive assets, and the establishment of improved corporate governance in business enterprises, a substantial portion of productive assets in China is still owned by the government. In addition, the PRC government continues to play a significant role in regulating industrial development by imposing industrial policies, and change of enforcement practice of such rules and policies can occur quickly with little advance notice. The PRC government also exercises significant control over China's economic growth by allocating resources, controlling payment of foreign currency-denominated obligations, setting monetary policy, regulating financial services and institutions and providing preferential treatment to particular industries or companies.

While the PRC economy has experienced significant growth in the past four decades, growth has been uneven, both geographically and among various sectors of the economy. The PRC government has implemented various measures to encourage economic growth and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may also have a negative effect on us. If we expand our operations into China, our business, financial condition and results of operations could be materially and adversely affected by government control over capital investments or changes in tax regulations that are applicable to us.

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 in the future, and then the market price of our ordinary shares, may also be adversely affected.

PRC regulation and oversight of loans to and direct investment in PRC entities by offshore holding companies and governmental control of currency conversion may delay or prevent us from using the proceeds of our IPO to make loans or additional capital contributions to our PRC subsidiaries in China, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

We are an offshore holding company conducting our operations in Taiwan through our Taiwan subsidiaries. We currently have one subsidiary in China, namely Innovative Biotech Co., Ltd., which has no operations and generates no revenue as of the date of this annual report. In the event that we elect to expand our operations into China in the future, we may make loans to our PRC subsidiary, or we may make additional capital contributions to our PRC subsidiary, or we may establish new PRC subsidiaries and make capital contributions to these new PRC subsidiaries, or we may acquire offshore entities with business operations in China in an offshore transaction.

Most of these ways are subject to PRC regulations and approvals or registration. For example, loans by us to our wholly owned PRC subsidiary to finance its activities cannot exceed statutory limits and must be registered with the local counterpart of SAFE. If we decide to finance our wholly owned PRC subsidiary by means of capital contributions, these capital contributions are subject to registration with the State Administration for Market Regulation or its local branch, reporting of foreign investment information with the PRC Ministry of Commerce, or registration with other governmental authorities in China.

SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming the Administration of Foreign Exchange Settlement of Capital of Foreign-invested Enterprises, or SAFE Circular 19, effective June 2015, in replacement of the Circular on the Relevant Operating Issues Concerning the Improvement of the Administration of the Payment and Settlement of Foreign Currency Capital of Foreign-Invested Enterprises, the Notice from the State Administration of Foreign Exchange on Relevant Issues Concerning Strengthening the Administration of Foreign Exchange Businesses, and the Circular on Further Clarification and Regulation of the Issues Concerning the Administration of Certain Capital Account Foreign Exchange Businesses. According to SAFE Circular 19, the flow and use of the RMB capital converted from foreign currency-denominated registered capital of a foreign-invested company is regulated such that RMB capital may not be used for the issuance of RMB entrusted loans, the repayment of inter-enterprise loans or the repayment of banks loans that have been transferred to a third party. Although SAFE Circular 19 allows RMB capital converted from foreign currency-denominated registered capital of a foreign-invested enterprise to be used for equity investments within China, it also reiterates the principle that RMB converted from the foreign currency-denominated capital of a foreign-invested company may not be directly or indirectly used for purposes beyond its business scope. Thus, it is unclear whether SAFE will permit such capital to be used for equity investments in China in actual practice. SAFE promulgated the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account, or SAFE Circular 16, effective on June 9, 2016, which reiterates some of the rules set forth in SAFE Circular 19, but changes the prohibition against using RMB capital converted from foreign currency denominated registered capital of a foreign-invested company to issue RMB entrusted loans to a prohibition against using such capital to issue loans to non-associated enterprises. Violations of SAFE Circular 19 and SAFE Circular 16 could result in administrative penalties. SAFE Circular 19 and SAFE Circular 16 may significantly limit our ability to transfer any foreign currency we hold, including the net proceeds from our IPO, to our PRC subsidiary, which may adversely affect our liquidity and our ability to fund and expand our business in China. On October 23, 2019, the SAFE promulgated the Notice for Further Advancing the Facilitation of Cross-border Trade and Investment, or the SAFE Circular 28, which, among other things, allows all foreign-invested companies to use Renminbi converted from foreign currency-denominated capital for equity investments in China, as long as the equity investment is genuine, does not violate applicable laws, and complies with the negative list on foreign investment. However, since the SAFE Circular 28 is newly promulgated, it is unclear how SAFE and competent banks will carry this out in practice.

In light of the various requirements imposed by PRC regulations on loans to and direct investment in PRC entities by offshore holding companies, we cannot assure you that we will be able to complete the necessary government registrations or obtain the necessary government approvals on a timely basis, or at all, with respect to future loans to our PRC subsidiary or future capital contributions by us to our PRC subsidiary. As a result, uncertainties exist as to our ability to provide prompt financial support to our PRC subsidiary when needed. If we fail to complete such registrations or obtain such approvals, our ability to use the proceeds we expect to receive from our IPO and to capitalize or otherwise fund our PRC operations may be negatively affected, which could materially and adversely affect our liquidity and our ability to fund and expand our business.

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

As we rely on third parties to conduct our clinical trials and provide other important services related to research and development, regulatory submissions, and commercialization, if we fail to maintain our relationships with these third parties or if they do not successfully carry out their contractual duties, comply with applicable laws, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business could be substantially harmed.

We have relied on and plan to continue to rely on third-party CROs to monitor and manage data for some of our ongoing clinical trials. We rely on these parties for the execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Our CROs have the right to terminate their agreements with us in the event of an unrectified material breach. If any of our relationships with our third-party CROs is terminated, we may not be able to (i) enter into arrangements with alternative CROs or do so on commercially reasonable terms or (ii) meet our desired clinical development timelines. In addition, there is a natural transition period when a new CRO commences work, and the new CRO may not provide the same type or level of services as the original provider and data from our clinical trials may be compromised as a result. There is also a need for relevant technology to be transferred to the new CRO, which may take time and further delay our development timelines.

Except for remedies available to us under our agreements with our CROs, we cannot control whether or not our CROs devote sufficient time and resources to our ongoing clinical, nonclinical and preclinical studies. If our CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, the impacts of any pandemic on their operations, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our results of operations and the commercial prospects for our drug candidates would be harmed and our costs could increase. In turn, our ability to generate revenues could be delayed or compromised.

We cannot guarantee that third parties perform duties complying with our standards or produce results in a timely manner. They may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these third parties, which could increase the risk that such information will be misappropriated. We currently have a limited number of employees, which limits the internal resources we have available to identify and monitor our third-party service providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future, and such challenges or delays could have a material adverse impact on our business, financial condition and prospects.

As we rely on third parties to conduct our preclinical studies and clinical trials, our business could be harmed if those third parties fail to comply with the applicable regulatory requirements.

We and our CROs are required to comply with cGCPs, cGLPs, and other regulatory regulations and guidelines enforced by the TFDA, the U.S. FDA, the International Conference on Harmonization, or ICH, and comparable foreign regulatory authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these cGCPs, cGLPs or other regulatory requirements through periodic inspections of study sponsors, investigators and study sites. If we or any of our CROs fail to comply with applicable cGCPs, cGLPs or other regulatory requirements, the relevant data generated in our preclinical studies and clinical trials may be deemed unreliable and the TFDA, the U.S. FDA or other comparable regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. There can be no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCPs requirements. In addition, our clinical trials must be conducted with drug candidates or products produced under governmental requirements. Failure to comply with these regulations may require us to repeat preclinical studies and clinical trials, which would delay the regulatory approval process.

We are highly dependent on third parties to supply the drug raw materials, such as API, for our developing and manufacturing activities, and the lack of availability or significant increases in cost of such drug raw materials could adversely influence our business.

The development and manufacture of drug products are complex and require significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Currently, our drug raw materials for our developing and manufacturing activities are supplied by multi-source suppliers. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted or if the costs of such drug materials were to significantly increase, our business would be materially harmed. For example, the COVID-19 pandemic, the monkeypox outbreak, geopolitical risk, wars and military conflicts could have an extensive impact on the production and supplies of active ingredients or other raw materials and result in a potential shortage of supply.

As mentioned elsewhere in this annual report, our API-1 supplier withdrew their consent to reference their Drug Master File on file with the U.S. FDA due to the relocation and restructuring of their manufacturing facility. The API-1 we used to perform our clinical trials of Botreso® is now unavailable to us, causing delays and additional expenses in the development of our drug candidates. As disclosed in "Item 14. Material Modifications to the Right of Security Holders and Use of Proceeds", approximately US$6 million have been allocated to fund the additional R&D, CMC, and Phase III trials of Botreso® using API-2. The estimated time for completing the Phase III trials of Botreso® using API-2 is approximately 1 to 2 years, depending on the processing and approval time from the U.S. FDA.

We have been conducting further research and development on Botreso® and identified an additional source for the botanical drug substance API-2. API-1 and API-2 are similar drug substances covered by the same patent owned by us; however, because they are sourced from raw materials manufactured in different locations, the U.S. FDA considers them to be different botanical drug substances. Therefore, we will conduct comparability study for API-1 and API-2. On June 26, 2023, the U.S. FDA informed us that the information we provided on API-2 was not sufficient to demonstrate comparability with API-1. In addition to current unavailability of API-1, the U.S. FDA explained that we had not demonstrated a statistically significant difference between Botreso® with API-1 and placebo in the primary efficacy endpoint in the MCS-2-US-a study. The U.S. FDA stated that without new clinical information, any resubmission of the NDA for Botreso® would be at risk of the U.S. FDA refusing to accept the application, a RTF action. We submitted a Type D WRO meeting request to the U.S. FDA on December 12, 2023. We asked that the U.S. FDA provide a written response to questions focused on obtaining U.S. FDA review and comments on a new, proposed Phase III clinical trial protocol for Botreso® with API-2 and a PK study. We proposed to address CMC information for Botreso® in a separate, future meeting. The U.S. FDA granted our WRO meeting request, and clarified that they viewed the meeting as a Type C meeting because it encompasses an entirely new drug development program, including Phase I PK study and Phase III clinical trial for Botreso® made from API-2, which the U.S. FDA characterizes as a new product with a new active pharmaceutical ingredient. We plan to schedule a special CMC meeting with the U.S. FDA in 2024 to discuss API-2, providing comprehensive CMC information for U.S. FDA review and comments. We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2 and submitted it to the U.S. FDA on October 16, 2024, and are awaiting feedback from the U.S. FDA. This process does not indicate a "shortage" of API-2. As of the date of this annual report, the Company is still in the process of providing the information required by the U.S. FDA and has not yet successfully demonstrated the comparability of API-1 and API-2. If the U.S. FDA confirms that API-1 and API-2 are comparable and deems the study results using API-2 acceptable, we will proceed to re-submit our NDA.

However, if we experience a shortage in supply of active ingredients or other raw materials, including API-2, whether due to the aforementioned factors or otherwise, we could not supply adequate levels of our drug candidates. Identifying a suitable replacement and demonstrating its equivalence to API-2 could require extensive research and development efforts, potentially leading to additional costs and delays. Additionally, substituting the original ingredient with an alternative substance may necessitate conducting further clinical trials to assess the safety and efficacy of such new material. These additional trials could prolong the time to market for our products and increase regulatory scrutiny, further impacting our business operations and financial performance.

We expect to seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

We may form or seek strategic alliances, create collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our drug candidates and any future drug candidates that we may develop. Any of these relationships may require us to incur recurring or non-recurring expenses and other charges, increase our near and long-term expenditures, 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 collaboration or other alternative arrangements for our drug 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 drug candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for the development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party.

Further, collaborations involving our drug candidates are subject to additional risks, which include, but are not limited to, the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue the development and commercialization of our drug candidates or may elect not to continue or renew the development or commercialization programs based on clinical trial results, change in their strategic focus due to the acquisition of competitive drugs, increased competition, availability of funding, or other external factors;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, discontinue a clinical trial, repeat or conduct new clinical trials, or require a new formulation of a drug candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drug candidates or future drugs;
- collaborators with marketing and distribution rights to one or more of our drug candidates or future 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;
- collaborators may not always be cooperative or responsive in providing their services in a clinical trial;
- disputes may arise between us and a collaborator that cause a delay or termination of the research, development or commercialization of our drug candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable drug candidates;
- collaborators may self-own intellectual property covering our drug candidates or future drugs that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property; and
- we may not be able to receive agreed development fees, royalties or milestone payments we expected when seeking collaborations.

As a result, if we enter into collaboration agreements or license our drugs, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate these collaborations or licenses with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our drug candidates or bring them to market and generate product sales revenue, which would harm our business, financial condition, results of operations and prospects.

Negotiations of collaborations are complex and time-consuming, and we may not able to find suitable collaborators and enter into agreements with them.

Any collaboration agreements that we enter into in the future may contain restrictions on our ability cooperate with other potential collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the drug candidate for which we are seeking to collaborate, 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.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to obtain and maintain patent and other intellectual property protection for our drug candidates, or if the scope of such intellectual property rights obtained is not sufficiently broad, third parties could develop and commercialize products and technologies similar or identical to ours and compete directly against us, and our ability to successfully commercialize any product or technology may be adversely affected.

Our success depends, in large part, on our ability to protect our proprietary technology and drug candidates from competition by obtaining, maintaining, defending and enforcing our intellectual property rights, including patent rights. As of the date of this annual report, our portfolio of self-own patents consisted of 29 issued patents in 16 countries and regions. We seek to protect and intend to seek to protect the drug candidates and technology that we consider commercially important by filing patent applications globally, relying on trade secrets or pharmaceutical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in all jurisdictions at a reasonable cost or 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.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our self-own pending and future patent applications may not result in patents being issued which protect our technology or drug candidates or which effectively prevent others from commercializing competitive technologies and drug candidates. The patent examination process may require us to narrow the scope of the claims of self-own pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure that all of the potentially relevant prior art relating to our self-own patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent application from being issued as a patent.

Even if patents do issue on any of these applications, there can be no assurance that a third party will not challenge their validity, enforceability, or scope, which may result in the patent claims being narrowed or invalidated, or that we will obtain sufficient claim scope in those patents to prevent a third party from competing successfully with our drug candidates. We may become involved in interference, *inter partes* review, post grant review, *ex parte* re-examination, derivation, opposition or similar other proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drug candidates and compete directly with us, or result in our inability to manufacture or commercialize drug candidates without infringing third-party patent rights. Thus, even if our self-own 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 self-own patents by developing similar or alternative technologies or drug candidates in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our self-own patents may be challenged in the courts or patent offices in the U.S., Taiwan and other countries. 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 drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such assets might expire before or shortly after such assets are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drug candidates similar or identical to ours.

Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our self-own patents or narrow the scope of our patent protection. For instance, under the America Invents Act enacted in 2011, the U.S. moved to this first-to-file system in early 2013 from the previous system under which the first to make the claimed invention was entitled to the patent. Assuming the other requirements for patentability are met, the first to file a patent application is entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our self-own patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

We enjoy only limited geographical protection with respect to certain patents and may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our drug candidates in all countries throughout the world could be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drug candidates and, further, may export otherwise infringing drug candidates to territories, where we have patent protection, but enforcement rights are not as strong as those in the U.S. These drug candidates may compete with our drug candidates, and our self-own patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the U.S., and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, are not as favorable as other jurisdictions with regard to the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our self-own patents or marketing of competing drug candidates in violation of our proprietary rights generally and specifically in certain jurisdictions. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our self-own patent applications at risk of not issuing as patents, and could provoke third parties to assert claims 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. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our drug candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our drug candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend and could require us to pay substantial damages, cease the sale of certain drugs or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all).

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to government patent agencies over the lifetime of our owned or licensed patents and applications. In certain circumstances, we rely on our licensing partners to pay these fees due to patent agencies. The government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Terms of our future self-own patents may not be sufficient to effectively protect our drug candidates and business in certain jurisdictions.

In many countries where we file applications for patents, 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 are limited. Even if we obtain patents covering our drug candidates, we may still be open to competition from other companies, as well as generic medications once the patent life has expired for a drug. For example, while there are patent regulations in the PRC in respect of regulatory data protection of new drugs containing new chemical components, there are currently no other clear mechanisms providing patent term extension or patent linkages for other drugs in the PRC. Therefore, it is possible that a lower-cost generic drug can emerge onto the market much more quickly. For additional information regarding potential generic competition for our products in China, see " — The uncertainty of patent linkage, patent term extension and data and market exclusivity for our future drug products could increase the risk of early generic competition with our products in our primary sales markets." These factors may result in weaker protection for us against generic competition in jurisdictions similar to the PRC than could be available to us in other jurisdictions, such as the U.S. In addition, patents which we expect to obtain in the PRC or similar jurisdictions may not be eligible to be extended for patent terms lost during clinical trials and the regulatory review process.

If we are unable to obtain patent term extensions or if such extensions are less than requested for, our competitors may obtain approval of competing products following our patent expirations and our business, financial condition, results of operations and prospects could be materially harmed as a result.

If the TFDA, the U.S. FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of data exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the drug candidate covered thereby becomes a "reference-listed drug" in the U.S. FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book. Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the U.S. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredients, dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug may be typically lost to the generic product.

Competition that our products may face from generic versions of our products could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those drug candidates.

The uncertainty of patent linkage, patent term extension and data and market exclusivity for our future drug products could increase the risk of early generic competition with our products in our primary sales markets.

In the U.S., the Federal Food, Drug and Cosmetic Act, as amended by the Drug Price Competition and Patent Term Restoration Act, or the Hatch-Waxman Act, provides the opportunity for patent-term restoration, meaning a patent term extension of up to five years to reflect patent term lost during certain portions of product development and the U.S. FDA regulatory review process. The Hatch-Waxman Act also has a process for patent linkage, pursuant to which the U.S. FDA will stay approval of certain follow-on applications during the pendency of litigation between the follow-on applicant and the patent holder or licensee, generally for a period of 30 months. Finally, the Hatch-Waxman Act provides for statutory exclusivities that can prevent submission or approval of certain follow-on marketing applications. For example, federal law provides a five-year period of exclusivity within the U.S. to the first applicant to obtain approval of a new chemical entity and three years of exclusivity protecting certain innovations to previously approved active ingredients where the applicant was required to conduct new clinical investigations to obtain approval for the modification. These provisions, designed to promote innovation, can prevent competing products from entering the market for a certain period of time after the U.S. FDA grants marketing approval for the innovative product.

Depending upon the timing, duration and specifics of any U.S. FDA marketing approval process for any drug candidates we may develop, one or more of our self-own U.S. patents, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent extension term of up to five years as compensation for patent term lost during clinical trials and the U.S. FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of drug approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. The application for patent term extension is subject to approval by the U.S. Patent and Trademark Office, or USPTO, in conjunction with the U.S. FDA. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Furthermore, 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 and adversely affected.

In Taiwan, the Patent Act grants the patent holder of drugs for human purposes the right to extend the patent term. Pursuant to the Patent Act, the patent term might be extended up to five years to reflect patent term lost during the clinical trial process and the Taiwan FDA regulatory review process. In addition, the Patent Act and the Pharmaceutical Affairs Act also provide the patent linkage process. As Taiwan adopts a double-track examination system in terms of patent prosecution, including the examination of Taiwan Intellectual Property Office ("TIPO") and the examination of the court, under the patent linkage process, the Taiwan FDA will stay approval of certain follow-on applications during the pendency of the invalidation action and the pendency of litigation between the follow-on applicant and the patent holder or licensee. The pendency of such litigation generally lasts for a period of 12-14 months. Finally, the Pharmaceutical Affairs Act provides a five-year period of exclusivity to the first applicant to exclusively hold the drug permit and a three-year period of exclusivity to restrict other pharmaceutical firms who may apply for registration of the same drug from citing the application data submitted by the first applicant.

For those drug candidates we may develop, one or more of our self-own Taiwan patents, if issued, may be eligible for limited patent term extension under the Patent Act. The Patent Act provides that only one patent may be extended. The application for patent term extension is subject to approval by TIPO, in conjunction with the Taiwan FDA. While the Patent Act explicitly provides that TIPO and the Taiwan FDA should take into consideration the impact on public health, we may not be granted the extension because of the authorities' discretion. In addition, if we fail to apply within applicable deadlines, fail to apply prior to the expiration of relevant patents, or otherwise fail to satisfy applicable requirements, we may not be granted the extension as well.

The Patent Act also provides that the extension term is restricted to be five years as a maximum, implying that we may be granted a shorter extension period than we request. Furthermore, pursuant to the Patent Act, any person may file an invalidation action of the granted patent term extension to the authorities, together with documents of proof. If anyone files such invalidation action with respect to our patents, the permit of the extension period may be withdrawn by TIPO.

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, or our extension permit is withdrawn by TIPO, our competitors may compete with us in an earlier stage, and our ability to generate revenues could be materially and adversely affected.

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

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patent rights. Obtaining and enforcing patents in the pharmaceutical market involves both technological and legal complexity, and is therefore costly, time-consuming, and inherently uncertain. For instance, the America Invents Act includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation, which could increase the uncertainties and costs surrounding the prosecution of our owned, co-owned and in-licensed patent applications and the enforcement or defense of patents issuing from those patent applications, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Although we do not believe that our currently self-own patents and any patents that may issue from our pending patent applications directed to our drug candidates, if issued in their currently pending forms, will be found invalid, we cannot predict how relevant regulatory authorities' future decisions 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.

We also may be subject to claims that our employees, consultants, or advisers have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants, and advisers, including our senior management, were previously employed at or contracted by other biotechnology or pharmaceutical companies. Some of these employees, consultants, and advisers, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees, consultants or advisors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual'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 advisors 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, and furthermore, the assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, each of 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, be a distraction to our management and scientific personnel and have a material adverse effect on our business, financial condition, results of operations and prospects.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our therapeutic programs and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation may lead to unfavorable publicity which may harm our reputation and any unfavorable outcome from such litigation could limit our research and development activities and/or our ability to commercialize our drug candidates.

During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our drug candidates, future drugs, programs or intellectual property could be diminished. Such announcements could also harm our reputation or the market for our drug candidates, which could have a material adverse effect on our business.

In the event of intellectual property litigation, there can be no assurance that we would prevail, even if the case against us is weak or flawed. If third parties successfully assert their intellectual property rights against us, prohibitions against using certain technologies, or prohibitions against commercializing our drug candidates, could be imposed by a court or by a settlement agreement between us and a plaintiff. In addition, if we are unsuccessful in defending against allegations that we have infringed, misappropriated or otherwise violated the patent or other intellectual property rights of others, we may be forced to pay substantial damage awards to the plaintiff. It is possible that the necessary license will not be available to us on commercially acceptable terms, or at all. This may not be technically or commercially feasible, may render our products less competitive, or may delay or prevent the launch of our products to the market. Any of the foregoing could limit our research and development activities, our ability to commercialize one or more drug candidates, or both.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex intellectual property litigation longer than we could. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our clinical trials, continue our internal research activities, in-license needed technology in the future, or enter into strategic collaborations that would help us bring our drug candidates to market.

In addition, any future intellectual property litigation, interference or other administrative proceedings will result in additional expense and distraction of our personnel. An adverse outcome in such litigation or proceedings may expose us or any future strategic partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms, if at all, each of which could have a material adverse effect on our business.

Claims that our drug candidates or the sale or use of our future products infringe, misappropriate or otherwise violate the patents or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

We cannot guarantee that our drug candidates or the sale or use of our future products do not and will not in the future infringe, misappropriate or otherwise violate third-party patents or other intellectual property rights. Third parties might allege that we are infringing their patent rights or that we have misappropriated their trade secrets, or that we are otherwise violating their intellectual property rights, whether with respect to the manner in which we have conducted our research, or with respect to the use or manufacture of the compounds we have developed or are developing. The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. Some claimants may have substantially greater resources than we have and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. Third parties might resort to litigation against us or other parties we have agreed to indemnify, which litigation could be based on either existing intellectual property or intellectual property that arises in the future.

It is also possible that we failed to identify, or may in the future fail to identify, relevant patents or patent applications held by third parties that cover our drug candidates. Publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications on, our drug candidates or for their uses, or that our drug candidates will not infringe patents that are currently issued or that are issued in the future. In the event that a third party has also filed a patent application covering one of our drug candidates or a similar invention, our self-own patent application may be regarded as a competing application and may not be issued in the end. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products or their use.

If a third party were to assert claims of patent infringement against us, even if we believe such third-party claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention, or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In addition, defending such claims would cause us to incur substantial expenses and could cause us to pay substantial damages, if we are found to be infringing a third party's patent rights. These damages potentially include increased damages and attorneys' fees if we are found to have infringed such rights willfully. In order to avoid or settle potential claims with respect to any patent or other intellectual property rights of third parties, we may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both, which could be substantial. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a drug candidate, or be forced, by court order or otherwise, to modify or cease some or all aspects of our business operations, if, as a result of actual or threatened patent or other intellectual property claims, we are unable to enter into licenses on acceptable terms. Further, we could be found liable for significant monetary damages as a result of claims of intellectual property infringement.

Defending against claims of patent infringement, misappropriation of trade secrets or other violations of intellectual property rights is likely to be costly and time-consuming, regardless of the outcome. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Thus, even if we were to ultimately prevail or settle at an early stage, such litigation could burden us with substantial unanticipated losses. Any claims of infringement, misappropriation or other violation of intellectual property made against us could have a material adverse effect on our business, financial condition, results of operations and prospects.

Issued patents covering one or more of our drug candidates could be found invalid or unenforceable if challenged in court.

Despite measures we take to obtain and maintain patent and other intellectual property rights with respect to our drug candidates, our intellectual property rights could be challenged or invalidated. For example, if we were to initiate legal proceedings against a third party to enforce a patent covering one of our drug candidates, the defendant could counterclaim that our self-own patent is invalid and/or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, non-enablement, lack of sufficient written description or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, the State Intellectual Property Office, or the SIPO, or the applicable foreign counterpart, or made a misleading statement, during prosecution. Although we believe that we have conducted our patent prosecution in accordance with a duty of candor and in good faith, the outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on a drug candidate. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our self-own patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. In addition, if the breadth or strength of protection provided by our self-own patents is threatened, it could dissuade companies from collaborating with us to license, develop, or commercialize our current or future drug candidates. Any loss of patent protection could have a material adverse impact on one or more of our drug candidates and 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 personnel 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 our stock price. 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 conduct such litigation or proceedings adequately. 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 and more mature and developed intellectual property portfolios. 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. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our competitive position may be adversely affected.

As of the date of this annual report, we had 58 registered trademarks in 46 territories. We may not be able to obtain trademark protection in territories that we consider of significant importance to us. In addition, any of our trademarks or trade names, whether registered or unregistered, may be challenged, opposed, infringed, cancelled, circumvented or declared generic, or determined to be infringing on other marks, as applicable. We may not be able to protect our rights to these trademarks and trade names, which we will need to build name recognition by potential collaborators or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish any of our drug candidates that are approved for marketing from the products of our competitors. Once we select trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

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

In addition to patents, we rely upon unpatented trade secrets, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect this trade secret and confidential information, in part, by entering into non-disclosure and confidentiality agreements with parties that have access to them, such as our employees, collaborators, CROs, consultants 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 or other third party, 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. In addition, we face the risk of cybercrime. For instance, someone could hack our information networks and gain illicit access to our proprietary information, including our trade secrets. Even if we are successful in prosecuting such claims, any remedy awarded may be insufficient to fully compensate us for the improper disclosure or misappropriation.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. For instance:

- our competitors may be able to make compounds that are similar to our drug candidates but that are not covered by the claims of our self-own patents;
- we might not have been the first to make the inventions covered by the issued patents or pending patent applications that we self-own, which could result in the patents applied for not being issued or being invalidated after issuing;
- we might not have been the first to file patent applications covering certain of our inventions, which could result in the patents applied for not being issued or being invalidated after issuing;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending and future self-own patent applications will not lead to issued patents;
- issued self-own patents may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors or other third parties;
- we may obtain patents for certain compounds many years before we receive regulatory approval for drugs containing such compounds, and because patents have a limited life, which may begin to run out prior to the commercial sale of the related drugs, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive drugs for commercialization in our major markets;
- we may fail to develop additional proprietary technologies that are patentable;
- we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we plan to sell our drug products;
- third parties may gain unauthorized access to our intellectual property due to potential lapses in our information systems;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may discover certain technologies containing such trade secrets or know-how through independent research and development and/or subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

RISKS RELATED TO OUR ORDINARY SHARES

An active trading market for our ordinary shares may not be sustained.

Our ordinary shares have been listed on Nasdaq only since June 17, 2025, and we cannot assure you that an active trading market for our ordinary shares will be sustained or maintained. The lack of an active trading market may impair the value of your shares and your ability to sell your shares at the time you wish to sell them. An inactive trading market may also impair our ability to raise capital by selling our ordinary shares and entering into strategic partnerships or acquiring other complementary products, technologies or businesses by using our ordinary shares as consideration. In addition, if we fail to satisfy exchange listing standards, we could be delisted, which would have a negative effect on the price of our ordinary shares.

The trading price of our ordinary shares may continue to be volatile, which could result in substantial losses to investors.

The price of our ordinary shares have fluctuated substantially since our IPO. As a relatively small-capitalization company with relatively small public float, we may experience greater stock price volatility, extreme price run-ups, lower trading volume and less liquidity than large-capitalization companies. Such volatility, including any stock-run up, may be unrelated to our actual or expected operating performance, financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our ordinary shares.

Moreover, the volatility and fluctuation of the trading price of our ordinary shares may happen because of broad market and industry factors, like the performance and fluctuation of the market prices of other companies with business operations located mainly in Taiwan that have listed their securities in the U.S. A number of Taiwan companies have listed or are in the process of listing their securities on U.S. stock markets. The securities of some of these companies have experienced significant volatility, including price declines in connection with their initial public offerings. The trading performances of these Taiwan companies' securities after their offerings may affect the attitudes of investors toward Taiwan companies listed in the U.S. in general and consequently may impact the trading performance of our ordinary shares, regardless of our actual operating performance.

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

- variations in our income, earnings and cash flow;
- announcements of new investments, acquisitions, strategic partnerships or joint ventures by us or our competitors;
- announcements of new services and expansions by us or our competitors;
- changes in financial estimates by securities analysts;
- detrimental adverse publicity about us, our services or our industry;
- additions or departures of key personnel;
- release of lock-up or other transfer restrictions on our outstanding equity securities or sales of additional equity securities; and
- potential litigation or regulatory investigations.

Any of these factors may result in large and sudden changes in the volume and price at which our ordinary shares trade. Furthermore, the stock market in general experiences price and volume fluctuations that are often unrelated or disproportionate to the operating performance of companies like us. These broad market and industry fluctuations may adversely affect the market price of our ordinary shares.

In addition, if the trading volumes of our ordinary shares are low, persons buying or selling in relatively small quantities may easily influence prices of our ordinary shares. This low volume of trades could also cause the price of our ordinary shares to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our ordinary shares may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low volume trading. If high spreads between the bid and asked prices of our ordinary shares exist at the time of purchase, the stock would have to appreciate substantially on a relative percentage basis for an investor to recoup their investment. Broad market fluctuations and general economic and political conditions may also adversely affect the market price of our ordinary shares. As a result of this volatility, investors may experience losses on their investment in our ordinary shares. A decline in the market price of our ordinary shares also could adversely affect our ability to issue additional ordinary shares or other of our securities and our ability to obtain additional financing in the future. No assurance can be given that an active market in our ordinary shares will develop or be sustained. If an active market does not develop, holders of our ordinary shares may be unable to readily sell the shares they hold or may not be able to sell their shares at all.

In the past, shareholders of public companies have often brought securities class action suits against those companies following periods of instability in the market price of their securities. If we were involved in a class action suit, it could divert a significant amount of our management's attention and other resources from our business and operations and require us to incur significant expenses to defend the suit, which could harm our results of operations. Any such class action suit, whether or not successful, could harm our reputation and restrict our ability to raise capital in the future. In addition, if a claim is successfully made against us, we may be required to pay significant damages, which could have a material adverse effect on our financial condition and results of operations.

If securities or industry analysts do not publish research or reports about our business, or if they adversely change their recommendations regarding our ordinary shares, the market price for our ordinary shares and trading volume could decline.

The trading market for our ordinary shares may be influenced by research or reports that industry or securities analysts publish about our business. If one or more analysts who cover us downgrade our ordinary shares, the market price for our ordinary shares would likely decline. If one or more of these analysts cease to cover us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the market price or trading volume for our ordinary shares to decline.

We have broad discretion to determine how to use the net proceeds from our IPO and may use them in ways that may not enhance our results of operations or the price of the ordinary shares.

We initially intended to primarily use our net proceeds from our IPO for researching and developing new drugs and clinical trials. However, as of the date of this annual report, we have used US$15,000 thousand for a loan to Linkage Gladden Enterprise Ltd., and US$2,495 thousand towards researching and developing new drugs and clinical trials, with the remaining funds used for general corporate purposes. Our management has broad discretion over the use of net proceeds from our IPO, and we could spend the net proceeds from our IPO in ways the holders of the ordinary shares may not agree with or that do not yield a favorable return. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. You will not have the opportunity, as part of your investment decision, to assess whether the net proceeds from our IPO are being used appropriately. You must rely on the judgment of our management regarding the application of the net proceeds of our IPO.

The sale or availability for sale of substantial amounts of our ordinary shares could adversely affect their market price.

Sales of substantial amounts of our ordinary shares in the public market, or the perception that these sales could occur, could adversely affect the market price of our ordinary shares and could materially impair our ability to raise capital through equity offerings in the future. The ordinary shares sold in our IPO are freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, and shares held by our existing shareholders may also be sold in the public market in the future subject to the restrictions in Rule 144 and Rule 701 under the Securities Act and the applicable lock-up agreements. There were 76,027,667 ordinary shares outstanding immediately after our IPO. In connection with our IPO, our directors and officers and holders of more than 5% of our outstanding shares as of the effective date of this registration statement entered into customary lock-up agreements in favor of the underwriters for a period of twelve (12) months from the date of our IPO. Most of our holders of less than 5% of our outstanding shares as of the effective date of the registration statement entered into customary lock-up agreements in favor of the underwriters for a period of six (6) months from the closing of our IPO, which expired in December 2025. Additionally, ordinary shares held by Taizhou City Optimization and Upgrade Investment Partnership (Limited Partnership) are subject to lock-up for five (5) years from the closing date of our IPO. We have agreed with the underwriters that, for a period of twelve (12) months from the closing of our IPO, we and any successors of us will not (a) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of us or any securities convertible into or exercisable or exchangeable for shares of capital stock of us; (b) file or caused to be filed any registration statement with the SEC relating to the offering of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock; or (c) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our capital stock, whether any such transaction described in clause (a), (b) or (c) above is to be settled by delivery of shares of our capital stock or such other securities, in cash or otherwise. However, the underwriters may release these securities from these restrictions at any time, subject to applicable regulations of the Financial Industry Regulatory Authority, Inc. In December 2025, following the expiration of the lock-up agreements signed by our shareholders holding less than 5%, the price of our ordinary shares experienced substantial decrease. We cannot predict what effect, if any, the expiration of the other lock-up agreement or market sales of securities held by our significant shareholders or any other shareholder or the availability of these securities for future sale will have on the market price of our ordinary shares.

Because we do not expect to pay dividends in the foreseeable future after our IPO, you must rely on price appreciation of our ordinary shares for return on your investment.

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 complete discretion as to whether to distribute dividends. Even if our board of directors decides to declare and pay dividends, the timing, amount and form of future dividends, if any, will depend on, among other things, our future results of operations and cash flow, our capital requirements and surplus, the amount of distributions, if any, received by us from our subsidiary, 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 our ordinary shares. There is no guarantee that our ordinary shares will appreciate in value after our IPO or even maintain the price at which you purchased the ordinary shares. You may not realize a return on your investment in our ordinary shares and you may even lose your entire investment in our ordinary shares.

There can be no assurance that we will not be a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for any taxable year, which could subject U.S. investors in our ordinary shares or ordinary shares to significant adverse U.S. federal income tax consequences.

We will be classified as a passive foreign investment company, or PFIC, for United States federal income tax purposes for any taxable year if either (a) 75% or more of our gross income for such year consists of certain types of "passive" income or (b) 50% or more of the value of our assets (generally determined on the basis of a quarterly average) during such year produce or are held for the production of passive income (the "asset test"). We will be treated as owning our proportionate share of the assets and earnings of any other corporation in which we own, directly or indirectly, more than 25% (by value) of the stock. Based upon our income and assets during the 2025 taxable year, including goodwill and other unbooked intangibles not reflected on our balance sheet (taking into account the proceeds from our IPO) and projections as to the market price of our ordinary shares immediately following our IPO, we were not classified as a PFIC for the 2025 taxable year.

Although for the 2025 taxable year, we were not classified as a PFIC, because the value of our assets for purposes of the asset test may be determined by reference to the market price of our ordinary shares, fluctuations in the market price of our ordinary shares may cause us to be classified as a PFIC for subsequent taxable years. The determination of whether we will be classified as a PFIC will also depend, in part, on the composition of our income and assets. In addition, the composition of our income and assets will also be affected by how, and how quickly, we use our liquid assets and the cash raised in our IPO. If we determine not to deploy significant amounts of cash for active purposes, our risk of being a PFIC may substantially increase. It is also possible that the U.S. Internal Revenue Service, or the IRS could challenge our classification of certain income and assets as non-passive, which could result in our company being or becoming a PFIC for the current or future taxable years. Because PFIC status is a factual determination made annually after the close of each taxable year, we will make this determination following the end of any particular tax year, and there can be no assurance that we will not be a PFIC for any future taxable year.

If we are a PFIC in any taxable year, a U.S. Holder (as defined in "Item 10. Additional Information—E. Taxation — U.S. Federal Income Tax Considerations") may incur significantly increased U.S. income tax on gain recognized on the sale or other disposition of the ordinary shares and on the receipt of distributions on the ordinary shares to the extent such distribution is treated as an "excess distribution" under the U.S. federal income tax rules, and such U.S. Holder may be subject to burdensome reporting requirements. Further, if we are a PFIC for any year during which a U.S. Holder holds our ordinary shares, we generally will continue to be treated as a PFIC for all succeeding years during which such U.S. Holder holds our ordinary shares, unless we were to cease to be a PFIC and the U.S. Holder were to make a "deemed sale" election with respect to the ordinary shares. For more information see "Item 10. Additional Information—E. Taxation — U.S. Federal Income Tax Considerations — PFIC Rules."

Our memorandum and articles of association contain anti-takeover provisions that could have a material adverse effect on the rights of holders of our ordinary shares.

Our second amended and restated memorandum and articles of association contain provisions to limit the ability of others to acquire control of our company or cause us to engage in change-of-control transactions. These provisions could have the effect of depriving our shareholders of an opportunity to sell their shares at a premium over prevailing market prices by discouraging third parties from seeking to obtain control of our company in a tender offer or similar transaction. Our board of directors has the authority, without further action by our shareholders, to issue preferred shares in one or more series and to fix their designations, powers, preferences, privileges, and relative participating, optional or special rights and the qualifications, limitations or restrictions, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights associated with our ordinary shares. Preferred shares could be issued quickly with terms calculated to delay or prevent a change in control of our company or make removal of management more difficult. If our board of directors decides to issue preferred shares, the price of our ordinary shares may fall and the voting and other rights of the holders of our ordinary shares may be materially and adversely affected.

You may face difficulties in protecting your interests, and your ability to protect your rights through U.S. courts may be limited, because we are incorporated under Cayman Islands law.

We are an exempted company incorporated under the laws of the Cayman Islands. Our corporate affairs are governed by our memorandum and articles of association, the Companies Act (As Revised) of the Cayman Islands and the common law of the Cayman Islands. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law 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 the common law of England, the decisions of whose courts are of persuasive authority, but are 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 laws than the U.S. Some U.S. states, 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 U.S.

Shareholders of Cayman Islands exempted companies like us have no general rights under Cayman Islands law to inspect corporate records or to obtain copies of lists of shareholders of these companies. No shareholder (other than a director of the Company) shall have any right of inspecting any accounting record or book or document of the Company except as conferred by law or authorised by the board of directors of the Company or the Company in general meeting. 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.

Certain corporate governance practices in the Cayman Islands, which is our home country, differ significantly from requirements for companies incorporated in other jurisdictions such as the U.S. Currently, we plan to rely on home country practice with respect to any corporate governance matter and, our shareholders may be afforded less protection than they otherwise would under rules and regulations applicable to U.S. domestic issuers.

As a result of all of the above, our 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 company incorporated in the U.S.

Certain judgments obtained against us by our shareholders may not be enforceable.

We are a Cayman Islands company and substantially all of our assets are located outside of the U.S. Substantially all of our current operations are conducted in Taiwan. In addition, all of our current directors and officers are nationals and residents of countries and regions other than the U.S. Substantially all of the assets of these persons are located outside 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 U.S. in the event that you believe that your rights have been infringed under the U.S. federal securities laws or otherwise. Even if you are successful in bringing an action of this kind, the laws of the Cayman Islands, Taiwan, Singapore, Hong Kong and the PRC may render you unable to enforce a judgment against our assets or the assets of our directors and officers. For more information regarding the relevant laws of the Cayman Islands, Taiwan, Singapore, Hong Kong and the PRC.

We have incurred increased costs as a result of being a public company.

As a public company, we have incurred significant legal, accounting, and other expenses that we did not incur as a private company prior to our IPO. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and the Nasdaq, impose various requirements on the corporate governance practices of public companies. Compliance with these rules and regulations has increased our legal and financial compliance costs and to make some corporate activities more time-consuming and costly. For example, operating as a public company has made it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. In addition, we have incurred additional costs associated with our public company reporting requirements.

The obligation to disclose information publicly may put us at a disadvantage to competitors that are private companies.

As a publicly listed company, we are required to file annual reports with the Securities and Exchange Commission. In some cases, we need to disclose material agreements or results of financial operations that we would not be required to disclose if we were a private company. Our competitors may have access to this information, which would otherwise be confidential. This may give them advantages in competing with our company. Similarly, as a U.S.-listed public company, we are governed by U.S. laws that some of our competitors are not required to follow. To the extent compliance with U.S. laws increases our expenses or decreases our competitiveness against such companies, our public listing could affect our results of operations.

We are a foreign private issuer within the meaning of the rules under the Exchange Act, and as such we are exempt from certain provisions applicable to United States domestic public companies.

Because we are a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the securities rules and regulations in the U.S. that are applicable to U.S. domestic issuers, including:

- the rules under the Exchange Act requiring the filing of quarterly reports on Form 10-Q or current reports on Form 8-K with the SEC;
- the sections of the Exchange Act regulating the solicitation of proxies, consents, or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the selective disclosure rules by issuers of material nonpublic information under Regulation FD.

We are required to file an annual report on Form 20-F within four months of the end of each fiscal year. In addition, under Nasdaq rules we must furnish a Form 6-K to the SEC within six months following the end of the second fiscal quarter, containing interim financial statements covering the first two fiscal quarters. . However, the information we are required to file with or furnish to the SEC is less extensive and less timely than that required to be filed with the SEC by U.S. domestic issuers. As a result, you may not be afforded the same protections or information that would be made available to you were you investing in a U.S. domestic issuer.

Because we are a foreign private issuer and are exempt from certain Nasdaq corporate governance standards applicable to U.S. issuers, you have less protection than you would have if we were a domestic issuer.

Nasdaq listing rules require listed companies to have, among other things, a majority of its board members be independent. As a foreign private issuer, however, we are permitted to, and we may follow home country practice in lieu of the above requirements, or we may choose to comply with the above requirement within one year of listing. The corporate governance practice in our home country, the Cayman Islands, does not require a majority of our board to consist of independent directors. Thus, although a director must act in the best interests of our Company, it is possible that fewer board members will be exercising independent judgment and the level of board oversight on the management of our Company may decrease as a result. Additionally, Nasdaq listing rules mandate that U.S. domestic issuers establish a compensation committee, a nominating and corporate governance committee, and an audit committee, each composed solely of independent directors. We, as a foreign private issuer, are not subject to these requirements. Nasdaq listing rules may require shareholder approval for certain corporate matters, such as requiring that shareholders be given the opportunity to vote on all equity compensation plans and material revisions to those plans, as well as certain ordinary share issuances. We intend to comply with the requirements of Nasdaq listing rules in determining whether shareholder approval is required on such matters, with regard to the requirement that a majority of our Board consists of independent directors and to appoint a nominating and corporate governance committee. We may, however, consider following home country practice in lieu of the requirements under Nasdaq listing rules with respect to certain corporate governance standards which may afford less protection to investors.

We are an emerging growth company, and the reduced disclosure requirements applicable to emerging growth companies may make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed US$1.235 billion or we issue more than US$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We have taken advantage of reduced reporting burdens in this annual report. In particular, in this annual report, we have provided only two years of audited consolidated financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our ordinary shares less attractive if we rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the trading price of our ordinary shares may be reduced or more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

If we cannot continue to satisfy the listing requirements and other rules of the Nasdaq Global Market, our securities may be delisted, which would negatively impact the price of our securities and your ability to sell them.

Our ordinary shares are listed on the Nasdaq Global Market, in order to maintain our listing on the Nasdaq Global Market, we are required to comply with certain rules of the Nasdaq Global Market, including those regarding minimum stockholders' equity, minimum share price, minimum market value of publicly held shares and various additional requirements. Even if we initially met the listing requirements and other applicable rules of the Nasdaq Global Market, we may not be able to continue to satisfy these requirements and applicable rules. If we are unable to satisfy the Nasdaq Global Market criteria for maintaining our listing, our securities could be subject to delisting.

If the Nasdaq Global Market subsequently delists our securities from trading, we could face significant consequences, including:

- a limited availability for market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our ordinary shares are a "penny stock," which would require brokers trading in our ordinary shares to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our ordinary shares;
- limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Item 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

OUR CORPORATE HISTORY

Jyong Biotech Ltd. is a Cayman Islands exempted company incorporated on January 26, 2018 and we primarily conduct our operations through our wholly owned subsidiaries in Taiwan. We commenced our commercial operations in July 2002 through Health Ever Bio-Tech Co., Ltd., which has been wholly owned by Jyong Biotech Ltd. since August 2018. In September 2019, we established Genvace Biotechnology Co., Ltd., a Taiwan subsidiary wholly owned by Health Ever Bio-Tech Co., Ltd. for the research and development of health products.

Our Hong Kong subsidiary, Top ShunXing Bio-Tech Co., Limited, was established in March 2019, with Jyong Biotech Ltd. as its sole shareholder. Top ShunXing Bio-Tech Co., Limited is a holding company and has no substantial operations in Hong Kong, except that in October 2020, all intellectual properties of Health Ever Bio-Tech Co., Ltd. were transferred to Top ShunXing Bio-Tech Co., Limited for the sake of centralized management and that in August 2019, it borrowed approximately US$ 2.3 million from third parties to invest our PRC subsidiary via capital contribution.

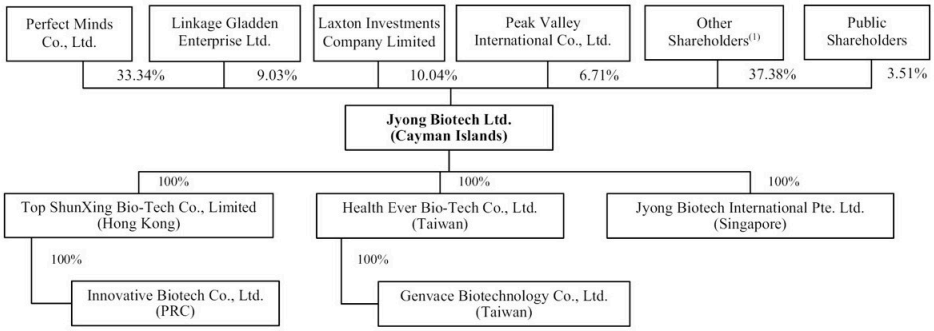
Our PRC subsidiary, Innovative Biotech Co., Ltd., was established in July 2019 pursuant to a collaboration framework agreement we entered with Taizhou Infrastructure Investment Group Co., Ltd. on December 21, 2018. In September 2019, according to an investment cooperation agreement Innovative Biotech Co., Ltd. entered with the successor of the Taizhou High-tech Industrial Park Management Committee, Innovative Biotech Co., Ltd. obtained the land use rights for a parcel of industrial land in Taizhou City, Zhejiang Province for the construction of manufacturing factory in the future. See "Item 4. Information on the Company — B. Business Overview — License and Collaboration Agreements — Taizhou Collaboration Framework Agreement" for more details. We planned to construct a manufacturing factory in 2023 and the construction is expected to be completed in October 2026. As of the date of this annual report, the construction has not yet taken place.

In September 2022, we established our Singapore subsidiary, Jyong Biotech International Pte. Ltd., with Jyong Biotech Ltd. as its sole shareholder, primarily for holding all our intellectual properties which were transferred from Top ShunXing Bio-Tech Co., Limited in January 2023.

In June 2025, we completed our IPO. In connection with our IPO, we issued and sold 2,666,667 ordinary shares, at a price to the public of $7.50 per share. As a result of the IPO, the Company received $17,771 thousand in net proceeds, after deducting underwriting discounts, commissions and offering costs.

OUR CORPORATE STRUCTURE

The following chart illustrates our corporate structure as of the date of this annual report.



(1) No single shareholder among "other shareholders" beneficially owns more than 5% of our ordinary shares.

CORPORATE INFORMATION

Jyong Biotech Ltd. was incorporated on January 26, 2018 as an exempted company limited by shares under the laws of Cayman Islands. Our registered office is located at 4th Floor, Harbour Place, 103 South Church Street, George Town, P. O. Box 10240, Grand Cayman KY1 1002, Cayman Islands.

Our principal executive offices of our operating subsidiaries are located at 23F-3, No. 95, Section 1, Xintai 5th Road, Xizhi District, New Taipei City, Taiwan, 221. Our telephone number at this address is +886-2-2732-5205.

Our agent for service of process in the United States is Cogency Global Inc. located at 122 East 42nd Street, 18th Floor, New York, NY 10168.

Investors should contact us for any inquiries through the address and telephone number of our principal executive office. Our principal website is *https://www.healtheverbiotech.com/*. The information contained on our website is not a part of this annual report.

B. Business Overview

OUR MISSION

We endeavor to develop and supply first-class innovative drugs to meet our customers' health needs. We seek to be a valuable business organization that is held in high esteem by the public.

OVERVIEW

We are a science-driven biotechnology company based in Taiwan and are committed to developing and commercializing innovative and differentiated new drugs (plant-derived) mainly specializing in the treatment of urinary system diseases, with an initial focus on the markets of the U.S., the EU and Asia.

Since our inception in 2002, we have built integrated capabilities that encompass all key functionalities of drug development, including early-stage drug discovery and development, clinical trials, regulatory affairs, manufacturing and commercialization. Leveraging our strong research and development capabilities and proprietary platform, we have been developing a series of botanical drug candidates, our primary botanical drug candidate, Botreso®, another clinical-stage botanical drug candidate, and other preclinical-stage botanical drug candidates.

We resubmitted a new drug application, or NDA, for Botreso® with the U.S. FDA on December 17, 2021, using Active Pharmaceutical Ingredient (API)-1. We voluntarily withdrew our NDA on November 30, 2022, in order to develop more information about API-2 for the U.S. FDA's review and to address ongoing questions regarding demonstrated difference between Botreso® and placebo for the primary efficacy endpoint in a clinical study for Botreso®, and to address other questions U.S. FDA had previously identified in our NDA regarding U.S. FDA's questions related to the drug substance and product, validation of methods used for measuring the effect of Botreso®, manufacturing, clinical and nonclinical testing, data, and statistical analyses, among others. In a June 26, 2023 response to our meeting request regarding refiling the NDA for Botreso® using API-2, the U.S. FDA informed us that the information we provided on API-2 was not yet sufficient to demonstrate comparability with API-1 since we only provided the preliminary comparative drug substance and drug product specifications between API-1 and API-2, and also mentioned the statistically significant difference between Botreso® and placebo in the primary efficacy endpoint in in Study MCS-2-US-a, one of our Phase III pivotal studies. The U.S.FDA's conclusions at that time were that without new clinical information, any NDA resubmission for Botreso® would be at risk of the U.S. FDA refusing to accept the application, referred to as "Refusal To File" (RTF).

We submitted a Type D WRO meeting request to the U.S. FDA on December 12, 2023. We asked that the U.S. FDA provide a written response to questions focused on obtaining U.S. FDA review and comments on a new, proposed Phase III clinical trial protocol for Botreso® with API-2 and a PK study. We proposed to address CMC data for our proposed drug product in a separate, future meeting. U.S. FDA granted our WRO meeting request but clarified that they viewed the meeting as a Type C meeting because it encompasses an entirely new drug development program, including Phase I PK study and Phase III clinical trial for a new product with a new active pharmaceutical ingredient.

If our new Phase I PK and Phase III studies are successful and after addressing other U.S.FDA-identified deficiencies summarized above, we plan to resubmit our NDA for Botreso® under the same NDA number to the U.S. FDA. The resubmission timeline is unclear at this point, depending on the comments from the U.S. FDA. Another of our clinical-stage key botanical drug candidates, PCP, has completed the phase II clinical trial in Taiwan, with data lock in May 2025 and statistical analysis completed in September 2025. Another drug candidate, IC, is under preclinical studies.

In the event that we are unable to establish comparability between API-1 and API-2, or we are unable to identify an active pharmaceutical ingredient that the FDA agrees is comparable to API-1, we will be required to repeat the Botreso® and PCP clinical trials using API-2, or to conduct other additional clinical trials as may be required by the U.S. FDA. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

We have not yet proven comparability between API-1 and API-2 and the following chart illustrates and summarizes our current drug candidates' status:

Category	Drug	Indications	Pre-clinical	Clinical			NDA	
				Phase I	Phase II	Phase III		
New Drug (plant-derived)	Botreso®	BPH/LUTS	US, TWN					Global Market
New Drug (plant-derived)	PCP	Prostate Cancer Prevention	TWN					Global Market
New Drug (plant-derived)	IC	IC/BPS	US, TWN					Global Market

Our pipeline features three innovative and differentiated new drug candidates, and we are developing them for (i) the treatment of benign prostate hyperplasia/lower urinary tract symptoms, or BPH/LUTS, (ii) prostate cancer prevention, and (iii) the treatment of interstitial cystitis, respectively.

- **Botreso®:** Botreso® is our new botanical drug candidate developed for treatment of BPH/LUTS. Botreso® is expected to be our core product in the future. Botreso® is a softgel capsule containing patented active pharmaceutical ingredients derived from botanical raw materials, specifically, *Lycopersicon Esculentum*. Botreso® contains, in the largest concentrations, five carotenoids including lycopene, phytoene, phytofluene, tocopherol and beta-carotene. We developed Botreso® using chylomicron technology to improve its bioavailability. Chylomicron is a type of lipoprotein particles consisting of triglycerides and phospholipids in human body.

  We have conducted four Phase III clinical trials for Botreso® in the U.S. and Taiwan, including two pivotal trials (one in the US and one in Taiwan) and two open-label extension studies (one in the US and one in Taiwan), using API-1. Our pivotal Phase III clinical trial for Botreso® in the U.S. failed to show a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population.

  We resubmitted an NDA for Botreso® using API-1 to the U.S. FDA on December 17, 2021. On February 22, 2022, the U.S. FDA accepted our NDA for review "with issues identified." In the February 22, 2022 Filing Issues Identified letter, the U.S. FDA identified, among other things, the lack of demonstrated difference between Botreso® and placebo for the primary efficacy endpoint in the MCS-2-US-a study. U.S. FDA identified additional issues, including issues regarding pharmacology, toxicology, and our pharmacokinetic submission, statistical analyses, and the content and format of our proposed Prescribing Information. We used one supplier for API-1, which was the basis for the NDA that has since been withdrawn by the Company. The supplier of API-1 sold a parcel of its land and is in the process of relocating and reconstructing its manufacturing facility, and as a result, API-1 is currently unavailable to us, and the supplier of API-1 withdrew its consent for us to reference their DMF on file with the U.S. FDA. This does not mean we would not be able to use API-1 in later studies or as a basis for additional filings with the U.S. FDA. The supplier's withdrawal of its consent to reference should not be interpreted as anything other than the supplier removing API-1 from availability for reference by us (or anyone else) in any submission to U.S. FDA. In a Mid-Cycle meeting and communication with the U.S. FDA on May 24, 2022, the U.S. FDA also identified the fact that API-1, the botanical drug substance used in our clinical trials and that was the basis for our NDA, was currently not available.

  Based upon these observations, we voluntarily withdrew our NDA on November 30, 2022, to develop more information about API-2 for the U.S. FDA's review, to address the U.S. FDA's concerns of a lack of demonstrated difference between Botreso® and placebo for the primary efficacy endpoint, and to resolve other issues the U.S. FDA had previously identified (and discussed above).

If we are able to satisfy U.S. FDA that API-1 and API-2 are comparable, that is if the U.S. FDA agrees with our data about the comparability between API-1 and API-2, then we may not need to conduct redundant studies using API-2. If we are unable to demonstrate comparability, we would have to perform more clinical trials. We will work with API vendors to follow FDA guidance to demonstrate comparability. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the Botreso® clinical trials using API-2. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we may be required to repeat our clinical trials for Botreso®, which could significantly delay our product development efforts and result in increased costs" on page 13.

Moreover, we are planning the CMC meeting with U.S. FDA, one purpose of which is to seek the U.S FDA's concurrence that API-2 is comparable to API-1. Those plans are no more speculative than the fact that we are engaged in an ongoing drug approval process with the U.S. FDA. It is not uncommon to maintain redundant API sources for the same finished drug to minimize the risk of shortages.

In the December 12, 2022 Acknowledge Withdrawal from the U.S. FDA, the U.S. FDA stated that "this withdrawal will not prejudice any future decisions on filing" if we decide to resubmit our NDA, and we can retain the application number (NDA 212872). The retention of the NDA number signifies the U.S. FDA's acknowledgment that they have not declined to approve NDA 212872. Instead, we voluntarily withdrew it. Retaining the application number allows U.S. FDA to review prior submissions and data when the Company resubmits in the future.

We have been conducting further research and development on Botreso® and identified an additional source for the botanical drug substance API-2. API-1 and API-2 are similar drug substances covered by the same patent owned by us; however, because they are sourced from raw materials manufactured in different locations, the U.S. FDA considers them to be different botanical drug substances. Therefore, we will conduct a comparability study for API-1 and API-2.

We submitted a meeting request to the U.S. FDA on April 14, 2023 with our very preliminary comparative specifications of API-1 and API-2, and request that the U.S. FDA provide a WRO to questions about our refiling of the NDA for Botreso® using API-2. The U.S. FDA agreed to our request and responded in writing on June 26, 2023. The U.S. FDA informed us that the information we provided on API-2 was not sufficient to demonstrate comparability with API-1. In addition to a lack of API source, U.S. FDA explained that we had not demonstrated a statistically significant difference between Botreso® with API-1 and placebo in the primary efficacy endpoint in the MCS-2-US-a study. The U.S. FDA stated that without new clinical information, any resubmission of the NDA for Botreso® would be at risk of the U.S. FDA refusing to accept the application, a RTF action.

We submitted a Type D WRO meeting request to the U.S. FDA on December 12, 2023. We asked that the U.S. FDA provide a written response to questions focused on obtaining U.S. FDA review and comments on a new, proposed Phase III clinical trial protocol for Botreso® with API-2 and a Phase I PK study. We proposed to address chemistry and manufacturing controls for Botreso® in a separate, future meeting. U.S. FDA granted our WRO meeting request but clarified that they viewed the meeting as a Type C meeting because it encompasses an entirely new drug development program, including Phase I PK study and Phase III clinical trial for Botreso® made from API-2, which the U.S. FDA characterizes as a new product with a new active pharmaceutical ingredient.

We provided its proposed additional Phase III study protocol and Phase I PK study synopsis using API-2 on December 12, 2023, for U.S. FDA to review and approve acceptability of the study design. The U.S. FDA sent us written responses on February 23, 2024, which included comments on the revisions in the Phase III protocol and asked for the SAP (statistical analysis plan) for the Phase III protocol. U.S. FDA also asked the Company to develop the protocol for the PK study from the submitted synopsis. We are following the U.S. FDA's requirements in each respect. In addition, we will need to perform studies demonstrating that the source of API-2 is sufficiently similar botanical drug substance. We plan to request a meeting with U.S. FDA to discuss the U.S. FDA's concerns regarding the CMC data separately and by providing to U.S. FDA more analytical testing for the API-2 for the U.S. FDA to assess whether API-1 and API-2 are comparable.

If our new Phase I PK and Phase III studies are successful and we address the other deficiencies the U.S. FDA has previously identified (including clinical, pharmacological, statistical, pharmaceutical manufacturing, validation, and other issues), we plan to resubmit our NDA for Botreso® under the same NDA number to the U.S. FDA. The resubmission timeline is unclear at this point, depending on the comments from the U.S. FDA.

BPH/LUTS is the most common urinary tract disease in the middle-aged male population. According to Frost & Sullivan, the global prevalence of BPH increased from 88.4 million in 2017 to 94.2 million in 2020, representing an increase of 6.5%. The global BPH drugs market increased from US$3.7 billion in 2017 to US$4.1 billion in 2020, representing a CAGR of 4.6%. We will set up internal sales and marketing departments, and plan to work with both domestic and international business partners to seize the great market opportunities and to help more patients reduce their distress caused by BPH/LUTS and drug side effects caused by chemical drugs.

- PCP: PCP is our new botanical drug candidate developed for the prevention of prostate cancer. PCP, like Botreso®, contains patented active pharmaceutical ingredients derived from botanical raw materials, specifically, *Lycopersecum Esculentum*. PCP contains, in the largest concentrations, five carotenoids including lycopene, phytoene, phytofluene, tocopherol and beta-carotene. PCP and Botreso® are essentially the same in terms of active ingredients, dosage form, strength and route of administration; however, they are different drug candidates targeting different indications. Our PCP Phase II study enrollment and treatment phase using API-1 has completed statistical analysis before drafting the clinical study report (CSR). To date, we have not had any discussions with the TFDA regarding the unavailability of API-1. We will discuss the statistical results of the PCP using API-2 with Taiwan regulator and proceed with the Phase III PCP study if the U.S. FDA accepts such results and determines that API-1 and API-2 are comparable. The PCP shall not proceed to Phase III until the U.S. FDA accepts the results and determines that API-1 and API-2 are comparable.

  We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2 and submitted it to the U.S. FDA on October 16, 2024, and are awaiting feedback from the U.S. FDA. As of the date of this annual report, the Company is still in the process of providing the information required by the U.S. FDA and has not yet successfully demonstrated the comparability of API-1 and API-2.

  We are currently collaborating with a supplier to prepare the API-2 CMC documents required by the U.S. FDA. Should the FDA concur that API-1 and API-2 are similar and comparable, we will sign the Quality Agreement with this supplier for the raw materials for API-2. If the U.S. FDA does not agree that API-1 and API-2 are comparable, we will continue to research additional API sources based on our own patent, to pursue additional outsourcing API vendors, and to follow U.S. FDA's guidance for demonstrating comparability between API-1 and API-2 to the U.S. FDA's satisfaction. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the PCP clinical trials using API-2. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

  Prostate cancer begins when cells in the prostate gland start to grow out of control. In general, the more quickly prostate cells grow and divide, the more chances there are for mutations to occur. According to Frost & Sullivan, the global prevalence of prostate cancer increased from 10.0 million in 2017 to 11.2 million in 2020, representing a CAGR of 3.9%. The global prostate cancer market increased from US$9.7 billion in 2017 to US$12.6 billion in 2019, representing a CAGR of 9.1%. In addition, the prostate-specific antigen abnormal population, or PSA abnormal population, representing men over 40 years old with a prostate-specific antigen test value of 4.0 ng/ml or higher, is exposed to a high risk of prostate cancer. From 2015 to 2020, the total number of PSA abnormal populations in the U.S., Taiwan and China increased from 5.0 million to 5.3 million.

- **IC:** Interstitial Cystitis (IC) is our additional key new drug candidate which is composed of polysorbate loaded micelles as nanocarriers which can be used in the intravenous injection and intravesical instillation. The micelles enhance the bioavailability by prolonging the duration of stay in the bladder and increase the penetration of drug across the bladder wall. IC/BPS, refers to interstitial cystitis and bladder pain symptoms that is often associated with voiding symptomatology and other systemic chronic pain disorders.

We incurred expenses in our research and development activities in the amount of approximately US$0.9 million and US$0.8 million for the years ended December 31, 2024 and 2025, respectively.

OUR STRENGTHS

We believe the following strengths have contributed to our success and differentiate us from others:

Innovative new drug (plant-derived) candidate developed for BPH/LUTS

Our core drug candidate, Botreso®, is an innovative drug we have internally developed for the treatment of BPH/LUTS.

BPH/LUTS is the most common urinary tract disease in the middle-aged male population. It is often considered a normal part of aging due to the increase in dihydrotestosterone. To date, there is no effective cure for BPH/LUTS, while the currently available drugs to control the disease are either limited in efficacy or can cause significant side effects, such as postural hypotension, dizziness, headache, fainting, general weakness, nasal congestion, rapid heartbeat, drowsiness, indigestion, abdominal pain, diarrhea, nausea, sexual dysfunction, and ejaculation difficulties. As BPH/LUTS often occurs in middle-aged male patients who usually require lifelong treatment to control the chronic disease conditions, the medical needs for safe and effective drugs are huge, which has been underserved in the long history of BPH/LUTS drug development.

We believe that Botreso® has the potential to satisfy the growing treatment needs of BPH/LUTS patients.

We have conducted four Phase III clinical trials for Botreso® in the U.S. and Taiwan, including two pivotal trials (one in the US and one in Taiwan) and two open-label extension studies, using API-1(one in the US and one in Taiwan). Our pivotal Phase III clinical trial for Botreso® in the U.S. failed to show a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population. The U.S. FDA granted our WRO meeting request and is reviewing our new drug development program for API-2, including Phase I PK study and Phase III clinical trial.

We believe there is a tremendous overall addressable market for Botreso® and significant commercial potentials. In order to facilitate global registrations and commercial launches of Botreso®, to which we own worldwide development and commercialization rights, we are actively seeking marketing approvals and formulating commercialization strategies for Botreso® in targeted markets. Our management team has been aggressively seeking strategic cooperation opportunities with business partners and potential marketing teams around the world.

Diverse drug portfolio and pipeline drug candidates focusing on the treatment of urinary system diseases

Our pipeline currently consists of three compelling new drug candidates focusing on the treatment of urinary system diseases. Leveraging our strong research and development capabilities and proprietary platform, we have been developing a series of botanical drug candidates, our primary botanical drug candidate, Botreso®, another clinical-stage botanical drug candidate, and other preclinical-stage botanical drug candidates.

Botreso® is our new botanical drug candidate developed for treatment of BPH/LUTS. Another two key drug candidates, PCP and IC, are developed for prostate cancer prevention and the treatment of interstitial cystitis, respectively. We initiated phase II clinical trials in Taiwan in November 2014 for PCP with 702 subjects and 20 medical centers being involved. Our new drug candidates either demonstrate the achievement of statistically significant endpoints in clinical trials or indicate great potentials to treat adaptive disease in preclinical studies. We believe each of our drug candidates has the potential to address significant medical needs in our target markets and for the treatment of urinary system diseases that have been historically underserved and lacked innovation.

In particular, the target users of Botreso® and PCP can be highly overlapping. Since only a portion of BPH/LUTS patients, who are potential users of Botreso®, will seek active treatment, the remaining part of them will likely be in need of pharmaceutical products to prevent BPH/LUTS and prostate cancer, considering that medical studies do show that BPH is associated with an increased risk of prostate cancer. If the follow-up research and development, or R&D, of PCP progresses smoothly, it would effectively synergize with Botreso® and enable us to seize a larger market share in the future.

We believe that we have created a diverse, balanced portfolio of new drug candidates specializing in the treatment of urinary system diseases, which represents significant market potentials and provides multiple avenues for value creation for us.

Leading R&D capabilities and proprietary platform for innovative drugs

We have built an innovative proprietary R&D platform focused on the discovery, research and development of innovative drugs. Leveraging our leading proprietary R&D platform, we are able to efficiently and swiftly develop a series of pharmaceutical products with cross-disciplinary expertise that spans a variety of fields, such as chemistry, biology, pharmacology, toxicology, pharmacovigilance, and translational and clinical research. Our main R&D center is located in New Taipei, Taiwan with a gross floor area ("GFA") of approximately 1,029 sq.m. Furthermore, we actively seek and leverage cooperation opportunities with preeminent academic researchers and institutions to keep us updated with the front R&D techniques, methods and information.

Utilizing our proprietary platform, our R&D team has developed three innovative and differentiated drug candidates that specializing in the treatment of BPH/LUTS and interstitial cystitis, as well as prostate cancer prevention. We have conducted four Phase III clinical trials for Botreso® in the U.S. and Taiwan, including two pivotal trials (one in the US and one in Taiwan) and two open-label extension studies (one in the US and one in Taiwan), using API-1. Our pivotal Phase III clinical trial for Botreso® in the U.S. failed to show a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population. The U.S. FDA granted our WRO meeting request and is reviewing our new drug development program for API-2, including Phase I PK study and Phase III clinical trial.

As of the date of this annual report, we have obtained 31 invention patents in 19 territories and 58 trademarks in 46 territories. We believe that our innovative proprietary R&D platform has contributed to our success and will continue to do so.

Integrated in-house capabilities that well position us for pharmaceutical innovation from bench to bedside

We have built fully integrated capabilities that encompass all the key functionalities of drug development, including early-stage drug discovery and development, clinical trials, regulatory affairs, manufacturing and commercialization. The full integration of these functionalities provides us with the opportunity to potentially bring our drug candidates efficiently from bench to bedside. This integration may enable us to identify and address potential clinical, manufacturing, and commercial opportunities, as well as issues early in the development process. It's important to note that as of now, none of our drug candidates have received regulatory approval. However, this approach allows us to focus our efforts on drugs that have the potential to become clinically active, cost-effective, and commercially viable. Besides, it also allows us to process product manufacturing, maintain consistent quality control and redeploy resources appropriately.

Leveraging rigorous trial design and trial operational excellence, we have achieved substantial progress in our innovative drug candidates. Led by Ms. Fu Feng Kuo, our founder and CEO, we have a team with approximately 15 employees, which supervises and manages our clinical trials and clinical activities, including clinical trial design, implementation and the collection and analysis of trial data. We maintain control and oversight over these key functions of clinical trials while partnering with reputable hospitals and contract research organizations, or CROs, for trial execution. We have established close relationships with 12 reputable hospitals and CROs in Taiwan to conduct Botreso® studies, and with 20 reputable hospitals and CROs in Taiwan to conduct PCP trials.

We have built a seasoned team of regulatory affairs specialists with rich experience in communicating and cooperating with drug regulatory agencies in Taiwan and the U.S. Leveraging our CEO's rich working experience in the pharmaceutical industry, we have substantial expertise in and familiarity with regulatory review requirements and processes, which enable us to communicate efficiently with regulatory authorities.

We have established one manufacturing facility in Taiwan. The GFA of our manufacturing facility, Yilan Letzer Pharmaceutical Factory, is approximately 1,944 sq.m. In addition, we have two new manufacturing facilities under planning in Yilan of Taiwan and Taizhou, Zhejiang Province of China which we believe will further enhance our production capacity in the future.

We intend to form a comprehensive internal sales and marketing mechanism conforming to the Code of Marketing Practices and the Good Distribution Practice drawn up by the International Research-Based Pharmaceutical Manufacturers Association, a Taiwanese non-profit organization established in 1992. In Taiwan, we are establishing a strong sales and marketing team that is expected to consist of employees with rich experience in relevant areas and our target markets. In other territories, we plan to cooperate with local pharmaceuticals and leverage their sales and marketing network. Our management team also brings us an average of 30 years of substantial operation, managerial and commercialization experience, resources and expertise that can be leveraged to accelerate the build-out of our proprietary commercialization infrastructure.

Visionary and experienced management and R&D team with extensive industry expertise

Our management team has extensive expertise in R&D of innovative drugs gained from their enriching experience in well-known companies and institutions in the pharmaceutical industry, as well as in-depth knowledge and understanding of our target markets and the access to top-tier hospitals and renowned medical experts, which we believe gives us an advantage in navigating the clinical development and regulatory approval process as well as the commercialization of our drug candidates.

Our founder and CEO, Ms. Kuo, brings over 20 years of experience in the discovery and development of innovative drugs (plant-derived) to our Company. Over the years, she has gained extensive experience in the discovery, preclinical studies, and clinical development of various drug products. She also led our conferences with regulatory authorities, joined meetings with CROs, assisted with the establishment of chemistry, manufacturing and controls data, or CMC data, monitored the execution of toxicology tests and clinical trials, and actively participated in the study of new drugs extraction technologies. She has full command of our key technologies and R&D plans. Our CTO, Dr. Fenglin Hsu is an expert in the research of natural medicinal chemistry, the R&D of Chinese herbal medicine, and the management of biotechnology medicine R&D. Dr. Hsu previously served as a professor at the School of Pharmacy and the director of the Institute of Pharmacology at Taipei Medical University. Our R&D team leader, Mr. Albert Pu has expertise in the research on natural medicinal chemistry and formulation development and previously served as an inspector at the TFDA.

We are proud of our R&D team which has been contributing to our growth. As of the date of this annual report, our R&D team consisted of 15 employees, including three holding doctorate degrees and eight holding master's degrees. Members of our core R&D team have an average of more than 15 years of experience in innovative drug development.

Our success is, to a large extent, the product of our management's leadership and our R&D team's expertise, which cover the full spectrum of the product development process, from preclinical studies through design and execution of clinical studies to regulatory approval.

OUR STRATEGIES

To achieve our mission, we intend to execute the following strategies:

Advance the clinical development of our core drug candidate Botreso® to seek regulatory approval and achieve commercialization in our target markets.

In order to obtain regulatory approval and commercial rights for our core drug candidate, Botreso®, in the U.S. and Taiwan, we have designed regulatory strategies that we believe will enable us to leverage data generated in our clinical trials that account for considerations specific to our licensed territories, including local clinical practice and patient preferences, with the goal of obtaining regulatory approval and maximizing patient reach for Botreso®.

In terms of preparation for manufacturing and quality control for future commercialization, we have already built the Yilan Letzer Pharmaceutical Factory with an aggregate GFA of approximately 1,944 sq.m. We are currently planning for a mass production trial at Yilan Letzer Pharmaceutical Factory and have already purchased customized equipment to support future operations. We plan to establish a second PIC/S GMP manufacturing facility in Lize, Yilan, Taiwan, following the completion of our second round of financing. We will further strengthen our seasoned commercialization team with extensive industry experience, which we believe will contribute to the marketing promotion of Botreso®. We are also actively seeking commercial partnerships with pharmaceutical companies to maximize the commercial value of Botreso®. We believe that these potential partners could bring significant strategic synergy with us in the pursuit of potential opportunities for strategic collaboration in order to gain reasonable commercial returns and expedite the practical use of Botreso® globally.

Leverage differentiated approaches to advance our development of other drug candidates, such as PCP, IC and other new small molecule drugs, toward regulatory approvals.

We will continue to devote substantial resources to the clinical trials of PCP and IC, and the innovative development of other new small molecule drugs. We have adopted and will continue to leverage differentiated development approaches for these drug candidates, which are specifically tailored based on the different development stages that the various drug candidates are undergoing, in order to maximize the value of these drug candidates and obtain potential regulatory approvals in the U.S., Taiwan, China and other territories.

- PCP: in November 2014, we initiated a phase II clinical trial of PCP in Taiwan, and have completed the data lock in May 2025, and statistical analysis was completed in September 2025. As of December 31, 2025, 702 subjects and 20 medical centers in Taiwan have been involved. A total of 170 serious adverse events (SAEs) occurred to date in the PCP Phase II clinical trial, including PCP and Placebo group, and all of the 170 SAEs have been professionally judged by clinicians and they are not related to PCP.

The following table indicates the serious adverse events (SAEs) occurred to date in the PCP Phase II clinical trial, including the PCP and Placebo group:

System Organ Class	Number	Relationship
Renal and urinary disorders	60	Not related
Cardiac disorders	23	Not related
Musculoskeletal and connective tissue disorders	19	Not related
Gastrointestinal disorders	18	Not related
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	18	Not related
Respiratory, thoracic and mediastinal disorders	6	Not related
Others	26	Not related
Total	170	

We intend to expedite our clinical development of PCP in Taiwan. We have pushed our CRO to add more personnel to manage the data. Now we have completed all the SDV (Source Data Verification), with data lock in May 2025, and statistical analysis completed in September 2025, and achieved positive results. The results indicated it met its primary endpoint, showing a reduction in positive biopsy rates and incidence of higher-grade tumors after 104 weeks of administration. Subsequently, the medical writer will draft the clinical study report (CSR). Once the CSR is available, we will discuss within the team and determine if this program should advance to Phase III. Should this program advances to Phase III, we plan to cooperate with international pharmaceutical companies and proceed to multinational Phase III clinical trials of PCP. We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2 and submitted it to the U.S. FDA on October 16, 2024, and are awaiting feedback from the U.S. FDA. As of the date of this annual report, the Company has not yet successfully demonstrated the comparability of API-1 and API-2. If the U.S. FDA agrees about comparability of API-1 and API-2, we will discuss with the TFDA the conduct of the Phase III PCP study using API-2.

We are currently collaborating with one supplier to prepare the CMC documents mandated by the U.S. FDA. Should the FDA concur that API-1 and API-2 are similar and comparable, we intend to sign the Quality Agreement with this supplier for the raw materials for API-2. We will only be able to proceed with Phase III PCP study the after the U.S. FDA accepts such results and determines that API-1 and API-2 are comparable. If there is any possibility that FDA does not agree that API-1 and API-2 are comparable, we will work with another supplier who is able to meet the comparability.

- ***IC:*** we are conducting the preclinical studies of IC. Phase I clinical trials of IC are expected to be conducted in Taiwan.

- ***Preclinical new small molecule drugs:*** our R&D team is developing several new small molecule drugs.

Establish and enhance integrated launch capabilities and strategically build commercial infrastructure customized to each of our drug candidates.

Our commercial strategy aims to efficiently maximize patient reach for each of our future products. For our core drug candidate, Botreso®, we intend to keep building and then utilize a focused salesforce in the U.S., the EU and Asia (primarily Taiwan and mainland China) in order to promote our products, if approved. We believe we will be able to leverage the commercial infrastructure we create for our core product candidate to benefit our other product candidates. For example, in the U.S., Taiwan and mainland China, prescription drugs across our therapeutic areas are primarily sold through hospitals. As a result, we believe the hospital relationships we may establish will lay the groundwork for the future launch of programs across our portfolio. Our overall launch approach will focus on early integration of medical, regulatory and commercialization preparation.

We may continue to pursue a co-commercialization strategy with strategic partners globally. In the past, we entered into a license agreement with a Cambodian corporation, Chhak Kamponngsaom Sez Co., Ltd., in 2016, which provides for the potential co-commercialization of Botreso® in Cambodia. We believe the co-commercialization strategy with strategic partners would enable us to access their extensive sales network and established commercial organization globally.

Continue to deepen our pipeline in existing therapeutic areas with new drugs that fit with our expertise, portfolio and strategy.

We seek to anchor each therapeutic focus area with a competitive drug product and build around these core areas. We will encourage the innovation and growth of our in-house talents and plan to recruit more high-quality talents, which we believe will support our expanding research and development efforts to deepen our pipeline. We also intend to collaborate with outstanding partners, electing programs with a strong scientific basis and compelling clinical data to build out a broad and clinically validated pipeline. We intend to opportunistically seek out additional hospitals and CROs as partners based on our market assessments. We consider our existing portfolio of product candidates, as well as those of our strategic collaborations, to identify and pursue novel combination approaches. We intend to continue building our portfolio with innovative new drugs that have the potential to become new standards of care in our target markets.

OUR DRUG CANDIDATES

We discover and develop innovative drugs based on differentiated or clinically validated efficacy and safety. To complement our in-house research and development efforts, we may also collaborate with third parties on the commercialization of our drug candidates through various arrangements. Please see "Item 4. Information on the Company — B. Business Overview — License and Collaboration Agreements" for more details.

Drug Candidates

Botreso®

Botreso® is our new drug candidate developed for BPH/LUTS treatment. Botreso® is expected to be our core product in the future. We have conducted four phase III clinical trials in the U.S. and Taiwan, including two pivotal trials and two open-label extension studies (one in the US and one in Taiwan) using API-1. One of the Phase III clinical trials for Botreso® in the U.S. failed to show a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population. Therefore, we did not reach the endpoint of Phase III clinical trials for Botreso®. We withdrew our NDA from U.S. FDA review for Botreso® with API-1. We have asked that the U.S. FDA to provide a written response to questions focused on obtaining U.S. FDA review and comments on a new, proposed Phase III clinical trial protocol for Botreso® with API-2 and a pharmacokinetic study. On May 23, 2024, we received a denial notice from the FDA, stating that it is premature for this stage of drug development, and until the company can provide complete Chemistry, Manufacturing, and Controls (CMC) information on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2, the U.S. FDA is unable to reach agreement on protocols designed to establish the safety and efficacy of Botreso®. We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2 and submitted it to the U.S. FDA on October 16, 2024, and are awaiting feedback from the U.S. FDA.

BPH/LUTS is the most common urinary tract disease in the middle-aged male population. According to Frost & Sullivan, in 2021, the global prevalence of BPH increased from 88.4 million in 2017 to 94.2 million in 2020, representing an increase of 6.5%. The global BPH drugs market increased from US$3.7 billion in 2017 to US$4.1 billion in 2020, representing a CAGR of 4.6%. We are establishing a strong sales and marketing team that is expected to consist of employees with rich experience in relevant areas and our target markets, and plan to work with both domestic and international business partners to seize the great market opportunity and to help more patients reduce their distress caused by BPH/LUTS and drug side effects caused by chemical drugs.

Disease Overview

BPH is a histologic diagnosis that refers to the proliferation of glandular epithelial tissue, smooth muscle, and connective tissue within the prostatic transition zone. The exact etiology of BPH is unknown. BPH can lead to an enlargement of the prostate called benign prostatic enlargement, or BPE, which may eventually cause obstruction at the level of the bladder neck and in turn caused termed benign prostatic obstruction, or BPO. Males' LUTS may be caused by a variety of conditions including BPE and BPO. Since when the entire prostate gland enlarges, the prostate tissue compresses the prostatic urethra and it then becomes more difficult for urine to pass through, so the urine builds up in the bladder and causes it to dilate. The stagnation of urine in the bladder also promotes bacterial growth and can lead to urinary tract infection. LUTS includes voiding or obstructive symptoms such as hesitancy, poor and/or intermittent stream, straining, prolonged micturition, feeling of incomplete bladder emptying, dribbling, and storage or irritative symptoms such as frequency, urgency, urge incontinence, and nocturia. BPH/LUTS is the most common urinary tract disease in the middle-aged male population and the risk of BPH/LUTS in the male population increases with age.

Current Standard Care

Conservative management and surgical treatment are current standards of care for BPH/LUTS. Conservative management includes lifestyle changes and pharmacological management. Surgical treatment of symptomatic BPH may be classified into three general types: (i) minimally invasive sinus surgery, or MIST, (ii) simple prostatectomy, and (iii) transurethral surgery. Although effects and benefits from surgical treatments can show up immediately, however, there are inherent risks of surgery, possibilities of recurrence, and post-operative side effects, such as hematuria, pain, retrograde ejaculation, impotence and urinary incontinence. In general, pharmacological management is still the prevailing method of BPH/LUTS treatment. Patients are treated with surgery only if pharmacological management is ineffective. The treatment of BPH focuses on relieving the lower urinary tract symptoms. This can be done through 5-α reductase inhibitors, or 5-Ari, and alpha-adrenergic blockers, or α-blockers. However, neither 5-Ari nor α-blockers can effectively cure BPH/LUTS. Patients generally need to take such drugs for life, but long-term use of these chemical drugs can lead to drug resistance and adverse effects such as cardiac failure. Due to drug-related adverse effects, physicians and patients have great concerns over using medications, and thus some patients choose to watch and wait instead of taking any drugs to treat BPH/LUTS.

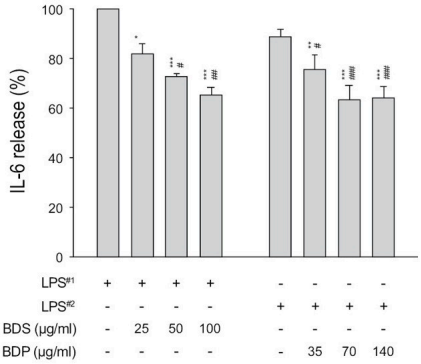
Mechanism of Action

Botreso® has an antioxidant capacity and can reduce inflammatory cytokines (IL-6). It may take effect by reducing oxidative stress and inflammation.

Oxidative stress is an important contributing factor in the development of chronic diseases. It is an imbalance between the production of reactive oxygen species, or ROS, and antioxidant defense, can lead to oxidative damage, caused by deficiency in antioxidant defense processes, elevation in ROS due to presence of toxins and activation of ROS mediated by chronic infection and inflammation. Based on the Cellular Antioxidant Activity, or CAA, method, the results showed a dose-dependent increase in CAA for Botreso®. Botreso® caused a concentration-dependent increase in cellular antioxidant assay and thus exhibited antioxidant activity. The following table indicates the cellular antioxidant assay unit obtained for different concentrations of standard materials and Botreso®:

Conc. (ppm)	**Standard**	**Botreso®**
	CAA	**CAA**
1	14.23±0.00	9.14±2.58
2	26.75±0.00	17.26±0.78
3	34.04±0.00	27.20±6.59
4	36.12±0.27	29.76±5.90
5	38.90±0.17	37.88±1.48

Chronically inflamed cells can release cytokines to functionally determine a constitutively active stroma and stimulate tumor growth and progression. Chronic inflammation in benign prostate biopsy specimens has been evident to be associated with high-grade prostate tumors in adjacent areas. IL-6 is a prototypical cytokine with various biological effects on a wide variety of cells. IL-6 is therefore involved in the control of immune responses and inflammation. It is produced, participating in host defense against infections and tissue injuries. However, over production of IL-6 leads to severe disease complications. Accordingly, IL-6 blockade was expected to become a therapeutic strategy for the diseases characterized by IL-6 overproduction. Based on an important pro-inflammatory cytokine, the IL-6 levels can be determined for the understanding of anti-inflammatory activity of Botreso®. Botreso® is able to cause a concentration-dependent inhibition of LPS-induced IL-6 release in differentiated THP-1 cells, suggesting an anti-inflammatory activity of Botreso®. The following diagram indicates that Botreso® has anti-inflammatory activity:



Notes:

(1) LPS means lipopolysaccharides which are large molecules consisting of a lipid and a polysaccharide that are bacterial toxins.
(2) BDS means botanical drug substance.
(3) BDP means botanical drug product.
(4) LPS$^{\#1}$ means 0.3 μg/ml LPS/0.1% DMSO.
(5) LPS$^{\#2}$ means 0.3 μg/ml LPS/0.1% DMSO and 0.004% soybean oil.
(6) * means $P < 0.05$, ** means $P < 0.01$ and *** means $P < 0.001$ compared with LPS$^{\#1}$.
(7) # means $P < 0.05$, ## means P < 0.01 and ### means $P < 0.001$ compared with LPS$^{\#2}$.

The purpose of this study is to evaluate the anti-inflammation effect of BDS and BDP by measuring LPS-induced IL-6 release. The data demonstrated that both BDS and BDP showed a concentration-dependent inhibition of LPS-induced IL-6 release. LPS is one of the main etiological factors in the pathogenesis of several diseases. LPS has been shown to stimulate host cells, including macrophages and fibroblasts, to produce cytokines. LPS can markedly increase the production of IL 6, IL 8 and TNF α in differentiated THP 1 cells. Therefore, based on an important pro-inflammatory cytokine, the IL-6 levels stimulated by LPS can be determined for the understanding of anti-inflammatory activity of the Botreso®.

Interleukin (IL)-6 is produced at the site of inflammation. IL-6 exerts stimulatory effects on T- and B-cells, thus favoring chronic inflammatory responses. Although its expression is strictly controlled by transcriptional and posttranscriptional mechanisms, dysregulated continual synthesis of IL-6 plays a pathological effect on chronic inflammation and autoimmunity. BDS (25, 50 and 100 μg/ml) and BDP (35, 70 and 140 μg/ml) were used, respectively. The data demonstrated that both BDS and BDP showed a concentration-dependent inhibition of LPS-induced IL-6 release in differentiated THP-1 cells, suggesting an anti-inflammatory activity of Botreso®.

Clinical Data

The data in the Clinical Data section for Botreso® from page 70 to page 81, pertains to the clinical trials utilizing API-1 ("Botreso® (API-1)"), which is currently unavailable. We will be conducting new studies using API-2 ("Botreso® (API-2)"). However, we must conduct API-1 and API-2 comparability studies first and if the FDA accepts such results and determines that API-1 and API-2 are comparable, only then we will be able to conduct the additional Phase I PK study and Phase III pivotal study using API-2. If the U.S. FDA does not agree that API-1 and API-2 are comparable, we will need to work with other API vendor to demonstrate the comparability that meet U.S. FDA's requirements.

Considering a variety of factors including the current unavailability of API-1, we voluntarily withdrew our NDA on November 30, 2022, in order to develop more information about API-2 for the U.S. FDA's review and to address ongoing questions regarding demonstrated difference between Botreso® and placebo for the primary efficacy endpoint in a clinical study for Botreso®, and to address other questions FDA had previously identified in our NDA regarding FDA's questions related to the drug substance and product, validation of methods used for measuring the effect of Botreso®, manufacturing, clinical and nonclinical testing, data, and statistical analyses, among others.

The U.S. FDA has reviewed our proposed Phase III protocol and Phase I pharmacokinetic (PK) synopsis, as reflected in their written response dated February 23, 2024. The U.S. FDA raised several concerns in this response:

(i) The U.S. FDA questioned whether one new Phase III study with API-2 would be sufficient, as they believe results from two positive Phase III efficacy studies provide more convincing evidence of effectiveness than results from a single trial. Additionally, a single Phase III efficacy study could make it challenging to collect the amount of safety information required for a new molecular entity.

(ii) The U.S. FDA noted its concern that Study MCS-2-US-a did not demonstrate a statistically significant difference between the drug and placebo in the primary efficacy endpoint. They also expressed concerns regarding the treatment effect of questionable significance in Study MCS-2-TWN-a.

(iii) The U.S. FDA was concerned that our study plan had not specified either the quantity or quality of the confirmatory evidence, and did not state a specific clinical circumstance, ethical or practical consideration, or unmet medical need that would preclude the conduct of a second adequate and well-controlled efficacy study.

(iv) Additionally, regarding the comparability of API-1 and API-2, the U.S. FDA commented that it will need more information on how we would demonstrate comparability between API-1 and API-2. They noted that their determination of whether our original Phase III studies with API-1 would be useful depends on the quality of support for a convincing link between products containing these APIs.

In response to these concerns and upon U.S. FDA's recommendation, we are developing a comparability plan to provide the U.S. FDA with convincing data to link between products containing API-1 and API-2. As of the date of this annual report, the Company is still in the process of providing the information required by the U.S. FDA and has not yet successfully demonstrated the comparability of API-1 and API-2.

After our submission of our comparability plan and, if U.S. FDA agrees our data demonstrates comparability between API-1 and API-2, we will be able to rely on trials that were previously conducted using API-1, and we then will initiate the Botreso® Phase III study and the PK study using API-2 simultaneously. As mentioned earlier, for Botreso® (API-1), we have conducted four Phase III clinical trials in the U.S. and Taiwan, including two pivotal trials (one in each location) and two open-label extension studies (also one in each location) using API-1. The U.S. FDA raised concerns about one pivotal Phase III trial in the U.S., which failed to demonstrate a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population. Additionally, the FDA expressed concerns regarding the reproducibility of some reported efficacy results for Study MCS-2-TWN-a. However, the U.S. FDA had no further comments on the two open-label extension studies in the U.S. and Taiwan using API-1. Therefore, if the FDA agrees that our data demonstrates comparability between API-1 and API-2, we will also need to conduct another pivotal Phase III study using API-2, and we will work with the FDA to address the reproducibility issue.

To address the U.S. FDA's concern that Study MCS-2-US-a did not demonstrate a statistically significant difference between the drug and placebo in the primary efficacy endpoint, we plan to conduct an additional Phase III study, MCS-2-US-b, using API-2.

Regarding the U.S. FDA's concerns about the reproducibility of the reported efficacy results for Study MCS-2-TWN-a, we propose to re-analyze the statistical results of the MCS-2-TWN-a study data using Clinical Data Interchange Standards Consortium (CDISC) data sets that match the FDA's requested data format. Then, we will submit the reanalysis for further discussions with U.S. FDA about its concerns.

On May 14, 2024, we asked U.S. FDA to provide a written response to our questions about obtaining U.S. FDA's review and comments on a newly proposed Phase III clinical trial protocol for Botreso® with API-2 and a pharmacokinetic (PK) study. On May 23, 2024, we received a denial notice from the U.S. FDA, stating that it was premature to provide such a written response at this stage of drug development, however, the U.S. FDA would continue its review of the study design of PK study and Phase III clinical trial using API-2. The U.S. FDA decided that until the company provides complete Chemistry, Manufacturing, and Controls (CMC) information on the active pharmaceutical ingredient-2 (API-2) with a plan to establish comparability between API-1 and API-2, the U.S. FDA is not in a position to reach any agreement on protocols designed to establish the safety and efficacy of Botreso®. We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2 and submitted it to the U.S. FDA on October 16, 2024, and are awaiting feedback from the U.S. FDA. If the U.S. FDA does not agree that API-1 and API-2 are comparable, we will continue to research additional API sources based on our own patent, to pursue additional outsourcing API vendors, and to follow U.S. FDA's guidance for demonstrating comparability between API-1 and API-2 to the U.S. FDA's satisfaction. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the Botreso® clinical trials using API-2. For further details, see the risk factor titled "**If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs**" on page 13.

In addition, we are in the process of finalizing the PK study protocol per U.S. FDA requirements and hope to satisfy the U.S. FDA of the comparability between API-1 and API-2. If the CMC comparability between API-1 and API-2 is approved, we will request a Type B meeting (WRO) with the U.S. FDA to discuss our revised Phase III protocol, Statistical Analysis Plan, and PK study protocol.

Phase I Clinical Studies

Phase I clinical studies of Botreso® focused on pharmacokinetics and clinical drug-drug interaction studies. **The data in the Phase I Clinical Studies section, pertains to the clinical trials utilizing API-1, which is currently unavailable. We will be conducting new studies using API-2 ("Botreso® (API-2)"). However, we must conduct API-1 and API-2 comparability studies first and if the FDA accepts such results and determines that API-1 and API-2 are comparable, only then we will be able to conduct the additional Phase I PK study and Phase III pivotal study using API-2. If the U.S. FDA does not agree that API-1 and API-2 are comparable, we will need to work with other API vendor to demonstrate the comparability that meet U.S. FDA's requirements.**

Pharmacokinetics

The study of pharmacokinetics of Botreso® (API-1) was a randomized, balanced, single-dose, two-treatment (fed versus fasted) study in healthy male adult subjects. The study was designed to evaluate the pharmacokinetics, or PK, of Botreso® (API-1) when it was administered in the fed and fasted state. 47 subjects were randomized to receive a single dose either in the fed (24 subjects) or fasted (23 subjects) state, and the PK parameters were evaluated and compared for the two treatment groups. Relevant trials were conducted in U.S. and were initiated on April 22, 2015 and completed on April 24, 2017, with 23 subjects in fed group and 22 subjects in fasted group had completed the study. The above study of the pharmacokinetics of Botreso® was conducted using API-1, which is currently unavailable. We are continuing development of Botreso® using API-2 in consultation with U.S. FDA. U.S. FDA provided comments on our proposed Phase III study, and we are finalizing the protocol for resubmission to the U.S. FDA. In addition, we are in the process of finalizing the PK study protocol per U.S. FDA requirements and hope to satisfy the U.S. FDA of the comparability between API-1 and API-2. If the CMC comparability between API-1 and API-2 is approved, we will request a Type B meeting (WRO) with the U.S. FDA to discuss our revised Phase III protocol, Statistical Analysis Plan, and PK study protocol.

As to the efficacy of Botreso® (API-1), the study compared serum active ingredient levels of five major biomarkers PL, PF, PE, TC and BC (code names of our active ingredients to represent the content of each carotenoid in our pharmaceutical composition), in subjects taking Botreso® (API-1) after a meal with those taking Botreso® (API-1) on an empty stomach. It is found that the proportion of active ingredient absorbed after a meal was better than after an empty stomach. Subjects were randomized to two groups in order to obtain their pre-prandial or postprandial medication status. The results showed that the adverse effects were well tolerated irrespective of the timing of administration (postprandial or postprandial), although absorption rates were higher when Botreso® (API-1) were taken after meals. The following figure indicates the concentration of active ingredients in serum:

Pharmacokinetics (Unit)	**Fed State**	**Fasted State**
AUC_{0-72} (day*μmol/L)	0.521	0.376
AUC_{0-last} (day*μmol/L)	0.457	0.236
C_{max} (day*μmol/L)	0.306	0.217
$t_{1/2}$ (day)	0.691	2.049
t_{max} (day)	1.133	0.724

Notes:

(1) AUC_{0-72} means area under the serum concentration-time curve, calculated from time zero to time 72 hours postdose by the linear trapezoidal rule (after correction for the baseline concentration).
(2) AUC_{0-last} means area under the serum concentration-time curve, calculated from time zero to the last measurable concentration by the linear trapezoidal rule (after correction for the baseline concentration).
(3) C_{max} means maximum (peak) serum drug concentration observed (after correction for baseline concentration).
(4) $t_{1/2}$ means half-life period.
(5) t_{max} means time of the maximum observed concentration.

As to the safety profile of Botreso® (API-1), data indicated that Botreso® was well-tolerated among 47 subjects. 22 subjects, or 46.8%, of all subjects reported at least one treatment emergent adverse event, or TEAE, during the study. The fasted group has a higher TEAEs rate (60.9%) than the fed group (33.3%), but the rate of Aes was similar for the two groups. Overall, the most frequently reported TEAEs were headache (19.1%), upper respiratory tract infection (8.5%), back pain (4.3%) and nasopharyngitis (4.3%). The fasted group reported higher rate of headaches than the fed group. The two groups had similar rates for other TEAEs. No subject experiences serious, severe, or life-threatening treatment emergent adverse events, or TEAEs. No TEAEs resulted discontinuation of the study and no death was caused. Other data such as the changes in blood pressure, heart rate, respiratory rate, weight and temperature were generally small and clinically insignificant.

Clinical Drug-Drug Interaction

The study of clinical drug-drug interaction of Botreso® (API-1) was an open-label, fixed-sequence, drug-drug interaction study to evaluate the effect of Botreso® (API-1) on the pharmacokinetics of 24 healthy male subjects. Relevant trials were initiated on May 20, 2018 and completed on September, 2018. A total of 24 subjects were enrolled in the study and 23 of them completed the study. One subject discontinued the study primarily due to a failure to meet compulsory criteria.

Midazolam is used to produce sleepiness or drowsiness and to relieve anxiety before surgery or certain procedures. Bupropion is indicated for the treatment of major depressive disorder, seasonal affective disorder, and as an aid to smoking cessation.

Since our in vitro drug-drug interaction study conducted in the U.S. concluded that our drug substance may be an inducer of CYP3A4 and CYP2B6 based on the calculated R values (< 0.9). U.S. FDA suggested that we further investigate the potential drug-drug interactions by conducting a clinical drug-drug interaction study using a sensitive index substrate. The sensitive index substrate is midazolam for CYP3A4 and bupropion for CYP2B6, respectively. Therefore, we conducted such study to assess the effect of Botreso® (API-1) on the PK of midazolam and bupropion following U.S. FDA's suggestion in 2018. The coadministration of Botreso® (API-1) with midazolam and bupropion generally would not affect the efficacy of midazolam and bupropion, and concluded that Botreso® is not an inducer of both midazolam (CYP3A4) and bupropion (CYP2B6).

The primary objective of this clinical drug-drug interaction study was to assess the effect of Botreso® (API-1) on the PK of midazolam and bupropion in healthy male subjects. The results indicated that the peak exposure (Cmax) and the total exposure to midazolam were not significantly affected by the co-administration of Botreso® (API-1). The total and peak exposures of bupropion, midazolam, and their measured metabolites were not significantly altered after multiple daily doses of Botreso® (API-1). The median time to peak concentration (Tmax) of bupropion, midazolam and their measured metabolites was not affected by multiple daily doses of Botreso® (API-1). The safety data indicated that the administration of Botreso® alone or the co-administration of Botreso®, midazolam and bupropion was generally tolerated by healthy male subjects in this study. Seven of 24 subjects (29.2%) treated with midazolam, bupropion, and/or Botreso® (API-1) experienced a total of 10 TEAEs. Six of 24 subjects (25.0%) treated with midazolam or bupropion experienced seven TEAEs. One of 24 subjects (4.2%) treated with Botreso® alone experienced two TEAEs. One of 23 subjects treated with midazolam/bupropion and Botreso® (API-1) experienced one TEAEs. The most frequently reported TEAEs were somnolence and others included headache, dry skin, macule, skin irritation and cough. However, 30% of TEAES were assessed as unrelated to the study. All TEAEs were assessed as mild in severity and fully recovered or resolved at the end of the study. No TEAEs resulted discontinuation of the study and no serious adverse effect, or SAE, or deaths were reported.

Overall summary and conclusions

According to the Phase I clinical studies, the administration of a single oral (API-1) was well-tolerated in the fed and fasted state in healthy male subjects. Subjects absorbed active ingredients of Botreso® (API-1) better when they took Botreso® (API-1) after meals. The administration of Botreso® alone or the co-administration of Botreso®, midazolam and bupropion was generally tolerated by healthy male subjects in this study. The coadministration of Botreso® (API-1) with midazolam and bupropion generally would not affect the efficacy of midazolam and bupropion. Our Phase I trial was completed several years later than Phase II and Phase III trials per U.S. FDA's requirements. Since our in vitro drug-drug interaction study conducted in the U.S. concluded that our drug substance may be an inducer of midazolam and bupropion based on the calculated R values (< 0.9). The U.S. FDA suggested that we conduct additional Phase I studies on both PK and DDI using a sensitive index substrate. Therefore, we conducted such additional study to assess the effect of PCP on the PK of midazolam and bupropion following the U.S. FDA's suggestion in 2018 after we had previously completed Phase II and Phase III studies. The clinical DDI study concluded that Botreso® (API-1) is neither an inducer of midazolam nor an inducer of bupropion.

Phase II Clinical Studies

The data in the Phase II Clinical Studies section, pertains to the clinical trials utilizing API-1, which is currently unavailable. We will be conducting new studies using API-2 ("Botreso® (API-2)"). However, we must conduct API-1 and API-2 comparability studies first and if the FDA accepts such results and determines that API-1 and API-2 are comparable, only then we will be able to conduct the additional Phase I PK study and Phase III pivotal study using API-2. If the U.S. FDA does not agree that API-1 and API-2 are comparable, we will need to work with other API vendor to demonstrate the comparability that meet U.S. FDA's requirements. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the Botreso® clinical trials using API-2. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

Trial Design

The phase II clinical trial in Taiwan was initiated on March 21, 2004 and completed on August, 2006. The phase II clinical study was a randomized exploratory intervention one with 65 subjects involved and 62 subjects completed the study. 32 subjects were administered 15 mg Botreso® (API-1) per day and 29 of them completed the study. 33 subjects were administered 30 mg Botreso® per day and all of them completed the study.

Efficacy

According to the results of phase II clinical trials in Taiwan, the primary endpoint was the change in International Prostate Symptom Score system, or I-PSS, which is a validated, reproducible scoring system that measures severity of lower urinary tract symptoms and responses to therapeutics, from Day one to Week 12. The mean (standard deviation [SD]) reductions in I-PSS from baseline decreased from 11.31 [5.84] to 9.52 [4.98] after four weeks, and decreased to 9.14 [5.86] after 12 weeks in low-dose group. Thus, for subjects who took one Botreso® (API-1) softgel (15 mg) per day, their I-PSS reduced by 15.8% and 19.2% after four and 12 weeks, respectively. In addition, the mean [SD] reductions in I-PSS from Day one decreased from 12.30 [6.45] to 9.00 [4.98] at 4 weeks, and decreased to 7.55 [3.97] at 12 weeks in high-dose group. Thus, for subjects who took two Botreso® (API-1) softgels (30 mg) per day, their I-PSS reduced by 26.8% and 38.6% after four and 12 weeks, respectively. The study result indicated that the 30 mg/day was the optimal dose. For subjects with moderate and severe BPH/LUTS, or to say, for those whose I-PSS larger than 10 points (inclusive), the I-PSS decreased by 16.3% and 22.1% after 4 and 12 weeks of Botreso® softgels (15 mg/day) treatment, and the I-PSS decreased by 28.6% and 44.4%% after 4 and 12 weeks of Botreso® softgels (30 mg/day) treatment.

Safety

Botreso® (API-1) were well tolerated by both groups of subjects. There were no adverse effects, or AEs, resulting in discontinuation of the study. And no unexpected or unanticipated events were reported. 14 subjects, or 20%, of all subjects reported AEs, but most of the AEs were reported by one subject. Only one kind of AE, influenza like syndrome, occurred with an incidence greater than 5%. One subject reported one SAE which was hospitalization. However, the subject reported hospitalization since it was a common practice in Taiwan to conduct transrectal ultrasound-guided prostate biopsies under intravenous general anesthesia, which must be carried out in a hospital setting. In the U.S., transrectal ultrasound-guided prostate biopsies are conducted in an outpatient setting. Therefore, should the subject locate in the U.S., it would not be hospitalized, and no SAE would be reported then.

Overall summary

Both levels of Botreso® (API-1) administration, 15 mg/day and 30 mg/day, were well tolerated by the subjects. The incidences of AEs and SAEs were relatively low and common side effects of 5-Ari and α-blockers were not reported during relevant trials, which showed an excellent tolerability profile of Botreso®.

Phase III Clinical Studies

The data in the Phase III Clinical Studies section, pertains to the clinical trials utilizing API-1, which is currently unavailable. We will be conducting new studies using API-2 ("Botreso® (API-2)"). However, we must conduct API-1 and API-2 comparability studies first and if the FDA accepts such results and determines that API-1 and API-2 are comparable, only then we will be able to conduct the additional Phase I PK study and Phase III pivotal study using API-2. If the U.S. FDA does not agree that API-1 and API-2 are comparable, we will need to work with other API vendor to demonstrate the comparability that meet U.S. FDA's requirements. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the Botreso® clinical trials using API-2. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

Phase III clinical trials were approved by the U.S. FDA in December 2009 and approved by Taiwan TFDA in February 2010. We have conducted four Phase III clinical trials for Botreso® (API-1) in the U.S. and Taiwan, including two pivotal trials (one in the US and one in Taiwan) and two open-label extension studies (one in the US and one in Taiwan) using API-1. Among four Phase III clinical trials, the U.S. FDA determined our pivotal Phase III clinical trial for Botreso® (API-1) in the U.S. failed to show a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population.

In addition, our API-1 supplier withdrew their consent to reference their DMF on file with the FDA, due to the relocation and restructuring of manufacturing facility. Considering a variety of factors, we voluntarily withdrew our NDA on November 30, 2022, in order to develop more information about API-2 for the U.S. FDA's review and to address ongoing questions regarding demonstrated difference between Botreso® and placebo for the primary efficacy endpoint in a clinical study for Botreso®, and to address other questions FDA had previously identified in our NDA regarding FDA's questions related to the drug substance and product, validation of methods used for measuring the effect of Botreso®, manufacturing, clinical and nonclinical testing, data, and statistical analyses, among others.

The U.S. FDA provided written responses on February 23, 2024. In the response, U.S. FDA questioned whether one new Phase III study with API-2 would be sufficient, noting again its concern that Study Botreso®-US-a did not demonstrate a statistically significant difference between the drug and placebo in the primary efficacy endpoint and concerns regarding the treatment effect of questionable significance in the Study Botreso®-TWN-a. The U.S. FDA also commented that it will need more information on how we would demonstrate comparability between API-1 and API-2 and that its determination of whether our original Phase III studies with API-1 would have utility, based upon the quality of support, for a convincing link between products containing API-1 and API-2.

We followed the U.S. FDA's advice to amend the Phase III protocol and develop the Phase I PK protocol. On May 14, 2024, we submitted a Type B meeting request to the FDA containing the amended protocols for their review and comments. On May 23, 2024, we received a denial notice from the FDA, stating that it is premature for this stage of drug development, and until the company can provide complete Chemistry, Manufacturing, and Controls (CMC) information on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2, the U.S. FDA is unable to reach agreement on protocols designed to establish the safety and efficacy of Botreso®. We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2 and submitted it to the U.S. FDA on October 16, 2024, and are awaiting feedback from the U.S. FDA.

If the comparability between API-1 and API-2 is accepted by the U.S. FDA, we plan to conduct additional Phase III pivotal study in the US using API-2 (MCS-2-US-b study). If the comparability between API-1 and API-2 is not accepted by the U.S. FDA, we will need to work with other API vendor to demonstrate the comparability that meet U.S. FDA's requirements and would have to perform more clinical trials. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the Botreso® clinical trials using API-2. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

More details are indicated in the following tablet:

	Short-term Clinical Studies		Long-term Clinical Studies	
Location	USA	Taiwan	USA	Taiwan
Approved Date	November 17, 2009	February 1, 2010	November 17, 2009	February 1, 2010
Date of the first subject randomized	September 8, 2010	July 5, 2010	December 1, 2010	September 27, 2010
Study Type	Phase IIb/III	Phase III	Open-label Extension	Open-label Extension
Objective	Comparison Study of Botreso® (API-1) and placebo: the efficacy and safety	Comparison Study of Botreso® (API-1) and placebo: the efficacy and safety	Long-term use of Botreso® (API-1): the safety	Long-term use of Botreso® (API-1): the safety
Study Design	Multi-center Double-Blind Randomized Placebo-controlled	Multi-center Double-Blind Randomized Placebo-controlled	Multi-center Open-Label Single arm	Multi-center Open-Label Single arm
Study drug Dosage administration	Two Botreso® (API-1) softgels Once daily Oral	Two Botreso® (API-1) softgels Once daily Oral	Two Botreso® (API-1) softgels Once daily Oral	Two Botreso® (API-1) softgels Once daily Oral
Diagnosis	BPH/LUTS	BPH/LUTS	BPH/LUTS	BPH/LUTS
Treatment Periods	12 weeks	12 weeks	24 weeks/40 weeks	24 weeks/40 weeks

The study completion dates included in the following table:

	Last Subject Last Visit	Clinical Study Report Date
MCS-2-US-a	2013-04-09	2017-06-21
MCS-2-US-c	2014-03-28	2017-06-22
MCS-2-TWN-a	2014-03-28	2017-01-20
MCS-2-TWN-c	2014-03-28	2017-01-20

The primary objective of phase III clinical trials is to investigate the clinical use of Botreso® (API-1), by measuring the difference in the changes of I-PSS between Botreso® group and placebo group after short term (12 weeks) and long-term (40 weeks). The whole clinical studies were up to 52 weeks, or one year. Despite the pivotal Phase III clinical trial for Botreso® (API-1) in the U.S. failing to demonstrate a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population, the remaining data, including one phase III US open label extension study and two phase III studies conducted in Taiwan, still indicated that the overall results indicated that Botreso® (API-1) softgels could reduce the I-PSS total score. However, the U.S. FDA has expressed concerns regarding the reproducibility of some of the reported efficacy results for Study MCS-2- TWN-a. To address the U.S. FDA's concerns about the reproducibility of the reported efficacy results for Study MCS-2-TWN-a, we propose to re-analyze the statistical results of the MCS-2-TWN-a study data using Clinical Data Interchange Standards Consortium (CDISC) data sets that match the FDA's requested data format. Then, we will submit the reanalysis for further discussions with U.S. FDA about its concerns.

As mentioned above, the data in the Phase I Clinical Studies section pertains to the clinical trials utilizing API-1, which is currently unavailable. We will be conducting new studies using API-2 ("Botreso® (API-2)"). If we are unable to demonstrate comparability, we would have to work with other API vendors to follow FDA guidance to demonstrate comparability. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the Botreso® clinical trials using API-2. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

Overview of clinical trials

The phase III clinical trials (pivotal studies) in the U.S. and Taiwan primarily aimed to investigate whether daily treatment of two Botreso® (API-1) softgels can improve LUTS in patients with BPH. The phase III clinical trials involved 546 subjects from two pivotal trials, including 274 subjects in the U.S. and 272 subjects in Taiwan. Among the 546 subjects, 545 of them received more than one dose of Botreso® (API-1). 42 subjects received 15 mg Botreso® per day, 338 subjects received 30 mg Botreso® per day, and 165 subjects received 0 mg Botreso® (API-1) per day.

	Botreso® (API-1)	**Botreso® (API-1)**	**Placebo**
Dosage	15 mg/day	30 mg/day	0 mg/day
Randomized	42	338	166
Received ≥ 1 Dose of Study Medication	42 (100%)	338 (100%)	165 (99.4%)

The following table indicates the demographics for phase III pivotal clinical studies.

		Botreso® (API-1)	**Botreso® (API-1)**	**Placebo**
Dosage		15 mg/day	30 mg/day	0 mg/day
Parameter	Statistic	N=42	N=338	N=165
Race, n (%)	American Indian/Alaskan Native	1 (2.4)	1 (0.3)	1 (0.6)
	Asian	1 (2.4)	184 (54.4)	88 (53.3)
	Black/African American	1 (2.4)	18 (5.3)	7 (4.2)
	Caucasian	38 (90.5)	129 (38.2)	65 (39.4)
	Other, Specify	1 (2.4)	3 (0.9)	2 (1.2)
	Taiwan Aboriginal	0	3 (0.9)	2 (1.2)
Age (Years)	n	42	338	165
	Mean (SD)	62.2 (8.6)	62.2 (8.3)	61.3 (8.9)
	Median	61.0	61.0	62.0
	Min-Max	43.0-78.0	44.0-86.0	40.0-82.0

Efficacy

The results of the treatment of LUTS caused by BPH were determined by the I-PSS.

The primary endpoint was the change in I-PSS from Day 1 to Week 12. According to the US-a Phase III clinical trial, the mean (standard deviation [SD]) reductions in I-PSS from Day 1 to Week 12 in the Botreso® (API-1) group were insignificant than that in the placebo group (-3.36 [1.00] vs. -3.42 [1.11], p=0.1204). According to the TWN-a Phase III clinical trial, the mean (standard deviation [SD]) reductions in I-PSS from Day 1 to Week 12 in the Botreso® (API-1) group were significant than that in the placebo group (-4.59 [4.58] vs. -2.69 [4.01], p=0.0134).

Table 1: Summary of the primary endpoint for the two-Phase III studies and meta-analysis.

Study/Population	**Change from Baseline in I-PSS at Week 12**				
TWN-a/ITT	Treatment	N	Baseline	12 Weeks	Change
	MCS – 2	148	17.30	12.72	-4.59
	Placebo	68	16.22	13.53	-2.69
	P-Value				0.0134
US-a/ITT	MCS – 2	156	18.62	15.32	-3.36
	Placebo	74	17.83	14.75	-3.42
	P-Value				0.12

Phase III open label extension studies, or OLEs, primarily aimed to evaluate the safety and tolerability of long-term administration of two Botreso® (API-1) softgels per day. The phase III OLEs involved a total of 361 subjects, including 181 subjects in the U.S. and 180 subjects in Taiwan. Among those, 226 subjects received 30mg to 30 mg Botreso® (API-1) per day and 107 subjects received 0 mg to 30 mg Botreso® (API-1) per day.

According to the US-c results of phase III OLEs, all subjects, including 102 subjects receiving 30 mg to 30 mg Botreso® per day and 51 subjects receiving 0 mg to 30 mg Botreso® (API-1) per day, were reported with significant decreases (P value < 0.05) in the I-PSS at Day 85, Day 169 and Day 281; and 28 subjects receiving 15 mg to 30 mg Botreso® (API-1) per day, were reported with significant decreases (P value < 0.05) in the I-PSS at Day 85 and Day 169. According to the results of TWN-c phase III OLEs, all subjects, including 124 subjects receiving 30 mg to 30 mg Botreso® per day and 56 subjects receiving 0 mg to 30 mg Botreso® (API-1) per day, were reported with significant decreases (P value < 0.05) in the I-PSS at Day 85, Day 169 and Day 281. Despite the pivotal Phase III clinical trial for Botreso® (API-1) in the U.S. failing to demonstrate a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population, the remaining data, including one phase III US open label extension study and two phase III studies conducted in Taiwan, still indicated statistically significant improvements with Botreso® (API-1) for up to one year, with no drug-related serious adverse events reported.

The following table displays the summary for the two open label extension studies.

Table 2: Summary for the two open label extension studies and meta-analysis:

Study/Population	Post-baseline Visit	Treatment	N	Change from baseline in I-PSS Mean (SD)	P-Value
US/ITT	**Day 281**	**30 mg/day to 30 mg/day**	**71**	**-3.3 (7.01)**	**0.0002**
		0 mg/day to 30 mg/day	**21**	**-5.1 (4.93)**	**0.0001**
Taiwan/ITT	**Day 281**	**30 mg/day to 30 mg/day**	**50**	**-4.9 (5.9)**	**<0.0001**
		0 mg/day to 30 mg/day	**23**	**-8.0 (4.6)**	**<0.0001**

Safety

According to the results of US-a phase III clinical, 108 subjects, or 39.4% of the 274 subjects, reported AEs. The administration of 15 mg Botreso® (API-1) and 30 mg Botreso® (API-1) per day for 12 weeks was indicated to be safe and well tolerated. The incidence of AEs and SAEs were lower in the Botreso® (API-1) compared to the placebo. There were no death or premature un-blinding during the study period, and there are no drug-related SAEs. The statistics of AEs, related AEs, or SAEs, of relevant subjects are indicated in the following table:

	Phase III Clinical Trials			
	Botreso® (API-1) 15 mg/day	**Botreso® (API-1) 30 mg/day**	**Placebo**	**Total**
	N=42	**N=156**	**N=76**	**N=274**
	N (%)	**N (%)**	**N (%)**	**N (%)**
Adverse Event (AE)	16 (38.1)	59 (37.8)	33 (43.4)	108 (39.4)
Related AE	6 (14.3)	21 (13.5)	14 (18.4)	41 (15.0)
Serious Adverse Event (SAE)	0 (0.0)	1 (0.6)	2 (2.6)	3 (1.1)

The parameter of correlation of relevant subjects are indicated in the following table:

Parameter	**15 mg N = 42 n (%)**	**30 mg N = 156 n (%)**	**0 mg N = 76 n (%)**	**Total N = 274 n (%)**
Subjects with ≥ 1 TEAE	16 (38.1)	59 (37.8)	33 (43.4)	108 (39.4)
Definitely	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Probably	0 (0.0)	6 (3.8)	3 (3.9)	9 (3.3)
Possibly	6 (14.3)	15 (9.6)	11 (14.5)	32 (11.7)
Not Related	10 (23.8)	38 (24.4)	19 (25.0)	67 (24.5)

According to the results of TWN-a phase III clinical trials, 106 subjects, or 39.1% of the 271 subjects, reported AEs. The administration of 30 mg Botreso® (API-1) per day for 12 weeks was indicated to be safe and well tolerated. The incidence of AEs and SAEs were lower in the Botreso® (API-1) compared to the placebo. There were no death or premature un-blinding during the study period, and there are no drug-related SAEs. The statistics of AEs, related AEs, or SAEs, of relevant subjects are indicated in the following table:

	Phase III Clinical Trials		
	Botreso® (API-1) 30 mg/day	**Placebo**	**Total**
	N=182 N (%)	**N=89 N (%)**	**N=271 N (%)**
Adverse Event (AE)	67 (36.8)	39 (43.8)	106 (39.1)
Related AE	9 (4.9)	6 (6.7)	15 (5.5)
5Serious Adverse Event (SAE)	2 (1.1)	2 (2.2)	4 (1.5)

The parameter of correlation of relevant subjects are indicated in the following table:

Parameter	**30 mg N = 182 n (%)**	**0 mg N = 89 n (%)**	**Total N = 271 n (%)**
Subjects with ≥ 1 TEAE	67 (36.8)	39 (43.8)	106 (39.1)
Definitely	1 (1.1)	0 (0.0)	2 (0.7)
Probably	1 (1.1)	0 (0.0)	2 (0.7)
Possibly	4 (2.2)	6 (6.7)	10 (3.7)
Not Related	59 (32.4)	33 (37.1)	92 (33.9)

The results of phase III clinical trials indicated that Botreso® (API-1) has fewer AEs and SAEs than that of placebo.

According to the US-c results of phase III OLEs, Botreso® (API-1) softgels showed excellent tolerability. No life-threatening adverse events occurred during 40/52 weeks of taking Botreso® (API-1) softgels.

	Phase III Clinical Trials (Long-term)			
	Botreso® (API-1) 0-30 mg/day	**Botreso® (API-1) 15-30 mg/day**	**Botreso® (API-1) 30 mg to 30 mg/day**	**Total**
	N=51 N (%)	**N=28 N (%)**	**N=102 N (%)**	**N=181 N (%)**
Adverse Event (AE)	25 (49.0)	5 (17.9)	42 (41.2)	72 (39.8)
Related AE	6 (11.8)	0 (0)	6 (5.9)	12 (6.6)
Serious Adverse Event (SAE)	3 (5.9)	0 (0)	6 (5.9)	9 (5.0)

The parameter of correlation of relevant subjects are indicated in the following table:

Parameter	**15 mg–30 mg N = 28 n (%)**	**30 mg–30 mg N = 102 n (%)**	**0 mg–30 mg N = 51 n (%)**	**Total N = 181 n (%)**
Subjects with ≥ 1 TEAE	5 (17.9)	42 (41.2)	25 (49.0)	72 (39.8)
Definitely	0 (0.0)	0 (0.0)	1 (2.0)	1 (0.6)
Probably	0 (0.0)	1 (1.0)	2 (3.9)	3 (1.7)
Possibly	0 (0.0)	5 (4.9)	3 (5.9)	8 (4.4)
Not Related	5 (17.9)	39 (38.2)	21 (41.2)	65 (35.9)

Most AEs were unrelated to Botreso® (API-1) as illustrated in the table above. In the group taking 30 mg-30 mg Botreso® (API-1), the occurrence of related AEs was all less than 1%. There were no related AEs reported in the group taking 15 mg-30 mg Botreso® (API-1).

According to the results of TWN-c Phase III OLEs, Botreso® (API-1) softgels showed excellent tolerability. No life-threatening adverse events occurred during 40/52 weeks of taking Botreso® (API-1) softgels.

	Phase III Clinical Trials (Long-term)		
	Botreso® (API-1) 0-30 mg/day	**Botreso® (API-1) 30 mg to 30 mg/day**	**Total**
	N=56	**N=124**	**N=180**
	N (%)	**N (%)**	**N (%)**
Adverse Event (AE)	39 (69.6)	71 (57.3)	110 (61.1)
Related AE	3 (5.4)	6 (4.8)	9 (5.0)
Serious Adverse Event (SAE)	2 (3.6)	5 (4.0)	7 (3.9)

The parameter of correlation of relevant subjects are indicated in the following table:

Parameter	**30 mg–30 mg N = 124 n (%)**	**0 mg–30 mg N = 56 n (%)**	**Total N = 180 n (%)**
Subjects with ≥ 1 TEAE	71 (57.3)	39 (69.6)	110 (61.1)
Definitely	1 (0.8)	0 (0.0)	1 (0.6)
Probably	1 (0.8)	0 (0.0)	1 (0.6)
Possibly	4 (3.2)	3 (5.4)	7 (3.9)
Not Related	69 (55.6)	39 (69.6)	108 (60.0)

Most AEs were unrelated to Botreso® (API-1) as illustrated in the table above. In the group taking 30 mg-30 mg Botreso® (API-1), the occurrence of related AEs was all less than 1%. There were no related AEs reported in the group taking 15 mg-30 mg Botreso® (API-1).

All identified serious adverse events have been determined to be “not related” to Botreso®, with the exception of a pancreatitis event observed in the MCS-2-US-c trial. In this instance, the pancreatitis lasted only three days, and the causality was assessed as “possibly related” but not “definitely related,” as the event was most likely attributable to Metformin, a medication used to treat diabetes mellitus.

Overall summary

The data of phase III clinical trials indicated that after taking Botreso® (API-1) softgels for 12 weeks, patients’ LUTS caused by BPH were improved as shown by the I-PSS results. When compared to the placebo group, despite the pivotal Phase III clinical trial for Botreso® (API-1) in the U.S. failing to demonstrate a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population, the remaining Botreso® (API-1) groups, including one phase III US open label extension study and two phase III studies conducted in Taiwan, still demonstrated a statistically significant improvement (P value < 0.05) based on meta-analysis. However, the U.S. FDA has expressed concerns regarding the reproducibility of some of the reported efficacy results for Study Botreso®- TWN-a. In addition, when compared with the baseline, there were significant decreases (P value < 0.05) in the I-PSS at Day 85, Day 169 and Day 281, which indicated long-term decreases in the I-PSS scores after taking Botreso® (API-1) softgels for up to 52 weeks.

There were no deaths reported for either the phase III clinical trials or the open-label extension studies. In the phase III clinical trials, the incidence of AEs was slightly higher in the placebo group when compared to the 15 mg and 30 mg Botreso® (API-1) treatment groups, respectively. The majority of reported AEs were considered unrelated to Botreso® (API-1).

As the U.S. FDA issued new statistical analysis standards in December 2016, we have to retain an outsourcing statistical team to re-create our study data programs, tabulation model and analysis data model database for its Phase III studies and evaluation of integrated safety and efficacy, in order to match with U.S. FDA’s electronic submission gateway, which resulted in a delay in our NDA submission in late 2021. This NDA was later withdrawn on November 30, 2022, and we currently do not have an NDA on file with the U.S. FDA.

However, the U.S. FDA also had concerns regarding the reproducibility of some of the reported efficacy results for Study MCS-2-TWN-a. On February 23, 2024, we received a written response from the U.S. FDA. In the response, the U.S. FDA noted again its concern that Study MCS-2-US-a did not demonstrate a statistically significant difference between the drug and placebo in the primary efficacy endpoint and concerns regarding the treatment effect of questionable significance in the Study MCS-2-TWN-a.

If the comparability is accepted by the U.S. FDA, we will conduct additional Phase III trial and Phase I PK study in the US using API-2 to support our NDA re-submission. If our comparability is not accepted by the U.S. FDA, we will need to work with other API vendor to demonstrate the comparability that meet U.S. FDA's requirements and would have to perform more clinical trials. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the Botreso® clinical trials using API-2. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

PCP

Disease Overview

Prostate cancer begins when cells in the prostate gland start to grow out of control. On a basic level, prostate cancer is caused by changes in the DNA of a normal prostate cell. Most gene mutations related to prostate cancer seem to develop during a man's life rather than having been inherited. In general, the more quickly prostate cells grow and divide, the more chances there are for mutations to occur. Therefore, anything that speeds up this process may make prostate cancer more likely. Although researchers do not know exact causes of prostate cancer, they have found some risk factors that might cause prostate cells to become cancer cells. Primary risk factors include age, race/ethnicity, geography, family history and gene changes. Factors with less clear effects on prostate cancer risk include diet, obesity, smoking, chemical exposures, inflammation of the prostate, sexually transmitted infections, and vasectomy. According to Frost & Sullivan, the global prevalence of prostate cancer increased from 10.0 million in 2017 to 11.2 million in 2020, representing a CAGR of 3.9%. The global prostate cancer market increased from US$9.7 billion in 2017 to US$12.6 billion in 2019, representing a CAGR of 9.1%. In addition, the prostate-specific antigen abnormal population, or PSA abnormal population, representing men over 40 years old with a prostate-specific antigen test value of 4.0 ng/ml or higher, is exposed to a high risk of prostate cancer. From 2015 to 2020, the total number of PSA abnormal populations in the U.S., Taiwan and China increased from 5.0 million to 5.3 million.

Current Standard Care

According to the U.S. National Cancer Institute, several protective factors may decrease the risk of prostate cancer. A 10-year study showed that the risk of prostate cancer was lower in men who had enough folate in their diets. Folate is a kind of vitamin B that occurs naturally in some foods, such as green vegetables, beans and orange juice. However, the risk of prostate cancer was increased in men who took 1 mg supplements of folic acid. Although some studies have shown that finasteride or dutasteride may lower the risk for prostate cancer, U.S. FDA made a safety announcement in June 2011 and informed that 5-Ari may increase the risk of a more serious form of prostate cancer (high-grade prostate cancer). Both finasteride or dutasteride may cause side effects such as impotence, decreased libido, ejaculation disorders, breast disorders, rash, asthenia, headache, hypotension, postural hypotension, peripheral edema, dizziness, somnolence, dyspnea, rhinitis, abnormal ejaculation, gynecomastia, dizziness, pruritus, urticaria, localized edema, serious skin reactions, angioedema, and sexual function abnormal. In addition, men with a benign prostatic hyperplasia diagnosis and exposed to 5-alpha reductase inhibitor had an increased association with cardiac failure. Currently, there is no drug available to prevent prostate cancer.

Mechanism of Action

Similar to Botreso®, PCP works through its mechanism of antioxidant and anti-inflammatory. PCP contains several types of patented pharmaceutical ingredients that reduce oxidative stress and inflammatory cytokines (IL-6), both of which are main causes of many chronic inflammatory diseases.

Antioxidant Activity

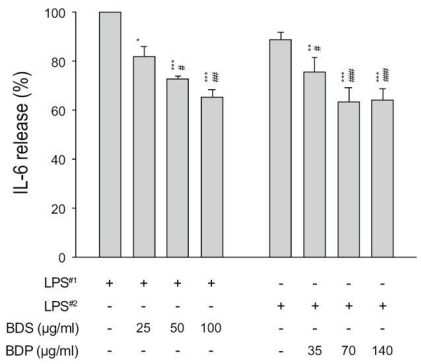
Free radicals are highly reactive chemicals that have the potential to harm cells. They are formed naturally in the human body and play an important role in many normal cellular processes. At high concentrations, however, free radicals can be hazardous to the human body and damage all major components of cells, including DNA, proteins, and cell membranes. The damage to cells caused by free radicals, especially the damage to DNA, may play a role in the development of cancer and other health conditions. Elevated rates of reactive oxygen species, or ROS, have been detected in almost all cancers, where they promote many aspects of tumor development and progression. A challenge for novel therapeutic strategies will be the fine-tuning of intracellular ROS signaling to effectively deprive cells of ROS-induced tumor-promoting events, towards tipping the balance to ROS-induced apoptotic signaling.

Antioxidants are also known as "free radical scavengers." Therapeutic antioxidants may prevent early events in tumor development. Antioxidants are chemicals that interact with and neutralize free radicals and thus prevent free radicals from causing damages. The pharmaceutical ingredients contained in PCP are potent antioxidants as they modify cell growth and induce apoptosis, and possess distinctive antioxidative properties including the protection of important biomolecules such as DNA from free radicals and thus could decrease incidence rates of cancers.

Anti-inflammatory Activity

Inflammation involves the induction of complex, coordinated chemical signals and associated physiological processes following an injury that promote the "healing" of damaged tissues. Early responses include increases in vascular permeability and activation, together with the directed migration of leukocytes (neutrophils, monocytes and eosinophils) towards the site of injury, where the groundwork is being laid for the formation of a new extracellular matrix. The directional migration is mediated by secreted chemokines (such as IL-6) that form a concentration gradient towards the site of inflammation. The extracellular matrix provides the structure upon which cells (fibroblasts and endothelial cells) can migrate and proliferate, regenerating new tissues and a vascular network. In the later stage of the inflammatory response, the macrophages are the dominant cell type, orchestrating and directing the healing process. Normally, inflammation is a self-limiting process due to the production of anti-inflammatory cytokines, which buffer the effect of pro-inflammatory cytokines. The cytokine/chemokine pattern persisting at the inflammatory site is important in the development of chronic diseases. The longer the inflammation persists, the higher the risk of associated carcinogenesis.

IL-6 is a prototypical cytokine with various biological effects on a wide variety of cells, which involves in the control of immune responses and inflammation. However, over production of IL-6 lead to severe disease complications. Therefore, as illustrated in the diagram below, IL-6-mediated inflammation could be a therapeutic target for prostate cancer, since anti-IL-6 receptor antibody administration suppressed tumor growth. PCP contains several types of patented pharmaceutical ingredients that can reduce IL-6 and thus address inflammation issues.



Notes:

(1) LPS means lipopolysaccharides which are large molecules consisting of a lipid and a polysaccharide that are bacterial toxins.
(2) BDS means botanical drug substance.
(3) BDP means botanical drug product.
(4) $LPS^{\#1}$ means 0.3 μg/ml LPS/0.1% DMSO.
(5) $LPS^{\#2}$ means 0.3 μg/ml LPS/0.1% DMSO and 0.004% soybean oil.
(6) * means $P < 0.05$, ** means $P < 0.01$ and *** means $P < 0.001$ compared with $LPS^{\#1}$.
(7) # means $P < 0.05$, ## means $P < 0.01$ and ### means $P < 0.001$ compared with $LPS^{\#2}$.

The purpose of this study is to evaluate the anti-inflammation effect of BDS and BDP by measuring LPS-induced IL-6 release. The data demonstrated that both BDS and BDP showed a concentration-dependent inhibition of LPS-induced IL-6 release. LPS is one of the main etiological factors in the pathogenesis of several diseases. LPS has been shown to stimulate host cells, including macrophages and fibroblasts, to produce cytokines. LPS can markedly increase the production of IL 6, IL 8 and TNF α in differentiated THP 1 cells. Therefore, based on an important pro-inflammatory cytokine, the IL-6 levels stimulated by LPS can be determined for the understanding of anti-inflammatory activity of the PCP.

Interleukin (IL)-6 is produced at the site of inflammation. IL-6 exerts stimulatory effects on T- and B-cells, thus favoring chronic inflammatory responses. Although its expression is strictly controlled by transcriptional and posttranscriptional mechanisms, dysregulated continual synthesis of IL-6 plays a pathological effect on chronic inflammation and autoimmunity. BDS (25, 50 and 100 μg/ml) and BDP (35, 70 and 140 μg/ml) were used, respectively. The data demonstrated that both BDS and BDP showed a concentration-dependent inhibition of LPS-induced IL-6 release in differentiated THP-1 cells, suggesting an anti-inflammatory activity of PCP.

Clinical Data

Phase I Clinical Studies

Phase I clinical studies of PCP focused on pharmacokinetics and clinical drug-drug interaction studies.

Pharmacokinetics

The study of pharmacokinetics of PCP was a randomized, balanced, single-dose, two-treatment (fed versus fasted) study in healthy male adult volunteers. The study was designed to evaluate the PK of PCP when the product was administered in the fed and fasted state. A total of 47 subjects were randomized to receive a single dose either in the fed (24 subjects) or fasted (23 subjects) state, and the PK parameters were evaluated and compared for the 2 groups of subjects. Relevant trials were initiated on April 22, 2015 and completed on April 24, 2017, with 23 subjects in fed group and 22 subjects in fasted group had completed the study.

As to the efficacy of PCP, the study compared serum active ingredient levels of five major biomarkers,
PL, PF, PE, TC and BC (drug codes for carotenoid chylomicrons), in subjects taking PCP after a meal with those taking PCP on an empty stomach, and found that the proportion of active ingredient absorbed after a meal was better than after an empty stomach. Subjects were randomized to two groups in order to obtain their pre-prandial or postprandial medication status. The results showed that the adverse effects were well tolerated irrespective of the timing of administration (postprandial or postprandial), although absorption rates were higher when PCP were taken after meals.

As to the safety profile of PCP, data indicated that 22 subjects, or 46.8%, of all subjects reported at least one treatment emergent adverse event, or TEAE, during the study. The fasted group has a higher TEAEs rate (60.9%) than the fed group (33.3%), but the rate of Aes was similar for the two groups. Overall, the most frequently reported TEAEs were headache (19.1%), upper respiratory tract infection (8.5%), back pain (4.3%) and nasopharyngitis (4.3%). The fasted group reported higher rate of headaches than the fed group. The two groups had similar rates for other TEAEs. There were no serious, severe, or life-threatening TEAEs and no deaths. No TEAEs resulted discontinuation of the study. Other data such as the changes in blood pressure, heart rate, respiratory rate, weight and temperature were generally small and clinically insignificant.

Clinical Drug-Drug Interaction

The study of clinical drug-drug interaction of PCP was an open-label, fixed-sequence, drug-drug interaction study to evaluate the effect of PCP on the pharmacokinetics of 24 healthy male subjects. Relevant trials were initiated on May 20, 2018 and completed on September, 2018. A total of 24 subjects were enrolled in the study and 23 of them completed the study. One subject discontinued the study primarily due to a failure to meet compulsory criteria.

Since our in vitro drug-drug interaction study conducted in the U.S. concluded that our drug substance may be an inducer of CYP3A4 and CYP2B6 based on the calculated R values (< 0.9). U.S. FDA suggested that we further investigate the potential drug-drug interactions by conducting a clinical drug-drug interaction study using a sensitive index substrate. The sensitive index of substrate is midazolam for CYP3A4 and bupropion for CYP2B6, respectively. Therefore, we conducted such study to assess the effect of PCP on the PK of midazolam and bupropion following U.S. FDA's suggestion in 2018. The coadministration of PCP with midazolam and bupropion generally would not affect the efficacy of midazolam and bupropion, and concluded that PCP is not an inducer of both midazolam (CYP3A4) and bupropion (CYP2B6).

The primary objective of this clinical drug-drug interaction study was to assess the effect of PCP on the PK of midazolam and bupropion in healthy male subjects. The results indicated that the peak exposure (Cmax) and the total exposure to midazolam were not significantly affected by the co-administration of PCP. The total and peak exposures of bupropion, midazolam, and their measured metabolites were not significantly altered after multiple daily doses of PCP. The median time to peak concentration (Tmax) of bupropion, midazolam and their measured metabolites was not affected by multiple daily doses of PCP.

The safety data Indicated that the administration of Botreso® alone or the co-administration of Botreso®, midazolam and bupropion was generally tolerated by healthy male subjects in this study. Seven of 24 subjects (29.2%) treated with midazolam, bupropion, and/or PCP experienced a total of 10 TEAEs. Six of 24 subjects (25.0%) treated with midazolam or bupropion experienced seven TEAEs. One of 24 subjects (4.2%) treated with PCP alone experienced two TEAEs. One of 23 subjects treated with midazolam/bupropion and PCP experienced one TEAE. The most frequently reported TEAEs were somnolence and others included headache, dry skin, macule, skin irritation and cough. However, 30% of TEAES were assessed as unrelated to the study. All TEAEs were assessed as mild in severity and fully recovered or resolved at the end of the study. No TEAE resulted discontinuation of the study and no SAEs or deaths were reported.

Overall summary and conclusions

According to the phase I clinical studies, the administration of a single oral PCP was well-tolerated among 24 subjects in both the fed and fasted states. Subjects absorbed active ingredients of PCP better when they took PCP after meals. The administration of Botreso® alone or the co-administration of Botreso®, midazolam and bupropion was generally tolerated by healthy male subjects in this study. The coadministration of PCP with midazolam and bupropion generally would not affect the efficacy of midazolam and bupropion.

Phase II Clinical Studies

Phase II clinical study of PCP was a double-blind, randomized, placebo-controlled, parallel one, with a group of 702 subjects for a two-year treatment of three arms, i.e. 15 mg PCP per day, 30 mg PCP per day, and placebo. As approved by TFDA, phase II clinical trials were initiated in November 2014. 20 medical centers in Taiwan were involved. The 702 subjects were men with high levels of prostate specific antigen, or PSA. As of the data of this annual report, phase II clinical trials are still in process. Our PCP Phase II study enrollment and treatment phase using API-1 completed source data verification (SDV) stage. PCP has completed the data lock in May 2025, and statistical analysis was completed in September 2025. The results indicated it met its primary endpoint, showing a positive trend in positive biopsy rates and incidence of higher-grade prostate cancer after 104 weeks of administration. In addition, beyond the oncological efficacy, the Phase II data indicated a significant secondary potential therapeutic profile regarding metabolic regulation. Those patients treated with PCP for two years exhibited a statistically significant reduction in total cholesterol ($P = 0.036$) and LDL levels ($P = 0.018$). The study further highlighted a favorable lipid-modulating trend where the PCP group showed decreased triglycerides ($P = 0.05$), alongside a significant increase in HDL ($P = 0.003$). In contrast, the placebo group experienced a statistically significant rise in fasting glucose ($P = 0.022$), however, the fasting glucose was stable ($P>0.05$) in the PCP group.

We are working with the U.S. FDA to establish the comparability of the API-1 and API-2. To date, we have not had any discussions with the TFDA regarding the unavailability of API-1. We will discuss the statistical results of the PCP using API-2 with Taiwan regulator and proceed with the Phase III PCP study if the U.S. FDA accepts such results and determines that API-1 and API-2 are comparable. The PCP shall not proceed to Phase III until the U.S. FDA accepts the results and determines that API-1 and API-2 are comparable.

We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2 and submitted it to the U.S. FDA on October 16, 2024, and are awaiting feedback from the U.S. FDA. As of the date of this annual report, the Company is still in the process of providing the information required by the U.S. FDA and has not yet successfully demonstrated the comparability of API-1 and API-2.

We are currently collaborating with a supplier to prepare the API-2 CMC documents required by the U.S. FDA. Should the FDA concur that API-1 and API-2 are similar and comparable, we will sign the Quality Agreement with this supplier for the raw materials for API-2. If the U.S. FDA does not agree that API-1 and API-2 are comparable, we will continue to research additional API sources based on our own patent, to pursue additional outsourcing API vendors, and to follow U.S. FDA's guidance for demonstrating comparability between API-1 and API-2 to the U.S. FDA's satisfaction. If the U.S. FDA does not agree that API-1 and API-2 are comparable, we will continue to research additional API sources based on our own patent, to pursue additional outsourcing API vendors, and to follow U.S. FDA's guidance for demonstrating comparability between API-1 and API-2 to the U.S. FDA's satisfaction. In the event that we are unable to establish comparability between API-1 and API-2, we will be required to repeat the PCP clinical trials using API-2. For further details, see the risk factor titled "If we are unable to identify a supplier capable of producing API-2 that is sufficiently comparable to API-1, we will be required to repeat our clinical trials for Botreso® and PCP, which could significantly delay our product development efforts and result in increased costs" on page 13.

Material Communications

As of the date of this annual report, we have not received any relevant regulatory authority's concerns or objections to our clinical development plans and no material unexpected or adverse changes have occurred since the date of issue of relevant regulations for PCP.

IC

Disease Overview

According to the definition adopted by American Urological Association, interstitial cystitis/bladder pain syndrome, or IC/BPS, refers to a bladder pain disorder that is often associated with voiding symptomatology and other systemic chronic pain disorders. The exact cause of IC/BPS is still not clear. Pain (including sensations of pressure and discomfort) is the hallmark symptom of IC/BPS. The prototypical IC/BPS patient also may present with marked urinary urgency and frequency. IC/BPS is most commonly diagnosed in individuals over 40, although the diagnosis may be delayed depending upon the index of suspicion for the disease, and the criteria used to diagnose it. IC/BPS most often affects women and can have a long-lasting impact on quality of life. Historically, IC/BPS in men has been considered relatively unusual with a female to male ratio of 10:1. However, uncontrolled clinical series over the past two decades have suggested the incidence of male IC/BPS may be higher than previously observed.

Current Standard Care

Current standard care for IC/BPS include: (i) behavioral/non-pharmacologic treatments; (ii) oral medications; (iii) intravenous injection and intravesical instillations; (iv) nerve stimulation; and (v) surgeries including fulguration, resection, bladder and augmentation. Intravesical instillations refers to a procedure where the prescription medication is placed into patients' bladders through a thin, flexible tube inserted through the urethra. Nerve stimulation techniques include transcutaneous electrical nerve stimulation, which may relieve pelvic pain and, in some cases, reduce urinary frequency; and sacral nerve stimulation, which may reduce urinary urgency but cannot relieve pains. Since surgery is irreversible and life-altering, it is rarely used to treat IC/BPS. While some patients have complete or near-complete symptom resolution after surgery, others have poor outcomes including persistent pain (even if the bladder is removed), complications or new symptoms with lifelong significant bother. Among all the treatment categories stated above, intravenous injection and intravesical instillations are comparatively effective methods to treat IC/BPS.

Clinical Data

Preclinical Studies

Data from our preclinical studies show that the micelles have favorable characteristics and stability. IC micelles with a target size of micromulsion under 100nm were developed for injection. We adopt a microemulsion technique of sonicating the mixture of substrate and surfactants and filtering through a sterilized 0.22-um membrane filter to obtain micelle. As a result, the mixture passed through a sterilized 0.22-um membrane filter to cut the bigger particles of micelle into the size of approximately 7.5 nm and 10.5 nm, respectively, with the narrow particle size distribution of low polydispersity of 0.033. The average size of micelle, based on the dynamic light scattering, or the DLS, and transmission electron microscopy analyses, is approximately 7.5 nm and 10.5 nm, respectively. The particle size distribution is narrow with low polydispersity of 0.033 being shown, indicating that a highly homogeneous microemulsion, the transparent or semi-transparent thermodynamically stable emulsion formed by two immiscible liquids, oil and water in the presence of surfactant or co-surfactant, has been successfully prepared. The zeta potential value of micelle implies a good stability of microemulsion. During the storage at 4°C or 25°C for three months or the heating at 100°C for four hours, only a minor difference in particle size (7.0 – 7.5 nm) was shown for micelle by the DLS analysis, demonstrating a high stability of this microemulsion.

COMMERCIALIZATION

Commercialization strategies

We are establishing a strong sales and marketing team dedicated to the commercialization of our pipeline drug candidates, especially for the commercialization of Botreso®. We expect our sales and marketing team in Taiwan to have employees with rich experience. We will also actively seek for cooperation with local pharmaceutical companies in other territories in order to benefit from their sales and marketing network. There will be a senior product manager who is familiar with Botreso® and we expect he or she will be primarily responsible for strategies' formulation. The head of our sales and marketing department, senior manager-level personnel, most of the regional managers and the preliminary sales team are in place as of the date of this annual report. In the U.S., we retained a local company to conduct the value research survey among urologists and payers and obtained positive feedbacks.

Leveraging the expertise and industry connections of our team, we will market the products primarily through a physician-targeted marketing strategy, focusing on direct and interactive communication with key opinion leaders and physicians in the respective therapeutic areas to promote the differentiating clinical aspects of our products. Such marketing efforts are expected to commence several months before the expected approval for the commercialization of a drug candidate. We will also actively organize academic conferences and seminars to publicize the clinical data and research results in relation of our drug candidates in order to raise our brand awareness and recognition. We are also pursuing licensing relationships with global pharmaceutical companies to promote and market our products worldwide.

Pricing Strategy

We primarily consider two factors when formulating our pricing strategies: (i) the overall impact of our drug candidates in the international market; and (ii) the market positioning of our drug candidates. When considering the first factor, if our drug candidate is expected to be marketed internationally, we will fully consider the global market price rather than the market price in a single region. When considering the second factor, we will evaluate the overall costs of production, market demand, targeted patients and competitive advantages in order to decide the proper position of our drug candidate.

We plan to position Botreso® as a high-end product in the BPH/LUTS pharmaceuticals market. In Taiwan, we expect to sell Botreso® through our own marketing team and we have consulted with the Bureau of National Health Insurance Ministry of Health and Welfare, or Taiwan NHI, regarding the pricing of Botreso®. Based on our preliminary communications, Taiwan NHI can determine the payment of new drugs developed in Taiwan by means of "cost-plus pricing" or "market reference price." Therefore, we expect that in the first two years after the launch of Botreso® in Taiwan, Botreso® might not be immediately included in the reimbursement list and patients need to purchase it at their own costs. In other territories, since we plan to cooperate with local pharmaceutical companies for the sale of Botreso®, we will make necessary adjustments depending on the pricing of comparable drugs and the local medical insurance payment level in each specified target market. In particular, our consultant in U.S. along with her commercial strategy team have conducted a price sensitivity analysis based on updated market predictions. We plan to collaborate with a renowned U.S. pharmaceutical company to distribute our Botreso® in U.S. market.

LICENSE AND COLLABORATION AGREEMENTS

Chhak License Agreement

In April 2016, we entered into a pharmaceutical license agreement with a Cambodian corporation, Chhak Kamponngsaom Sez Co., Ltd., or the "Chhak License Agreement." Under the Chhak License Agreement, we granted Chhak Kamponngsaom Sez Co., Ltd., or Chhak, exclusive sale and marketing rights of Botreso® in Cambodia, and Chhak agreed not to sub-license any rights related to Botreso® without our prior written consent. Chhak also agreed to use the best efforts to help us obtain necessary regulatory approvals for Botreso® and to promote and enhance the sale of Botreso® in Cambodia. We agreed to provide Chhak with information related to Botreso® as may be known or possessed by us and as may be reasonably necessary for the sale and marketing of Botreso® in Cambodia. We would be Chhak's sole manufacturer and supplier of Botreso®. In addition, we owned all the intellectual property rights of Botreso® or any improvements to Botreso® and we both agreed to maintain the other party's confidential information in confidence.

Under the terms of the Chhak License Agreement, Chhak should pay license fees with a total amount of US$0.25 million In addition, upon the regulatory approval of Botreso® in Cambodia, Chhak should pay us a royalty of 25% of its net sales of Botreso® every six months. Chhak should also deliver to us a written report showing its computation of royalties due under this agreement. We reserved the rights to review Chhak's book, records and other supporting data as may be necessary to verify Chhak's computation of royalties.

We should indemnify and hold harmless Chhak, from and against any and all claims, losses, costs, damages, fees and expenses arising out of or in connection with intellectual property right infringement. Chhak agreed to indemnify, held harmless and defended us (including our directors, officers, employees and agents) from and against any and all losses we became legally obligated to pay due to any claim against Chhak (i) arising out of Chhak's breach of this agreement; or (ii) for any product liability, liability for death, illness, personal injury or other liabilities under any laws re regulations, to the extent that such claims are due to reasons caused by Chhak.

Chhak would have the right to terminate this agreement in its entirety by providing us with 60 days prior written notice. We would have the right to terminate this agreement if (i) Chhak experienced a change of control; (ii) the quantity of Botreso® sold by Chhak was diverted to other markets; (iii) we reasonably determined that Chhak was unable to maintain the quality of Botreso®; (iv) Chhak was in material breach of its duties of non-sublicensing and confidentiality or violated the consensus that we were the sole manufacture and provider of Botreso®, or (v) Chhak became insolvent. We would not be held liable for any losses Chhak might incur if we terminated the agreement based on any of the aforementioned five reasons. In case either party breached the agreement, the non-breaching party under the Chhak License Agreement would have the right of termination but should provide written notice to the breaching party to cure such breach, and no party should be relieved of any obligations incurred prior to such termination.

In case either party breached the agreement, the non-breaching party under the Chhak License Agreement would be able to terminate this agreement but should provide a written notice to the breaching party who would be given a chance to cure such breach.

Taizhou Collaboration Framework Agreement

On December 21, 2018, we entered into a collaboration framework agreement, or the "2018 Taizhou Agreement," with Taizhou High-tech Industrial Park Management Committee, or the "Taizhou High-tech Committee," and Taizhou Infrastructure Investment Group Co., Ltd., pursuant to which Taizhou High-tech Committee agreed to grant up to (i) 40 mu (approximate 26,666.66 sq.m.) industrial land to us with a favorable price of RMB0.4 million per mu, (ii) 20 mu commercial land to us with a favorable price of RMB4.08 million per mu and (iii) 1,500 mu industrial land to us subject to further negotiation. Under the 2018 Taizhou Agreement, we might also receive several government grants and subsidies when we met prerequisites as agreed. 2018 Taizhou Agreement does not specify the term and termination provision. We would conduct projects under the 2018 Taizhou Agreement primarily through our subsidiary in China, Innovative Biotech Co., Ltd., which was established in 2019 pursuant to the 2018 Taizhou Agreement.

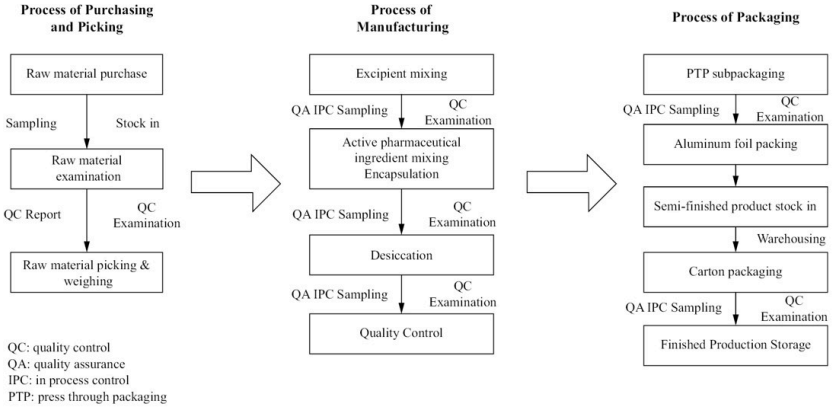
On September 12, 2019, based on the 2018 Taizhou Agreement, we entered into an investment cooperation agreement with the successor of the Taizhou High-tech Committee, or the 2019 Taizhou Agreement, which further specified details relating to projects related to Botreso® manufacturing facilities with no material deviation from the 2018 Taizhou Agreement. 2019 Taizhou Agreement does not specify the term and termination provision. In December 2019, under the terms and conditions of the Land Use Right Agreement with the Taizhou Resources Bureau, Innovative Biotech Co., Ltd. obtained the use right over 26,680 square meters of industrial land in Taizhou by paying a consideration of RMB16.5 million with tax included. According to such Land Use Right Agreement, Innovative Biotech Co., Ltd. was obligated to commence construction of the Factory Project by May 28, 2020, and conclude construction by November 28, 2022, as well as to meet several requirements on the specifics of the construction, including, but not limited to, the amount of the total investment, investment amount per mu, proportion of land dedicated to non-production facilities, plot ratio, and building density. As of the date of this annual report, the 26,680 square meter industrial land we acquired for the factory project have been seized by the Taizhou Court. For risks associated with the legal proceeding, see more details under "Item 3. Key Information — D. Risk Factors — Risks Related to Our Business and Industry — We have been involving in legal proceedings in the ordinary course of our business, and are currently involved in active legal proceedings.

MANUFACTURING AND QUALITY CONTROL

We are preparing for commercial-scale manufacturing capabilities to ensure large scale delivery of high-quality products. We have already built Yilan Letzer Pharmaceutical Factory with an aggregate GFA of approximately 1,944 sq.m. Our manufacturing team consists of three employees as of the date of this annual report.

We have in-house capabilities to manufacture our drug candidates, and we employ advanced technology to produce our core drug candidate Botreso®. Yilan Letzer Pharmaceutical Factory intends to adopt PIC/S GMP standard of production and was authorized by TFDA to conduct drug manufacturing, packaging, laboratory operations, transportation, and storage. We expect our new manufacturing facilities in Yilan and Taizhou will be in compliance with PIC/S GMP standards and have sufficient capacity to meet our commercial manufacturing needs in the foreseeable future.

The following flowchart indicates our general process of drug manufacturing we designed for future production:



Our Quality Assurance team performs the quality control function to oversee the quality of our facilities and our products, as well as the quality systems in research and development, manufacturing and commercialization of drug candidates and potential future commercial products. The tasks for quality control include (i) ensuring quality control throughout the manufacturing process, including specification of the drug substance and the drug product, testing of raw materials, and product quality assessments; (ii) establishing a quality assurance system across the entire business, including employee training programs, audits of various business segments and product manufacturing; and (iii) validation of facilities and equipment, which includes laboratory tests to verify that a particular process, method, program, equipment or material works properly.

SUPPLIERS

We procure raw materials and equipment for the development and manufacture of our drug candidates from industry-leading and highly reputable manufacturers and suppliers around the world. For the years ended December 31, 2024 and 2025, our purchases from our five largest suppliers in the aggregate accounted for approximately 75.5%, and 88.41% of our total purchases, respectively. Our purchases mainly include raw materials, third-party contracting services for research and development purposes, machines and equipment, clinical trials, project construction and administrative services. When choosing our suppliers, we consider their qualification and reputation, their response speed in general, and the proposed pricing. There are several raw material suppliers and third-party contracting services we can choose from, providing alternatives if the suppliers that the company works with are unable to provide the material or service we need. However, the stability of the raw material supplier is critical to our business. We must assess the quality of the raw materials before selecting an outsourcing supplier. Changing suppliers and sourcing new materials will necessitate additional clinical studies and potentially regulatory approval, significantly impacting our business and potentially delaying our regulatory approval process. To initiate the additional Phase III and Phase I PK studies, it is necessary to first identify a supplier for the raw materials required to produce API-2. We are currently collaborating with one supplier to prepare the CMC documents mandated by the U.S. FDA. Should the FDA concur that API-1 and API-2 are similar and comparable, we will sign the Quality Agreement with this supplier for the raw materials for API-2. We will only be able to proceed with the Phase III PCP study after the U.S. FDA accepts such results and determines that API-1 and API-2 are comparable. If there is any possibility that FDA does not agree that API-1 and API-2 are comparable, we will work with another supplier who is able to meet the comparability.

We used one supplier for API-1, which was the basis for our now withdrawn NDA. The supplier of API-1 sold a parcel of its land and is in the process of relocating and reconstructing its manufacturing facility, and as a result, API-1 is currently not available to us and the supplier of API-1 withdrew its consent for us to reference their Drug Master File on file with the U.S. FDA. We have been conducting further research and development on Botreso® and identified an additional source for the botanical drug substance API-2. API-1 and API-2 are similar drug substances covered by the same patent owned by us; however, because they are sourced from raw materials manufactured in different locations, the U.S. FDA required us to do the comparability study. Only when FDA concur that API-1 and API-2 is comparable, we are able to conduct the Phase I PK study and Phase III clinical trial with this API-2.

The U.S. FDA provided written responses on February 23, 2024. In the response, the U.S. FDA questioned whether one new Phase study with API-2 would be sufficient, noting again its concern that Study MCS-2-US-a did not demonstrate a statistically significant difference between the drug and placebo in the primary efficacy endpoint and concerns regarding the treatment effect of questionable significance in the Study MCS-2-TWN-a. The U.S. FDA also commented that it will need more information on how we would demonstrate comparability between API-1 and API-2 and that its determination of whether our original Phase III studies with API-1 would have utility, based upon the quality of support, for a convincing link between products containing API-1 and API-2. The U.S. FDA provided comments on our proposed Phase III study, and we are finalizing the protocol for submission to the U.S. FDA. In addition, we are in the process of finalizing the PK study protocol per U.S. FDA requirements and hope to satisfy the U.S. FDA of the comparability between API-1 and API-2.

COMPETITION

Our industry is highly competitive, rapidly evolving and subject to significant change. Although we believe that our core competencies in the identification, research and development of innovative therapies and our management team's regulatory and commercialization expertise provide us with distinct competitive advantages, we face significant competition from companies of all sizes around the world, including major and specialty pharmaceutical companies, generic drug companies, academic institutions, government agencies and research institutions.

Many of our competitors have significantly greater resources, including greater access to capital, technical capabilities and human resources, as well as more experience in the development and regulatory approval process than we have. Mergers and acquisitions in our industry may result in even more resources being concentrated among a smaller number of our competitors. Our commercial opportunities could be reduced or eliminated if our competitors develop or market novel therapies or other products that are more effective, safer or less costly than our current or future product candidates, or obtain regulatory approval for their products more rapidly than we may obtain approval for our product candidates.

OUR HONORS AND AWARDS

We have received numerous honors and a wealth of awards for our innovative drug development achievements. From 2004 to 2020, we were consecutively endorsed the Symbol of National Quality (SNQ) by the Institute for Biotechnology and Medicine Industry in Taiwan. As early as 2008, our core drug candidate, Botreso®, was recorded in *Physician's Desk Reference 2009 (63rd Edition)*, a widely used source of drug information by American physicians and patients. The following table sets forth significant honors and awards we have received over the years:

Honor/Award Name	Issuing Authority	Year
National Pharmaceutical Science and Technology Research and Development Award	Food and Drug Administration, Department of Health, Taiwan	2009
Biotech and New Pharmaceuticals Company	Ministry of Economic Affairs, Taiwan	2010
Taipei Biotechnology Award – Invention and Creation Award	Taipei Municipal Government, Taiwan	2012
National Industrial Innovation Award	Ministry of Economic Affairs, Taiwan	2015
Biotech and New Pharmaceuticals Company	Ministry of Economic Affairs, Taiwan	2015
Drug Research and Development Science and Technology Award	Department of Health and Ministry of Economic Affairs, Taiwan	2016
Drug Research and Development Science and Technology Award	Department of Health and Ministry of Economic Affairs, Taiwan	2017
National Invention and Creation Award	Ministry of Economic Affairs, Taiwan	2018
Taipei Biotech Awards: Innovation Award-Pharmaceutical Category Gold Award	Taipei Municipal Government, Taiwan	2025

INTELLECTUAL PROPERTY

Intellectual property rights are important to the success of our business. We actively seek patent protection for our drug candidates in Taiwan and other major jurisdictions worldwide, and file additional patent applications, when appropriate, to cover improvements to our technologies. We rely on a combination of patents, trademarks and trade secrets as well as employee and third-party confidentiality agreements to safeguard our intellectual property.

As of the date of this annual report, we were not involved in any proceedings in respect of, and we had not received notice of any claims of infringement of, any intellectual property rights that may be threatened or pending, in which we may be a claimant or a respondent.

Patents

All of our patents are self-developed based on our in-house R&D capabilities. We either own all material patents for each of our product candidates or have filed relevant patent applications with the authorities. The term of individual patents depends on the legal term for patents in the jurisdictions in which they are granted. The following table indicates our key invention patents which have all been granted as of the date of this annual report:

Type	Territory	Period of Validity
Invention – Composition of matter (medical grade ingredients)	Taiwan	May 1, 2016 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	South Korea	January 18, 2017 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Singapore	April 13, 2017 to December 9, 2034
Invention – Composition of matter[(1)] (medical grade ingredients)	United States	January 10, 2017 to December 9, 2034
Invention – Composition of matter[(2)] (medical grade ingredients)	United States	March 28, 2017 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Japan	June 30, 2017 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Malaysia	January 30, 2018 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Philippines	June 20, 2018 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Vietnam	December 4, 2020 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Russia	March 29, 2018 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Indonesia	July 10, 2018 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Saudi Arabia	September 16, 2018 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	China	December 18, 2018 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Canada	April 2, 2019 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Macao	May 9, 2019 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Israel	July 1, 2019 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Hong Kong	January 17, 2020 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	India	February 16, 2024 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	Thailand	August 23, 2023 to December 9, 2034
Invention – Composition of matter (medical grade ingredients)	European	April 10, 2024 to December 9, 2034

Notes:

(1) The patent number is 9,539,219 B2, and the patent is pharmaceutical composition of carotenoid micelle. IC is covered by this patent with the compositions comprising a micelle and a carotenoid, suspended in an aqueous solution and suitable for intravenous administration.

(2) The patent number is 9,603,811 B2, and the patent is pharmaceutical composition of carotenoid with chylomicron technology. Botreso® and PCP are both covered by this patent for oral administration. This invention covers pharmaceutical compositions comprising carotenoid with chylomicron technology. The bioavailability of the carotenoid with chylomicron technology in the pharmaceutical composition is higher than the bioavailability of free carotenoid.

Trade secrets

In addition to patents, we also rely upon unpatented trade secrets and know-hows and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology and information, in part, by entering into confidentiality agreements with our senior management and certain key members of our research and development team and other employees who have access to trade secrets or confidential information about our business.

Trademarks and domain names

As of the date of this annual report, we have 58 trademarks in 46 territories.

As of the date of this annual report, we have registered the following domain names: hebiotech.com and healtheverbiotech.com.

LICENSES, PERMITS AND APPROVALS

As of the date of this annual report, we have obtained all requisite licenses, permits and approvals from relevant authorities that are material to our pharmaceutical manufacturing operations. The table below sets forth the relevant details of the material licenses we hold for our operation in Taiwan:

License/Permit	Holder	Issuing Authority	Issue Date	Expiration Date
Pharmaceutical Manufacturing License	Health Ever Bio-Tech Co., Ltd., Yilan Letzer Pharmaceutical Factory	Department of Health, Taiwan	October 23, 2014	N/A
Factory Registration Certificate	Health Ever Bio-Tech Co., Ltd., Yilan Letzer Pharmaceutical Factory	Yilan County Government, Taiwan	August 31, 2018	N/A

EMPLOYEES

As of the date of this annual report, we had 27 employees in total. The following table sets forth the number of our employees categorized by function as of the date of this annual report:

Function	Number	% of Total
Management	5	18.52
Auditing Office	1	3.70
Information Center	1	3.70
R&D and Manufacturing Department	14	51.85
Financial and Accounting Department	4	14.81
Business Operation and Development Department	2	7.42
Total	**27**	**100.0**

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. We also enter into separate confidentiality and non-competition agreements with our senior management and certain key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

To maintain the quality, knowledge and skill levels of our workforce, we provide continuing education and training programs, including internal and external training, for our employees to improve their technical, professional or management skills. We also provide training programs to our employees from time to time to ensure their awareness and compliance with our policies and procedures in various aspects.

We consider our relations with our employees to be good. As of the date of this annual report, we have not experienced any strikes or labor disputes which had a material effect on our business.

FACILITIES

Our headquarters is located in New Taipei, Taiwan. As of the date of this annual report, the approximate GFA of our leased properties was approximately 1,964.8 sq.m. in aggregate. As of the same date, we owned two properties with approximately 1,944.88 sq.m. in aggregate in Yilan County, Taiwan, two parcels of land with approximately 4,000.2 sq.m. in aggregate in Yilan County, Taiwan. We believe our properties are sufficient for our current needs and that, should it be needed, suitable additional space will be available on commercially reasonable terms to accommodate any such expansion of our operations.

LEGAL PROCEEDINGS AND COMPLIANCE

In the ordinary course of our business, we are subject to legal or administrative proceedings from time to time. As of the date of this annual report, we are a party to a legal dispute with one of our shareholders concerning a claim of redemption, which may have material and adverse impact on our business, financial condition, or the results of operations.

Taizhou Investment Dispute

On May 15, 2019, Taizhou City Optimization and Upgrade Investment Partnership (Limited Partnership), or the Plaintiff, entered into a share purchase agreement, or the Share Purchase Agreement, with (i) Medi-life Co., Limited and Sira View Corp., collectively, the Transferring Shareholders, (ii) Jyong Biotech Ltd., or "Jyong," (iii) our Taiwan subsidiary, Health Ever Bio-Tech Co., Ltd., or HEB, and (iv) our CEO, Ms. Fu Feng Kuo, under which the Plaintiff purchased 1,794,258 shares of Jyong from the Transferring Shareholders at an aggregate price of RMB112,500,000 (US$16,366 thousand), or the Share Purchase Transaction. Pursuant to the Share Purchase Agreement, on July 1, 2019, our Hong Kong subsidiary, Top ShunXing Bio-Tech Co., Limited, or Top ShunXing, established our only PRC subsidiary, Innovative Biotech Co., Ltd., or Innovative Biotech, and later on July 22, 2019, Top ShunXing pledged 100% equity interests in Innovative Biotech to the Plaintiff as a guarantee for the performance of buyback shares obligation of the Transferring Shareholders, if Jyong would not accomplish the "Qualified Issuance and Listing" (defined as Jyong's potential public filing of shares and listing on the main board of the HKEx which never occurred) within 5 years after the closing of the Share Purchase Transaction, or any other redemption events occurred under the Share Purchase Agreement. Please also see "Note 18 Commitments and Contingencies — Commitment with the Taizhou Company" on pages F-26 and F-27 for more details. In August 2022, we sent a written notice to the Plaintiff by mail and informed that we were preparing for our IPO. However, as of the date of this annual report, we have not received the Plaintiff's written consent as required under section 8 of the Share Purchase Agreement.

On November 15, 2022, we received a complaint for civil suit filed by the Plaintiff to the Taizhou Intermediate People's Court, or the Taizhou Court, against the Transferring Shareholders, Jyong, HEB, Top ShunXing, Innovative Biotech and Ms. Fu Feng Kuo (collectively, the "Defendants"), requesting, among other claims: (i) redemption by the Transferring Shareholders for all shares purchased by the Plaintiff under the Share Purchase Agreement for the original purchase price of RMB112,500,000 (US$16,366 thousand) and corresponding interests from July 29, 2019 to the date of actual payment calculated at the loan prime rate in China, or the Redemption; (ii) the Taizhou Court to hold Jyong, HEB and Ms. Fu Feng Kuo jointly liable for the Redemption; (iii) the Taizhou Court to confirm Plaintiff's right to liquidate all equity interest in Innovative Biotech held by Top ShunXing that was pledged to the Plaintiff; and (iv) the Taizhou Court to hold Innovative Biotech liable for the obligations of other Defendants within the scope of the benefits it received from the investment made under the Share Purchase Agreement. This dispute went on trial before the Taizhou Court on March 16, 2023 and November 29, 2023, respectively. We estimated the fair value of guarantee liabilities at the fair value of the shares at the inception of this guarantee and recorded guarantee liabilities of US$19.4 million and accrued liabilities – guarantee obligation of US$21.6 million as of December 31, 2024 and 2025, respectively. On March 25, 2024, the Taizhou Court entered into a judgement partially in favor of the Plaintiff, ordering, among other things, the Transferring Shareholders to pay the Redemption price of RMB112,500,000 and corresponding interests, and Jyong, HEB, and Ms. Fu Feng Kuo to be jointly liable for such obligation. The Taizhou Court also ruled that the Plaintiff is entitled to liquidate all equity interest in Innovative Biotech pledged to it in order to realize the payment of the aforementioned obligations. We filed an appeal against this judgement on April 29, 2024 to the High People's Court of Zhejiang Province (the "High Court"). The High Court held a hearing for this case on August 9, 2024, and later issued a judgement against us to sustain the ruling of the Taizhou Court. As of December 31, 2025, our total potential liability under this judgement is approximately RMB149.1 million (USD 21.6 million).

The judgment is final and non-appealable, and the settlement agreement shall become legally binding upon execution by the parties. Pursuant to applicable Chinese law, Taizhou is entitled to initiate enforcement proceedings to recover approximately RMB 149.1 million (USD 21.6 million) in cash, with Jyong, HEB, and Ms. Fu Feng Kuo jointly liable for such obligations. As of the date of this annual report, the Plaintiff has initiated enforcement procedure before competent courts respectively in Taiwan, Hong Kong and Cayman Islands, however, the concerned parties are actively engaged in negotiation to reach a settlement and thus postpone or suspend the enforcement procedure.

On November 19, 2025, the judgment was registered with the Court of First Instance of the High Court of Hong Kong. As of that registration date, the total outstanding obligation, including interest and legal fees, amounted to RMB 149,458 thousand (approximately $21,372 thousand). The Transferring Shareholders were formally notified of this registration on December 11, 2025. The Transferring Shareholders did not an appeal against this registration prior to December 31, 2025. On December 17, 2025, the Shilin District Court in Taipei recognized the Judgment. While HEB filed an appeal against this recognition prior to December 31, 2025. On March 10, 2026, the Financial Services Division of the Grand Court of the Cayman Islands recognized the Judgment. The Company filed a defense in the Grand Court of the Cayman Islands opposing enforcement of the Judgment on May 5, 2026.

Under PRC's civil procedure, after a judgement from civil litigation enters into effect, the parties may, at any time before and during the enforcement procedure, and until such enforcement procedure is completed, choose to enter into a settlement agreement and file to the competent court to perform such agreement in lieu of enforcing the judgement. We are actively negotiating with the Plaintiff for a settlement of this legal proceeding.

The Company and Taizhou have mutually agreed to expedite the resolution of the dispute through negotiation. The key terms and conditions of the settlement are currently under discussion and pending confirmation by the relevant parties. The proposed resolution under negotiation involves a third party acquiring the shares held by Taizhou at a price equivalent to the share subscription cost, potentially including all or part of the accrued interest. It is anticipated that the contemplated transaction will be structured as a post-IPO bulk trade, intended to be executed following the Company's listing and the expiration of the applicable lock-up period. The Company affirms that no proceeds from the offering will be utilized for any payment related to the Taizhou dispute. However, there can be no assurance that a settlement will be reached. In the event that a settlement is not concluded, Jyong, HEB, and Ms. Fu Feng Kuo may be required to jointly pay the full amount of approximately RMB 149.1 million (USD 21.6 million) in cash.

However, this dispute may still incur substantial costs of settlement or litigation, and may result in an outcome adverse to our interests. In the opinion of our legal counsel for this lawsuit, should we eventually fail to reach a settlement with the Plaintiff, this case is likely to result in an outcome unfavorable to us. For risks associated with the legal proceeding, see more details under "Item 3. Key Information — D. Risk Factors — Risks Related to Our Business and Industry — We have been involving in legal proceedings in the ordinary course of our business, and are currently involved in active legal proceedings. Any adverse outcome of these legal proceedings could have a material adverse effect on our business, results of operations and financial condition."

Taizhou Administrative Penalty

On November 29, 2019, Innovative Biotech Co., Ltd., our PRC subsidiary, entered into the Land Use Right Agreement with Taizhou Resources Bureau. Under the terms and conditions of the Land Use Right Agreement, Innovative Biotech shall commence construction on the parcel granted by May 28, 2020 and complete the construction by November 28, 2022, otherwise, liquidated damages shall be paid to Taizhou Resources Bureau for each day of delay, being 0.1% of the total amount of the land use right grant price of approximately RMB16.0 million plus tax. On November 23, 2022, Taizhou Resources Bureau issued a formal notice of reminder of default, requiring Innovative Biotech to pay liquidated damages of RMB13,080,170, with the amount of damages accruing from November 24, 2022 to the date of actual construction to be calculated separately. As of the date of this annual report, we have not paid the liquidated damages of RMB13,080,170 (US$ 1,803.8 thousand) yet and we are currently in litigation with Taizhou Resources Bureau and awaiting the judgment. In addition, under the Land Use Right Agreement, apart from the liquidated damages, Innovative Biotech is obliged to pay a land idling fee if the land is left idle for more than one year but less than two years, and Taizhou Resources Bureau has the right to take back the land use right if the land is left idle for more than two years. On September 26, 2024, the Taizhou Resources Bureau issued a notice regarding taking back the land use right without compensation, giving Innovative Biotech Co., Ltd. the right to file for an administrative hearing within five business days of receipt of notice. While the Company initially applied for the administrative hearing, it subsequently decided to relinquish the land use rights to the Taizhou Resources Bureau in accordance with the notice. As a result, the Company will no longer proceed with the hearing process. On February 8, 2025, the Bureau issued a formal Decision Letter confirming the reclamation of IB's land use rights without compensation. IB timely filed an application for administrative reconsideration with the Taizhou Municipal People's Government. On June 26, 2025, the Municipal Government issued its decision upholding the Bureau's reclamation order. Dissatisfied with the outcome, IB initiated an administrative lawsuit with the Taizhou Intermediate People's Court of Zhejiang Province on July 23, 2025. On January 19, 2026, the Court rendered a judgment dismissing IB's claims and ordering IB to bear the litigation costs of RMB 50. Although IB filed an appeal against this judgment on February 2, 2026, management, based on the advice of our local legal counsel, assesses that there is a high probability that the unfavorable judgment will be upheld on appeal. As of the date of this annual report, the appellate process remains ongoing.

According to the 2018 Taizhou Agreement and 2019 Taizhou Agreement, we were obligated to complete the construction of a pharmaceutical factory project, or the Factory Project, by 2022, which shall be ready for production by 2023. As of the date of this annual report, the construction of the Factory Project has been suspended. In addition, RMB30 million of Innovative Biotech Co., Ltd.'s registered capital shall be actually paid within one year of its registration. As of the date of this annual report, only RMB16,562,000 (US$2,284 thousand) of Innovative Biotech Co., Ltd.'s registered capital has been paid. Furthermore, our PRC subsidiary shall pay cash deposit of RMB 10,000 (US$1.4 thousand) per mu after signing the "standard parcel" development and construction agreement, or the Construction Agreement, with the Taizhou Industry District Committee. As of the date of this annual report, no such deposit has been paid after the Construction Agreement was signed. According to the 2018 Taizhou Agreement, failure to commence and conclude the construction of the Factory Project on schedule as agreed may entitle the Taizhou Municipality the rights to replace the granted parcel, adjust or withdraw the preferential policies available under such agreement (including but not limited to the government subsidy of RMB12.0 million (US$1,654.9 thousand) Innovative Biotech Co., Ltd. has already received), and take back the parcel with the original purchase price of RMB400,000 (US$55.2 thousand) per mu. See also "Item 4. Information on the Company — B. Business Overview — License and Collaboration Agreements — Taizhou Collaboration Framework Agreement."

The claims and proceedings discussed above, and other potential claims or proceedings relating to this issue, may incur substantial costs of settlement or litigation, and may result in outcome adverse to our interests. For risks associated with the legal proceeding, see more details under "Item 3. Key Information — D. Risk Factors — Risks Related to Our Business and Industry — We have been involving in legal proceedings in the ordinary course of our business, and are currently involved in active legal proceedings. Any adverse outcome of these legal proceedings could have a material adverse effect on our business, results of operations and financial condition."

On November 29, 2019, our PRC subsidiary, Innovative Biotech Co. ("IB") entered into the Construction Agreement with the Taizhou Industry District Committee. The Construction Agreement provided specifics regarding the Factory Project IB was required to meet, including but not limited to the period of construction, plot ratio, amount of investment and tax income per mu. The Construction Agreement stipulates that before construction of the Factory Project meet the requirements of amount of investment and plot ratio under the Construction Agreement, IB and its shareholder shall not transfer the acquired parcel, directly or via transfer or pledge of equity, to a third party. Should IB breaches this agreement and causes the purpose of the Construction Agreement unable to be realized, the Taizhou Industry District Committee shall have the right to terminate the Construction Agreement and claim corresponding damages. The Taizhou Industry District Committee did not explicitly consent to the pledging of IB's shares to the Taizhou City Optimization and Upgrade Investment Partnership (Limited Partnership). However, as of the date of this annual report, the Taizhou Industry District Committee has yet to raise any claims against IB based on the event discussed above. As of December 31, 2024 and 2025, IB classified the liquidated damages and accrued interests of US$2.9 million, and US$3.0 million as other current liabilities, respectively.

Taizhou Government Subsidy Dispute

On November 29, 2022, the Taizhou Bay New District Administrative Committee (the "Plaintiff"), successor of the Taizhou Industry District Committee, filed a civil complaint to the Taizhou Intermediate People's Court ("the Taizhou Court") against our PRC subsidiary, Innovative Biotech Co. ("IB"), claiming that IB has materially breached the 2019 Taizhou Agreement by failing to initiate and conclude the construction of the Factory Project in accordance with the schedule stipulated by the 2019 Taizhou Agreement and the Land Use Right Agreement. The Plaintiff requested the Taizhou Court to terminate the 2019 Taizhou Agreement, and to order IB to return the government subsidy of RMB 12.0 million (US$1,654.9 thousand) IB previously received under the 2019 Taizhou Agreement, and to pay corresponding interests calculated at the Loan Prime Rate published by the National Inter-bank Funding Center. On December 1, 2022, the Taizhou Court issued an order of preliminary asset preservation, freezing the RMB 10.7 million deposit in IB's bank account. This dispute went on trial on February 13, 2023, and two hearings were held on May 6, 2023 and August 17, 2023, respectively. On September 8, 2023, the Taizhou Court entered into a judgement in favor of the Plaintiff, terminating the 2019 Taizhou Agreement and ordering IB to return the government subsidy of RMB12.0 million and corresponding interest and expenses to the Plaintiff. On September 14, 2023, we filed an appeal with the High People's Court of Zhejiang Province (the "High Court") regarding each of the Court's rulings described above. The High Court held a hearing for this case on October 24, 2023. On December 12, 2023, the High Court issued a judgment against IB to affirm the Taizhou Court's ruling in its entirety. On January 5, 2024, the Taizhou Court issued an order of enforcement, stipulating, among other things, freezing and assignment of IB's deposit in its bank account or withholding of IB's income up to RMB 12.0 million and corresponding interests, and the seizure, attachment and freezing of IB's property valued at RMB 12.0 million and corresponding interests, and restrictions on making certain high expenses by IB and related personnel. As of the date of this annual report, the 40 mu (approximate 26,680 sq.m.) industrial land we acquired for the Factory Project have been seized by the Taizhou Court, and IB's RMB 11.1 million deposit in its bank account has been transferred to the Plaintiff. On December 27, 2023, we filed a petition for retrial to the Supreme People's Court of the People's Republic of China (the "Supreme Court"). The Supreme Court issued a decision to reject our petition for retrial on August 21, 2024. As of December 31, 2024 and 2025, IB accrued US$0.4 million, and US$0.4 million of other current liabilities for the loss contingencies for this dispute, respectively. For risks associated with the legal proceeding, see more details under "Item 3. Key Information — D. Risk Factors — Risks Related to Our Business and Industry — We have been involving in legal proceedings in the ordinary course of our business, and are currently involved in active legal proceedings.

This dispute has resulted in an outcome adverse to our interests, which may in turn result in financial loss and adversely affect our business, financial conditions and results of operations.

Even though we are currently involved in the legal proceedings as aforementioned, we are committed to maintaining the highest standards of compliance with the laws and regulations applicable to our business in the future. Apart from the legal proceedings discussed above, we are not engaged in, nor are we aware of, any legal proceeding, investigation or claim which, in the opinion of our management, is likely to have a material adverse effect on our business, financial condition or results of operations. We may from time to time be subject to various legal or administrative claims and proceedings arising in the ordinary course of business. Litigation or any other legal or administrative proceeding, regardless of the outcome, is likely to result in substantial costs and diversion of our resources, including our management's time and attention.

INSURANCE

We maintain insurance policies that we consider to be in line with market practice and adequate for our business. We currently maintain insurance for adverse events in clinical trials as we estimate the risk exposure to be minimal. We currently do not maintain product liability insurance or key person insurance.

REGULATIONS

We are subject to a variety of U.S. and Taiwan laws, rules and regulations across a number of aspects of our business. This section sets forth a summary of the most significant laws and regulations that are applicable to our current business activities within the territory of U.S. and Taiwan.

U.S. Government Regulation and Product Approval

The U.S. Food and Drug Administration, or the U.S. FDA, and other regulatory authorities in the United States at federal, state and local levels extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, recordkeeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of and for drug products. Along with third-party contractors, we are required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The processes for obtaining regulatory approvals in the United States and in foreign jurisdictions, along with subsequent compliance with applicable laws and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

The failure to comply with applicable statutory and regulatory requirements may subject a sponsor, applicant or marketer to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by the U.S. FDA, the U.S. FDA's refusal to approve pending applications or supplemental applications, withdrawal of an approval, "Warning Letters" (official messages from the U.S. FDA to a manufacturer or other organization providing notice that it has violated federal law) or "Untitled Letters" (initial correspondences from the U.S. FDA that cite violations that do not meet the threshold of regulatory significance for a Warning Letter and request correction of the violation), product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the U.S. FDA, the Department of Justice, or the DOJ, or other governmental entities.

Review and Approval for Licensing Drugs

The U.S. FDA regulates drugs primarily under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the Public Health Service Act, and their associated implementing regulations. Our product candidates must be approved by the U.S. FDA through the new drug application, or the NDA, process before they may be legally marketed in the United States. The process required by the U.S. FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive preclinical studies, including preclinical laboratory tests, preclinical animal studies and formulation studies all performed in compliance with applicable regulations, including the current good laboratory practice, or the cGLP, regulations;

- submission to the U.S. FDA of an investigational new drug application, or an IND, which must become effective before human clinical trials may begin and must be updated annually and when significant changes are made, such as initiating a new clinical trial;

- manufacture, labeling and distribution of an investigational drug in compliance with current good manufacturing practices, or cGMP;

- approval by an institutional review board, or IRB, or ethics committee at each clinical site before each clinical trial may be initiated and obtaining informed consent of all clinical trial participants;

- performance of adequate and well-controlled human clinical trials in accordance with the U.S. FDA's current good clinical practices requirements, or cGCP, clinical trial registration, and other clinical trial related regulations, to provide substantial evidence of effectiveness and evidence of safety for the drug product's proposed indication;

- preparation of and submission to the U.S. FDA of an NDA after completion of all pivotal clinical trials requesting marketing approval for one or more proposed indications;

- satisfactory completion of an U.S. FDA Advisory Committee review, where appropriate or if applicable, as may be requested by the U.S. FDA to assist with its review;

- satisfactory completion of one or more U.S. FDA pre-approval inspections of the manufacturing facility or facilities at which active pharmaceutical ingredient, or API, and finished drug product, or components thereof, are produced to assess compliance with cGMP and data integrity requirements to assure that the facilities, methods, and proposed chemistry, manufacturing, and controls, or CMC, are adequate to preserve the drug's identity, safety, quality, purity, potency and efficacy;

- satisfactory completion of U.S. FDA audits of selected preclinical and/or clinical investigation sites to assure compliance with cGLP and cGCP requirements and the integrity of the preclinical and/or clinical data;

- payment of user fees under the Prescription Drug User Fee Act, or, as amended, the PDUFA, for the relevant year;

- obtaining U.S. FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States; and

- compliance with all post-approval requirements, including but not limited to, cGMP, CMC, post-market reporting and pharmacovigilance, registration and listing, advertising and promotional requirements, the potential requirement to implement risk evaluation and mitigations strategies, or REMS, and the potential requirement to conduct post-approval studies.

In addition to drug-specific requirements, combinations of differently regulated articles, such a drug and device (e.g., a drug delivery system or companion diagnostic) could also result in various additional requirements to consider, such as device and combination product requirements of the FDCA and its implementing regulations with respect to investigation, marketing, and post-market requirements.

The approval process for botanical drug products is similar to that of conventional chemical drugs. The standards for the safety and efficacy of a botanical drug are the same as those for a conventional chemical drug with the same indication. However, the quality control of botanical drugs is more complex than that of conventional chemical drugs due to the variability of botanical raw materials. Given botanicals' chemical and biological complexity, efforts in characterizing the pharmacology, demonstrating therapeutic efficacy, and ensuring quality consistency remain scientific and regulatory challenges. For botanical drug products in particular, which may be heterogeneous in nature and may carry additional uncertainty about their active constituents in comparison to synthetic small-molecule drug products, one of the critical issues during drug development is ensuring that the therapeutic effect for marketed drug product batches is consistent. The U.S. FDA has determined that therapeutic consistency can generally be supported by a "totality of the evidence" approach, which the U.S. FDA has outlined in a 2016 guidance for industry entitled Botanical Drug Development.

Development of data and other information sufficient to support an NDA approval requires substantial time, effort and financial resources and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. From time to time, new legislation is enacted that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the U.S. FDA. In addition to new legislation, U.S. FDA regulations and policies are often revised or interpreted by the U.S. FDA in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative changes will be enacted or whether U.S. FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

Preclinical Development

The data required to support an NDA is generated in two distinct development stages: preclinical and clinical. For new chemical entities, or NCEs, the preclinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, evaluating purity and stability, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. The conduct of the preclinical studies must comply with federal regulations, including cGLPs. The sponsor must submit the results of the preclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol or protocols, to the U.S. FDA as part of its IND. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. An IND is a request for authorization from the U.S. FDA to administer an investigational product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. An IND acts as an exemption from the FDCA that allows an unapproved drug to be shipped in interstate commerce for use in an investigational clinical trial. Such authorization must be secured prior to interstate shipment. Any subsequent protocol amendments must be submitted to the U.S. FDA as part of the IND, and the U.S. FDA must allow these amendments to the IND to go into effect prior to their execution. Frequently, sponsors are also required to conduct additional animal studies after an IND is obtained and human clinical testing begins, and is often referred to as ‘preclinical’ or ‘nonclinical’ testing, even though it occurs in parallel with the clinical phase of development.

Clinical Development

Human clinical trials subject to the U.S. FDA’s jurisdiction may not begin until an IND is effective. The IND automatically becomes effective 30 days after receipt by the U.S. FDA, unless the U.S. FDA raises safety concerns or questions about the proposed clinical trial within the 30-day time period. In such a case, the IND may be placed on clinical hold and the IND sponsor and the U.S. FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in U.S. FDA authorization to begin a clinical trial.

The U.S. FDA may also place a clinical hold or partial clinical hold on such study following commencement of a clinical trial under an IND. A clinical hold is an order issued by the U.S. FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after the imposition of a clinical hold or partial clinical hold, the U.S. FDA will provide the sponsor with a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the U.S. FDA has notified the sponsor that the investigation may proceed. The U.S. FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the U.S. FDA that the investigation can proceed.

Clinical studies involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCP regulations. Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments.

Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before the clinical trial begins at that site, and must monitor the study until completed. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board, or the DSMB. DSMBs provide authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if a DSMB determines that there is an unacceptable safety risk for subjects or based on other grounds, such as no demonstration of efficacy. Other grounds for suspension or termination may be made based on evolving business objectives and/or competitive climate. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

A sponsor may choose, but is not required, to conduct a foreign clinical trial under an IND. When a foreign clinical trial is conducted under an IND, all U.S. FDA IND requirements must be met unless waived. When the foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study complies with cGCP regulations in order to use the study as support for an IND or application for marketing approval, including review and approval by an independent ethics committee and informed consent from subjects. If conducting a clinical study in a non-U.S. population, acceptance of clinical trial results by the U.S. FDA will depend, among other things, on whether the non-U.S. population that enrolled in the study is sufficiently similar to the indicated U.S. population that the results of the trial would fairly represent expected results in the U.S. population. The same issue can also arise in multi-national trials where non-U.S. sites are enrolling subjects that will become part of the data submitted to the U.S. FDA.

For purposes of drug approval, clinical trials are typically conducted in the following sequential phases that may overlap or be combined:

- Phase I: The investigational product is initially introduced into a small number of healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans and the side effects associated with increasing doses. These studies may also yield early evidence of effectiveness.

- Phase II: The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks.

- Phase III: The investigational product is administered to an expanded patient population generally at multiple geographically dispersed clinical trial sites to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety. These clinical trials are intended to generate sufficient data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval by the U.S. FDA and labeling of the drug product.

In some cases, the U.S. FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product, sometimes referred to as “Phase IV” studies. Such post-approval studies, when applicable, are conducted following initial approval, typically to develop additional data and information relating to the biological characteristics of the product and the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the U.S. FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the U.S. FDA for any of the following: suspected serious and unexpected adverse reactions; findings from epidemiological studies, pooled analysis of multiple studies, animal or in vitro testing, or other clinical trials, whether or not conducted under an IND, and whether or not conducted by the sponsor, that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the rate of a serious suspected adverse reaction over such rate listed in the protocol or investigator brochure, which is a comprehensive document summarizing the body of information about an investigational product obtained during clinical and non-clinical trials.

Each of Phase I, Phase II and Phase III clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the U.S. FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with such IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, if a clinical trial is overseen by a Data Safety Monitoring Board, or DSMB, the DSMB will provide authorization for whether or not a study may move forward at designated check points based on access to certain data from the study.

Concurrent with clinical trials, companies must develop additional information about the chemistry and physical characteristics of the drug 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 candidate, and cGMPs impose, among other things, extensive procedural, substantive and recordkeeping requirements to ensure and preserve the long-term stability and quality of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life. Any changes to the drug product during development, and especially after Phase II, can raise questions with respect to impact of changes on study results, and whether results may be extrapolated to support approval of a final finished dosage form for which approval is sought.

During the clinical development process, earlier phase drug results may be promising, but it cannot be assumed that subsequent phases of development will be successful. In fact, it is often the case that drugs with promising early phase data fail to ultimately show sufficient efficacy or safety to support approval in later phases of development.

NDA Submission and Review

Following study completion, study results and data are analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials are then submitted to the U.S. FDA as part of an NDA, along with relevant patent information, proposed labeling for the drug, information about the manufacturing process and facilities that will be used to ensure drug quality, results of analytical testing conducted on the chemistry of the drug and other relevant information. The NDA is a request for approval to market the drug and must contain adequate evidence of safety and substantial evidence of efficacy, which is demonstrated by extensive preclinical and clinical testing. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a use of a drug, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational drug product to the satisfaction of the U.S. FDA.

Under the PDUFA, each NDA must generally be accompanied by a significant application user fee. The U.S. FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business which has fewer than 500 employees; in assessing whether an application qualifies as a 'first application' and calculating the number of employees, affiliates of the small business making the NDA submission are considered. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The U.S. FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The U.S. FDA conducts a preliminary review of an NDA within 60 days of receipt and informs the sponsor by the 74th day after the U.S. FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the U.S. FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the U.S. FDA under PDUFA, the U.S. FDA has ten months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the filing date for a "priority review" NDA. The U.S. FDA does not always meet its PDUFA goal dates for standard and priority review NDAs, and the review process is often significantly extended by U.S. FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the U.S. FDA reviews the NDA to determine, among other things, whether the proposed drug is safe and effective for its intended use, and whether the drug is being manufactured in accordance with cGMP to assure and preserve the drug's identity, strength, quality, purity and efficacy. The U.S. FDA may refer applications for novel drugs or product candidates that present difficult questions of safety or efficacy to an advisory committee. Typically, an advisory committee consists of a panel that includes clinicians and other experts who will review, evaluate and provide a recommendation as to whether the application should be approved and, if so, under what conditions. The U.S. FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions and usually follows such recommendations. The U.S. FDA may re-analyze the clinical trial data, which could result in extensive discussions between the U.S. FDA and us during the review process.

Before approving an NDA, the U.S. FDA will also conduct a pre-approval inspection of the manufacturing facilities for the new drug to determine whether they comply with cGMPs. The U.S. FDA will not approve the drug unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the drug within required specifications. In addition, before approving an NDA, the U.S. FDA may also audit data from clinical trials to ensure compliance with cGMP requirements. After the U.S. FDA evaluates the application, manufacturing process and manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter usually describes all of the specific deficiencies in the NDA identified by the U.S. FDA. The complete response letter may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to preclinical studies or clinical trials or manufacturing. 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. Even if such data and information is submitted, the U.S. 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 U.S. FDA may interpret data differently than we interpret the same data.

If a drug receives marketing approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited. Further, the U.S. FDA may require that certain contraindications, warnings or precautions be included in the drug labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved drugs. For example, the U.S. FDA may require Phase IV testing which involves clinical trials designed to further assess a drug's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved drugs that have been commercialized. The U.S. FDA may also place other conditions on approvals including the requirement for a REMS to ensure that the benefits of a drug or biological product outweigh its risks. If the U.S. FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS and the U.S. FDA will not approve the NDA without a REMS that the U.S. FDA has determined is acceptable. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of a drug. Drug approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

Post-Approval Requirements

Any products manufactured or distributed pursuant to U.S. FDA approvals are subject to pervasive and continuing regulation by the U.S. FDA, including, among other things, requirements relating to monitoring, recordkeeping, registration and listing, periodic reporting, reporting of certain deviations and adverse experiences, providing the regulatory authorities with updated safety and efficacy information, drug sampling and distribution requirements, complying with applicable promotion and advertising requirements, and the provision and maintenance of data about each sale of prescription drugs to authorized trading partners in a secure and interoperable manner, and systems for the identification and management of suspect and illegitimate products. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to U.S. FDA review and approval and may require the development and submission of data, including clinical data. There also are continuing user fee requirements, under which the U.S. FDA assesses an annual program fee for each product identified in an approved NDA.

U.S. FDA regulations also require that approved products be manufactured in specific approved facilities and in accordance with cGMP. We currently use contract manufacturing organizations, or CMOs, to manufacture the drugs used in our clinical trials and expect to rely on third parties for the production of commercial quantities of our products in accordance with cGMP regulations. NDA holders using CMOs, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and their third-party contractors are required to register their establishments with the U.S. FDA and certain state agencies. These establishments are subject to routine and periodic unannounced inspections by the U.S. FDA and certain state agencies for compliance with cGMP and data integrity requirements, which impose certain procedural and documentation requirements to assure quality of manufacturing and product. Any interference with U.S. FDA inspection activities at our company or at CMOs can result in substantial penalties. The U.S. FDA has increasingly observed cGMP violations involving data integrity during site inspections and investigating compliance with data integrity requirements is a significant focus of its oversight. Requirements with respect to data integrity include, among other things, controls to ensure data are complete and secure; requiring that activities are documented at the time of performance; audit trail functionality; requiring authorized access and limitations; validated computer systems; and the review of records for accuracy, completeness and compliance with established standards.

Post-approval changes to the manufacturing process, including changes of the site of manufacture, are strictly regulated, and, depending on the significance of the change, may require U.S. FDA approval before being implemented. U.S. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party CMOs that we 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, data integrity, pharmacovigilance (*i.e.*, post-marketing safety reporting obligations) and other aspects of regulatory compliance.

The U.S. FDA may withdraw a product approval if compliance with regulatory requirements and standards 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, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-approval studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS. Other potential consequences include:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, Warning Letters, Untitled Letters or holds on post-approval clinical trials;
- refusal of the U.S. FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the U.S. FDA to permit the import or export of products that it believes present safety problems by issuing an Import Alert;
- permanent injunctions and consent decrees, including the imposition of civil or criminal penalties;
- adverse publicity;
- voluntary or mandatory product recall; and
- recoupment of payment and damages for noncompliant drug products based on various legal theories, including a theory that reimbursement for noncompliant products violates federal and state false claims laws (e.g., the federal False Claims Act).

The U.S. FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. A company can make only those claims relating to safety and efficacy, identity, strength, quality, purity and potency that are approved by the U.S. FDA and in accordance with the provisions of the approved label. Promotional claims relating to a product's safety or effectiveness are prohibited before the drug is approved. After approval, a product generally may not be promoted for uses that are not approved by the U.S. FDA, as reflected in the product's prescribing information. In the United States, healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug's labeling, known as off-label uses, because the U.S. FDA does not regulate the practice of medicine. However, U.S. FDA regulations impose rigorous restrictions on manufacturers' communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in non-promotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information in accordance with the U.S. FDA's good reprint practices or unsolicited request doctrine.

If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the U.S. FDA, the DOJ or the Office of the Inspector General of the Department of Health and Human Services, as well as other federal and state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion, and has also requested that such companies enter into consent decrees and permanent injunctions under which specified promotional conduct is changed or curtailed. Among other legal theories, penalties may be sought based on a theory that off-label promotion causes submission of claims that for an unapproved use in violation of state and federal false claims laws.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous regulatory authorities in addition to the U.S. FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration for controlled substances, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. The activities of pharmaceutical manufacturers are subject to federal and state laws designed to prevent "fraud and abuse" in the healthcare industry. The laws generally limit financial interactions between manufacturers and health care providers or other participants in the healthcare industry, require disclosure to the government and public of such interactions, and govern various matters regarding reimbursement of healthcare products. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Pharmaceutical manufacturers are also required to provide discounts or rebates under government healthcare programs or to certain government and private purchasers in order to obtain coverage under federal healthcare programs such as Medicaid. Participation in such programs may require tracking and reporting of certain drug prices. Manufacturers are subject to fines and other penalties if such prices are not reported accurately. Additionally, the handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Drugs must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of prescription drugs and biologics are subject to the Drug Supply Chain Security Act, which requires manufacturers and other stakeholders to comply with product labeling, tracing, verification, detection and disposition of suspect and illegitimate products, notifications regarding illegitimate products, and products with a high risk of illegitimacy, and state permitting or licensing requirements. Manufacturers of prescription drugs must develop secure, electronic and interoperable recordkeeping systems that track transaction data at the package level when they sell prescription products to their authorized downstream customers and be able to produce those records when requested by U.S. FDA. In addition, the Prescription Drug Marketing Act and its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the Drug Supply Chain Security Act imposes requirements to ensure accountability in distribution and to identify, quarantine, investigate, and remove from the market prescription drug and biological products that may be counterfeit, stolen, contaminated, or otherwise harmful.

Hatch-Waxman Protections

Patent Term Restoration

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and U.S. FDA review of an NDA if approval of the application is the first permitted commercial marketing or use of a drug containing the API under the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between IND and NDA submission, and all of the review phase, which is the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if the U.S. FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of U.S. FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The US Patent and Trademark Office (US PTO), in consultation with the U.S. FDA, reviews and approves the application for patent term restoration.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the US PTO must determine that approval of the product candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a product candidate for which an NDA has not been submitted.

Patent Listing and the Orange Book

In seeking approval for a drug through an NDA, applicants are required to list with the U.S. FDA each drug substance, drug product, and method-of-use patent whose claims cover the NDA drug product. Upon approval of the NDA, each of the patents listed in the application for the drug is published in the U.S. FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors as reference listed drugs, or RLDs, in support of approval of an abbreviated new drug application, or ANDA, or 505(b)(2) NDA which relies upon the RLD's approval to support its own.

An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical or clinical tests (beyond, potentially, bioequivalence studies) to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug under various state laws. A 505(b)(2) NDA is generally used where there are one more difference from the RLD in terms of dosage form, labeling, or other properties, but where an applicant may nonetheless rely upon U.S. FDA's prior approval determinations with respect to the RLD to support safety and/or efficacy of the 505(b)(2) NDA drug product.

An ANDA or 505(b)(2) NDA applicant is required to certify to the U.S. FDA concerning any patents listed for the RLD in the U.S. FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. An ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA label does not contain or carve out any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA or 505(b)(2) NDA will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA or 505(b)(2) NDA applicant has provided a Paragraph IV certification to the U.S. FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or 505(b)(2) NDA has been accepted for filing by the U.S. FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the U.S. FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant.

The ANDA or 505(b)(2) NDA also will not be approved until any applicable non-patent market exclusivity listed in the Orange Book for the referenced product have expired.

Market Exclusivity

Upon NDA approval of a new chemical entity (NCE), which is a drug that contains no active moiety that has been approved by the U.S. FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the U.S. FDA cannot receive any ANDA or 505(b)(2) NDA seeking approval that uses the NDA as its RLD. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the U.S. FDA cannot approval an ANDA or 505(b)(2) NDA seeking approval that uses the NDA as its RLD.

An ANDA or 505(b)(2) NDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA or 505(b)(2) may be filed before the expiration of the exclusivity period.

The Federal Food, Drug, and Cosmetic Act directs the U.S. FDA to meet with sponsors, pursuant to a sponsor's written request, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in an NDA. If an agreement is reached, the U.S. FDA will reduce the agreement to writing and make it part of the administrative record. This agreement is called a special protocol assessment, or an SPA. While the U.S. FDA's guidance on SPAs states that documented SPAs should be considered binding on the review division, the U.S. FDA has latitude to change its assessment if certain exceptions apply. Exceptions include public health concerns emerging that were unrecognized at the time of the protocol assessment, identification of a substantial scientific issue essential to the safety or efficacy testing that later comes to light, a sponsor's failure to follow the protocol agreed upon, or the U.S. FDA's reliance on data, assumptions or information that are determined to be wrong.

An SPA request can be requested after a pre-Phase III meeting with the U.S. FDA. It allows the U.S. FDA and sponsor to agree on the study design for a Phase III study whose efficacy results will be the basis of an NDA. There is no guarantee that we will request or be able to receive and maintain Fast Track designation, Breakthrough Therapy designation, Priority Review designation, Accelerated Approval designation or a Special Protocol Assessment for any of our product candidates.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain U.S. FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product, patient population, phase of investigation, clinical trial sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these clinical trials after completion if the product candidate is ultimately approved, and disclosure of the results of these clinical trials will be delayed until such approval. Competitors may use this publicly-available information to gain knowledge regarding the design and progress of in development programs.

U.S. Healthcare Regulation

Pharmaceutical Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, 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 establish the coverage and reimbursement policies for pharmaceutical products, and the marketability of any products for which we may receive regulatory approval for commercial sale depends on those payors' coverage policies and reimbursement rates. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include one or more of our product candidates, if approved. Third-party payors, together with regulators and others, are increasingly challenging the prices charged for pharmaceutical products and health services, in addition to their cost-effectiveness, safety and efficacy. In addition, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval process apart from Medicare determinations. Therefore, coverage and reimbursement rates can vary significantly from payor to payor.

Moreover, obtaining coverage and adequate reimbursement is a time-consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval will be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that our product candidates will be considered cost-effective by third-party payors. This process could delay the market acceptance of any product candidates for which we may receive approval and could have a negative effect on our future revenues and operating results.

Other U.S. Healthcare Laws and Compliance Requirements

Our business may be subject to healthcare fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business, particularly once third-party reimbursement becomes available for one or more of our products. The healthcare fraud and abuse laws and regulations that may affect our ability to operate include, but are not limited to:

- 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 the Medicare and Medicaid programs, or other federal healthcare programs;

- The federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which prohibits, among other things, knowingly presenting, or causing to be presented, claims for payment of government funds that are false or fraudulent, or knowingly making, or using or causing to be made or used, a false record or statement material to a false or fraudulent claim to avoid, decrease, or conceal an obligation to pay money to the federal government;

- HIPAA, which, among other things, prohibits executing a scheme to defraud any healthcare benefit program, including private third-party payors, and prohibits (i) knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation and (ii) making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities, including health plans, healthcare clearinghouses and certain healthcare providers, and their business associates, individuals or entities that perform certain services on behalf of a covered entity that involve the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;

- Federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- The federal Physician Payments Sunshine Act, being implemented as the Open Payments Program, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to direct or indirect payments and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held in a company by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and

- U.S. state and local laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that restrict the ability of manufacturers to offer co-pay support to patients for certain prescription drugs; state laws that require drug manufacturers to report information related to clinical trials, or information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require drug manufacturers to report information on the pricing of certain drugs; state laws and local ordinances that require identification or licensing of sales representatives; state and local laws regarding the manufacturing and distribution of drugs; 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 often are not pre-empted by HIPAA, thus complicating compliance efforts.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Even then, governmental authorities may 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 governmental authorities find that our operations violate any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our operations and business. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. The extent to which future legislation or regulations, if any, relating to health care fraud and abuse laws or enforcement, may be enacted or what effect such legislation or regulation would have on our business remains uncertain.

Healthcare Reform

In the United States there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, enacted in March 2010, has substantially changed healthcare financing and delivery by both governmental and private insurers. Among other things the Affordable Care Act included the following provisions:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which through subsequent legislative amendments, will be increased to 70%, starting in 2019, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- a methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected; and
- a licensure framework for follow-on biological products.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Various portions of the Affordable Care Act are currently undergoing legal and constitutional challenges in the United States Supreme Court and members of Congress have introduced several pieces of legislation aimed at significantly revising or repealing the Affordable Care Act. The implementation of the Affordable Care Act is ongoing, the law appears likely to continue the downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the Affordable Care Act are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2030 unless additional Congressional action is taken. These reductions have been suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. The Consolidated Appropriations Act of 2021, extended the suspension period to March 31, 2021. An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes, signed into law on April 14, 2021, has extended the suspension period to December 31, 2021. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. For example, for the fiscal year of 2023, the U.S. Department of Health & Human Services, or the HHS, proposes $127.3 billion in discretionary funding and $1.7 trillion in mandatory funding, including Medicare and Medicaid. On March 10, 2020, the previous administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses and place limits on pharmaceutical price increases. Further, the previous administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change, which was effective as of January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Biden administration have each indicated that they will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, it is possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the ongoing COVID-19 pandemic.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical study and that are undergoing investigation for U.S. FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical studies and without obtaining U.S. FDA permission under the U.S. FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act. If we obtain approval to market a product candidate in the United States, any healthcare reforms adverse to drug manufacturers, including but not limited to, any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs, that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

TAIWAN REGULATION

Regulations on Company Establishment

The establishment, operation and management of companies in Taiwan is governed by the Taiwan Company Act, which was latest amended on December 29, 2021. There are four types of companies in Taiwan: unlimited company, unlimited company with limited liability shareholders, limited company and company limited by shares. Unlimited company and unlimited company with limited liability shareholders are rarely used in practice; a company limited by shares is the most common form of business undertaken for foreign investors in Taiwan. The Taiwan Company Act applies to both Taiwan domestic companies and foreign-invested companies, unless otherwise provided in the relevant foreign investment laws and regulations.

Regulations on Foreign Investment

The principal regulations governing foreign investments in Taiwan are the Statute for Investment by Foreign Nationals, the Regulations for Verification of Investment by Overseas Chinese and Foreign Nationals, and the Regulations Governing Investment in Securities by Overseas Chinese and Foreign Nationals. In order to efficiently provide services and manage foreign investments, Taiwan government has specifically established the Investment Commission under the Ministry of Economic Affairs.

All investments made by foreign nationals within the territory of Taiwan must comply with the provisions of the Statute for Investment by Foreign Nationals and receive permission from the Investment Commission. According to the administrative ordinance “Negative List for Investment by Overseas Chinese and Foreign Nationals” issued by the Investment Commission, Taiwan maintains a negative list of industries closed to foreign investment as the authorities determine that they relate to national security and environmental protection, including public utilities, power distribution, natural gas, postal service, telecommunications, mass media, and air and sea transportation.

Regulations on Merger and Acquisition

The main laws and regulations governing merger and acquisition ("M&A) activities in Taiwan are the Business Merger and Acquisitions Act, the Company Act, the Securities and Exchange Act and the Fair Trade Act.

The competent authority in charge of the regulations in relation to M&A is the Ministry of Economic Affairs. The main regulatory body in charge of public M&A transactions is the Securities Futures Bureau of the Financial Supervisory Commission, the government agency in charge of public companies. Other relevant regulatory bodies include the Fair Trade Commission, the authority in charge of antitrust clearance, and the Investment Commission, the authority in charge of reviewing foreign and PRC investments. If the M&A target holds any special license, the transaction may also be subject to the review of the authority in charge of such special license.

Except for certain specific sensitive activities, foreign investments are generally not restricted in Taiwan but are subject to the prior approval from the Investment Commission of Taiwan where a foreign investor seeks to acquire 10% or more of the shares of a Taiwan listed company. The approval must be obtained before the final completion of the transaction.

Drug Regulations

Government Regulation and Competent Authority

The legal structure of Taiwan consists of the constitution, laws, and regulations. Taiwan's Legislative Yuan established the Pharmaceutical Affairs Act in accordance with the Constitution to protect people's health and sanitation. The Pharmaceutical Affairs Act provides that the drugs are prohibited to be marketed for sale unless they are approved by the Taiwan Food and Drug Administration ("TFDA"). In addition to the provisions regarding the licensing procedures, the Pharmaceutical Affairs Act also address the management of pharmaceutical companies, patent linkage of drugs, sales and manufacture of drugs, and drug advertisement.

The TFDA is the competent authority for drug management in Taiwan. The TFDA is responsible for approving the license application required by the Pharmaceutical Affairs Act. In addition, the TFDA should continuously monitor and inspect the safety of the drugs from the development stage to the marketing and sales stage. Furthermore, it has the power to penalize those who violate the provisions in the Pharmaceutical Affairs Act.

Review and Approval for Licensing Drugs

Before a drug is permitted to sale as a product on the market, the pharmaceutical firm is required to obtain the following approvals or licenses:

- Approval for the investigational new drug application ("IND");
- Drug license;
- Drug manufacturing factory registration;
- Drug manufacturing license;
- Western pharmaceuticals distribution license;
- Approval to publish or broadcast drug advertisement.

The process required by the TFDA before a drug may be marketed in Taiwan generally involves the following steps:

- Completion of the preclinical research which is incompliance with the Good Laboratory Practice ("GLP");
- Submission of the IND to the TFDA, which application should be approved before starting the clinical trial;
- Completion of the clinical trial which is incompliance with the Regulations for Good Clinical Practice and the Guidance for Good Clinical Practice (collectively as "GCP");
- Starting from the stage of the clinical trial stage, the investigational drugs and the drug products should be in compliance with the Good Manufacturing Practice ("GMP");
- Submission of the NDA to the TFDA, along with the complete risk evaluation and mitigation strategy ("REMS");
- Register the drug manufacturing factory with the Ministry of Economic Affairs and comply with the Factory Management Act;
- After obtaining the approval of the NDA from the TFDA, the pharmaceutical firm should continuously report the adverse drug reactions ("ADR") of the drugs to the TFDA, and counsel the obligations provided by the Regulations for the Management of Drug Safety Surveillance and the Good Pharmacovigilance Practices ("GPvP");
- After the drug products are manufactured, the pharmaceutical firm shall distribute the products in compliance with the Good Distribution Practice ("GDP"); and
- Every time when the pharmaceutical firm would like to publish or broadcast drug advertisement, it should obtain the TFDA's approval regarding the contents of the advertisement.

Preclinical Development

As a requirement to apply for the IND, the applicant shall submit the documents containing the drug characteristic data (non-clinical and clinical trial data such as drug physical and chemical properties, toxic pharmacological effects, pharmacokinetics, etc.). In order to collect the data, the applicant shall conduct pre-clinical research.

In order to encourage the pharmaceutical firms to develop new drugs, the TFDA has engaged a non-profit organization, Center for Drug Evaluation ("CDE"), to involve in the whole process before the new drugs are approved to market in Taiwan. Anyone who intends to apply for the IND can reach out to the CDE for advice before he/she submits the application. When CDE receives the request, it will meet with the potential applicant and provide its advice from the preclinical research stage.

Different from the clinical trial which is human study, the preclinical research is animal testing or testing with the human biological samples in the laboratory. To perform an experiment which may be approved by the TFDA when applying for the IND, the researchers shall conduct the research in compliance with the GLP. If the applicant for the IND fails to conduct the preclinical research in compliance with the GLP, the TFDA may reject the application for the IND.

Clinical Development

The IND is valid subject to both the TFDA's and the Institutional Review Board ("IRB")'s approvals. After the sponsor submits the application documents to the TFDA, including the approval letter of the IRB, the TFDA will starts to examine the application. Depending on the TFDA's discretion, it may form a professional consulting committee, a committee formed by pharmaceutical and medical experts, to evaluate the feasibility of the clinical trial. In practice, if it is the first time for the drug to be applied on human studies, the TFDA is more likely to form the committee and come out with the decision after considering the committee's conclusion. Generally, the TFDA comes out with a decision whether to approve the application or not around 60-90 days. Once the sponsor obtains the TFDA's approval, the sponsor is permitted to administer the investigational product to humans.

The clinical trials are typically conducted in the following three phases:

- Phase I: The purpose for Phase I is mainly to understand the safe dose of the drug, the highest dose that can be tolerated by the human body. This phase is usually performed by experienced physicians in specific clinical trial wards. Pursuant to Regulations for Registration of Medicinal Products, there should be at least 10 valid Taiwanese subjects for a Phase I clinical trial, such as pharmacokinetics study or pharmacodynamics study.

- Phase II: Through studying with a group of patients with high homogeneity, the efficacy and safety of the drug is able to be explored out. Phase II is a clinical trial for a small number of patients, usually dozens of people. The outcome of the Phase II clinical trial will be referred to evaluate how many subjects should be included in Phase III. Pursuant to Regulations for Registration of Medicinal Products, there should be at least 20 valid Taiwanese subjects for a phase II clinical trial.

- Phase III: In this phase, a larger-scale clinical trial will be conducted. The design is generally carried out in the form of random allocation, double-blind and controlled trials, etc., mainly to verify the efficacy and safety of the drug, as a pre-marketing trial. Pursuant to Regulations for Registration of Medicinal Products, there should be at least 80 valid Taiwanese subjects for a Phase III pivotal trial; and the results have to show the similarity between Taiwan and other countries.

Though Regulations for Registration of Medicinal Products provides the standard number of the subjects, if the TFDA deems necessary, it has the power to request the investigator or the sponsor to include more subjects on grounds of the improvement in quality, safety or efficacy of the drug, the nation's welfare or special circumstances.

During the whole process of the clinical trials, the clinical trials shall always comply with the GCP Rules. The obligations provided in the GCP Rules include the following four aspects:

Alarm Reporting Requirements

If any of the following events occurs, the investigator or the sponsor of the clinical trial shall report to the TFDA:

- The investigator or the sponsor decides to suspend or terminate the clinical trial;

- If the clinical trial has a data safety monitoring board ("DSMB"), and the DSMB decides that certain issues should be reported to the TFDA;

- If the investigator has implemented the deviation or change of the protocol; and

- Any unexpected serious adverse reactions have occurred.

Submitting the Reports

Under the GCP rules, the investigator or the sponsor is not required to provide periodic reports to the TFDA. However, the TFDA is entitled to request the investigator or the sponsor to provide specific reports. For example, the TFDA may require the investigator or the sponsor to provide the safety reports or the report elaborating the trial status. Though the periodic reports are not a requirement, the sponsor is required to submit a clinical trial report upon the end of the clinical trial. Along with the clinical trial report, a risk management plan should also be submitted.

Complying with the GMP

The GCP Rules provides that the manufacturing, handling and storage of the investigational product(s) shall comply with the GMP. Whether the product complies with the GMP is relevant to the quality of the products. Therefore, the GMP compliance requirement is required not only in the clinical trial stage, but also in the stage after the NDA is approved.

To verify whether the clinical trial complies with the GCP Rules, the TFDA has the power to inspect the sponsor and the trial site at any time. In practice, the TFDA does not inspect all of the clinical trials but focus only on those trials relating to human studies involving new drugs. If the TFDA requests to inspect, the sponsor and the trial site shall cooperate with the inspection without interruption.

Bridging Study Evaluation

If the clinical trial is conducted outside Taiwan, the TFDA may accept the outcome from such foreign clinical trial as part of the NDA documents, provided that the applicant has completed the bridging study evaluation ("BSE") in Taiwan.

A BSE is carried out through evaluating the data of pharmacokinetics/pharmacodynamics, efficacy, safety, and dosage to evaluate whether the foreign clinical trial data can be extrapolated to the corresponding population in Taiwan. The BSE data can be used to support new drug applications and to reduce duplicate clinical trials. An applicant should submit documents in accordance with the requirements set forth in the Guidelines on Bridging Studies, and verify whether the drug is regarded as requiring a BSE before submission.

In addition to the BSE requirement, if a foreign clinical trial is included in the NDA, the TFDA will also evaluate if the foreign clinical trial is in compliance with those laws and regulations which the domestic clinical trial shall comply, such as the GCP and GMP.

NDA Submission and Review

After the clinical trial is completed, and the applicant has prepared the required documents, the applicant can submit the NDA to the TFDA. The NDA review process conducted by the TFDA mainly focuses on three aspects.

The first aspect is to examine the safety and the efficacy of the drugs. At this stage, the TFDA focuses on (i) if the chemical, manufacturing and regulatory data can show that the quality of the raw materials and preparations of the drug is well controlled, and has stable quality consistency between different batches; (i) if the pharmacological and toxicological data of animals can support the mechanism of action of the drug and can fully evaluate the possible potential toxic reactions; (iii) if the basic pharmacokinetics/pharmacodynamics of the drug can be understood from the pharmacokinetic/pharmacodynamic data of animals and humans The pharmacokinetic information of the drug in special groups and the interaction information with other drugs are helpful to evaluate the rationality of the dosage adjustment of the drug in special groups and in combination with other drugs; and (iv) if the results of clinical trials can show that the drug has credible curative effect and acceptable safety in the group of declared indications, so as to support the rationality of the claimed usage and dosage.

The second aspect is to examine the quality of the drugs. At this stage, the TFDA will examine the chemistry, manufacturing and controls ("CMC"), and will perform the audit to examine if the clinical trial is in compliance with the GMP, GLP and GCP.

The third aspect is to examine the labeling of the drugs. At this stage, the TFDA will evaluate whether the direction of use shown on the labeling is appropriate and will not mislead the patients.

After the TFDA receives the NDA, it will convene a filing meeting within 30 days to verify if the application is submitted along with all required documents. If the application lacks required documents, the TFDA will issue a notice before the 42^{th} day to inform the applicant that the application is not qualified. On the other hand, if the application meets the requirements, the TFDA will not issue any notice to the applicant on the 42^{th} day. The TFDA will then convene a review meeting before the 100^{th} day. On the review meeting, if the examiners decide that the applicant should provide supplementary documents, the TFDA will issue a request letter to the applicant before the 120^{th} day. If the applicant provides the supplementary documents on time, the TFDA will then convene another review meeting before the 210^{th} day and will complete the review report before the 315^{th} day. If the TFDA decides to approve the NDA, it will issue the approval letter before the 330^{th} day. Generally, the applicant is able to obtain the drug license around the 360^{th} day after the submission.

Post-Approval Requirements

After the TFDA approves the NDA, the new drug products are obligated to comply with several laws and regulations. The post-approval requirements under the Pharmaceutical Affairs Act and its relative regulations mainly relating to four aspects:

Manufacturing

Pursuant to the Pharmaceutical Affairs Act, the manufacturer of the drugs is prohibited from manufacturing prior to registering its manufacturing factory with the Ministry of Economic Affairs and obtaining the manufacturing License from the TFDA ("Manufacturing License"). In practice, the registration of the factory and the Manufacturing License will be issued by the respective authorities at almost the same time upon the approval of the NDA.

When operating the factory, the manufacturers are required to continuously comply with applicable laws and regulations; otherwise, the Ministry of Economic Affair is entitled to de-register the factory.

The Manufacturing License is valid for two years. When the two year period expires, the manufacturer shall apply for another Manufacturing License. As continuous compliance of the GMP is the requirement for the TFDA to issue the Manufacturing License, the manufacturer shall always comply with the GMP.

Distribution

The manufacturer of pharmaceuticals is obliged to obtain a pharmaceuticals distribution license ("Distribution License") before distributing the products. The requirement for the TFDA to issue the Distribution License is that the manufacturer shall comply with the GDP. The Distribution License is valid for 3-5 years, subject to the TFDA's discretion. If the manufacturer fails to comply with the GDP, the TFDA is entitled to reject the renewal of the Distribution License, leading to the suspension of the distributing of the drug products.

Advertisement

In order to prevent pharmaceutical firms from conveying misleading information to the public, the Pharmaceutical Affairs Act provides that the pharmaceutical firm should obtain the approval of the TFDA before publishing or broadcasting drug advertisement. If the pharmaceutical firm fails to comply with the provision, the TFDA shall announce in the newspaper the name of the responsible person of the pharmaceutical firm, the name of the drug, and the act of violation. In the case of serious violation, the approval of the NDA may be revoked by the TFDA, along with the restriction that no application for use of the original name of the said drug shall be accepted within a period of two years thereafter.

Drug Safety Surveillance

In order to ensure the quality, efficacy and safety of drugs, and to reduce the incidence of adverse drug reactions, the pharmaceutical firm is required to survey the safety of the drugs and to report any serious adverse reactions caused by drugs to the TFDA.

The Regulations for the Management of Drug Safety Surveillance ("Surveillance Regulations") provides the main obligations which the pharmaceutical firm shall fulfil. Under the current Surveillance Regulations, in addition to reporting any serious adverse reactions within the period provided by the Regulations for Reporting Severe Adverse Reactions of Drugs, the pharmaceutical firm shall also submit drug safety update reports periodically during the first five years after the pharmaceutical firm obtains the drug license.

Though such provisions are still in effect as of now, the TFDA has already promulgated the amendment of the Surveillance Regulations in April 2022, and the amendment will come into effect from January 1, 2023. Pursuant to the amendment, the TFDA extends the surveillance period from the first five years upon the pharmaceutical firm obtaining the drug license to the whole effective period of the drug license. As long as the drug license is in effect, the pharmaceutical firm shall keep tracking the safety of the drugs. Pursuant to the amendment, the pharmaceutical firm shall have a pharmacovigilance plan as its internal policy. During the surveillance period, which is also the effective period of the drug license, the pharmaceutical firm shall follow its own pharmacovigilance plan and take mitigation measures, if necessary. In addition to keep submitting the periodic drug safety update reports during the first five years just as current practice, the pharmaceutical firm shall also submit a drug safety summary report at the end of the first five years of the surveillance period. For the remaining period of the surveillance period, the pharmaceutical firm should only keep implementing its pharmacovigilance plan without submitting the update reports to the TFDA. However, if the TFDA considers necessary, it may request the pharmaceutical firm continues to collect the data and submit the periodic update for a designated period. Furthermore, the TFDA may provide such request more than once.

Regulations on Intellectual Property Rights

Patent Protection

Pursuant to the Taiwan Patent Act, amended on May 4, 2022, there are three types of patents in Taiwan: invention patents, utility model patents, and design patents. The respective patent terms are 20, 10, and 15 years, all calculated from the filing date of a patent application, while the patent rights are actionable from the issue date of the patent. An extension of patent term of a maximum of 5 years is possible for invention patents involving pharmaceuticals, agrichemicals, or manufacturing processes thereof to compensate for the regulatory delay caused by marketing authorization procedures.

In terms of the infringement disputes of a patent, the civil division of the Intellectual Property Court ("IP Court") hears civil actions relating to patent infringement. If the defendant of an infringement action challenges the validity of the disputed patent as a defense, the civil division will deal with the infringement and validity issues simultaneously. However, any person who intends to invalidate the disputed patent in all aspects must file revocation proceedings (invalidation action) with the TIPO. Decisions of the TIPO in an invalidation action can be appealed to the Ministry of Economic Affairs, and subsequently to the IP Court by way of filing an administrative lawsuit.

Patent Term Extension

Pursuant to the Patent Act, where a regulatory approval shall be obtained for the exploitation of an invention patent involving a pharmaceutical or agrichemical, or the manufacturing process thereof, if such regulatory approval is obtained after the publication of the concerned invention patent, the patentee may apply for one and only one extension of the patent term of said invention patent based on the first regulatory approval. The said regulatory approval is allowed to be used only once for seeking patent term extension.

The calculation of the extension period includes: (i) the period of clinical trials conducted for obtaining a pharmaceutical license from the TFDA; and (ii) the period for the NDA review process. The extension period approved shall not exceed the length of time when the patent cannot be exploited because of the filing of a request for the regulatory approval with the competent authorities in charge of the business. If the time needed to obtain the said regulatory approval exceeds five years, the granted patent term extension shall still be five years. When requesting for patent term extension, the request shall be submitted within three months after obtaining the first regulatory approval; no request for patent term extension shall be filed within six months prior to the expiry of the original patent term.

Patent Linkage System

Taiwan has established the patent linkage system through the Patent Act and the Pharmaceutical Affairs Act in 2018. In order to reduce the patent search burden of generic drug manufacturers and achieve the goal of early listing of generic drugs, the first important procedure of the patent linkage system is to enable generic drug manufacturers to quickly grasp the patent status of the brand drug. That is to say, since the purpose of patent linkage system is to avoid patent infringement disputes of generic drugs on the market, the generic pharmaceutical firm should be able to know what patent rights the brand drug has. Therefore, after the brand drug manufacturer obtains the drug license, patent information of new drugs should be disclosed within the statutory period.

Since the brand drug manufacturer is obliged to announce the patent rights of the new drug, there should be a corresponding procedure to require the generic pharmaceutical company to clarify and determine whether it will have a patent in the future within certain period. If the brand drug does not involve any patent rights or all patent rights have been extinguished, the TFDA should allow the generic drug to be marketed. In addition, if the brand drug is still protected by the patent right, and the generic pharmaceutical company has no intention of having an infringement dispute with the brand drug pharmaceutical company, then the TFDA should only allow the generic drug to be marketed after all patent rights have expired. On the other hand, if a generic drug intends to obtain the drug license earlier, it should avoid infringing on the patent right in the future.

As Taiwan adopts a double-track examination system in terms of patent invalidation procedures, anyone who intends to invalidate a patent may take two kinds of measures; one is to submit the application of ground for patent invalidation to the Taiwan Intellectual Property Office ("TIPO"); the other one is to file a lawsuit. Subject to such double-track examination system, if the generic drug manufacturer intends to obtain the drug license earlier, it may the following actions:

(i) Engaging in patent avoidance designs;

(ii) Challenging the validity of the drug patent right through submitting the application of ground for patent invalidation to the TIPO;

(iii) While the brand drug pharmaceutical firm files a patent infringement lawsuit against the generic drug pharmaceutical company, it may defend that the patent right of the brand drug has grounds for revocation; and

(iv) Filing a lawsuit to request the court to confirm that the generic drug does not infringe the patent right.

Before it is clarified whether the generic drug manufacturer has successfully avoided infringing the patent right or whether the patent right of the brand drug is invalid, patent infringement disputes may arise if the generic drug has been approved to obtain the drug license. Therefore, the Pharmaceutical Affairs Act provides that the drug license cannot be issued within 12 months, commencing from the date when the brand drug manufacturer receives the notice from the generic drug manufacturer regarding whether the drug patent is in doubt. With such provision, the brand drug manufacturer and the generic drug manufacturer have a certain period of time to clarify doubts through filing the application to the TIPO or filing the patent infringement lawsuit.

Market Exclusivity

As a supporting measure of the patent linkage system, the Pharmaceutical Affairs Act rewards generic drug manufacturers who take positive actions to achieve the legislative intention of promoting the early marketing of generic drugs. Such reward is that those generic drugs which meet the legal requirements have a 12-month exclusive sales period. During this 12-month exclusive period, only the brand drug and the generic drug exist on the market. Before the period expires, the TFDA will not approve other generic drugs for marketing, so that generic drugs that actively challenge the validity of the patent of the brand drug or engage in patent avoidance design may enjoy certain profits and rewards.

Copyright

The Taiwan Copyright Law provides that original copyrightable works shall enjoy exclusive rights automatically upon their completion, with no form of registration required. The competent authority for the application and registration of trademarks is the Taiwan Intellectual Property Office ("TIPO") under the Ministry of Economic Affairs. A copyrighted work is protected throughout the author's lifetime and 50 years after.

As a copyright holder, when enforcing a copyright, bears the burden of proving the copyright ownership (and sometimes even the creation time of the copyright, if such issue is being raised), relevant evidence of copyright ownership can be preserved by having the evidence notarized by a notary public. For important copyrighted work, it is recommendable to obtain a copyright certificate issued by a copyright owners' organization to serve as prima facie evidence of the completion and ownership of the copyright. However, it is important to note that such private organizations do not and cannot conduct any substantive examination of the copyrightability of a work. Therefore, when a work's copyrightable is being challenged, only a court will have a final say over such dispute on a case-by-case basis.

Trademarks

Trademark rights in Taiwan are governed by the Trademark Act. The competent authority for the application and registration of trademarks is the TIPO. Types of protection include trademarks, certification marks, collective membership marks and collective trademarks. The trademarks which are registered are protected for 10 years from publication in the Trademark Gazette. This term may be extended successively every 10 years via application for renewal.

Trade Secrets

The Taiwan Trade Secret Act mainly governs the following items: (1) the required elements of a trade secret; (2) ownership of a trade secret; (3) the licensing of a trade secret; (4) misappropriation of a trade secret; (5) the civil remedy and criminal penalty for the misappropriation of a trade secret; (6) the issuance of a protective order during criminal investigation. Pursuant to the Trade Secret Act, the information that can be protected under the Trade Secret Act is defined as any method, technique, process, formula, program, design, or other information that may be used in the course of production, sale or operation, and must meet the following requirements: (1) secrecy; (2) economic value; and (3) reasonable measures to maintain secrecy. Under the Trade Secret Act, the types of misappropriation include acquisition, use and divulging of a trade secret by unlawful means. The Trade Secret Act provides civil remedies and criminal penalties for trade-secret misappropriation.

TFDA Expedited Programs

The TFDA has developed five expedited programs to help to accelerate the application process, include abbreviated review program, priority review program, accelerated approval program, breakthrough therapy program, and pediatric and rare severe disease priority review voucher program. The TFDA is responsible for evaluating applications for designation. There are specific criteria for each expedited program. If a drug meets these criteria, it is eligible for expedited programs. At the time of NDA submission, the applicant should provide the designation letter.

For the abbreviated review program, the qualifying criteria include that (i) the drug should be New chemical entities ("NCE"); (ii) the drug has been approved by two of the three regulatory agencies (U.S. FDA, EMA, or MHLW/PMDA); and (iii) No ethnic difference in BSE. Under the abbreviated review program, the review process may be completed within 180 days, commencing from the submission date of the NDA.

For the priority review program, the drug should qualify two of the three qualifying criteria, including (i) the drug is NCE or new administration routes or new therapeutic compounds; (ii) the drug is intended to treat a serious condition and address an unmet medical need with major clinical advance; (iii) the drug is intended to address a public health or an unmet medical need which is under priority counseling and grant for research from the government. The review process will be shorter than standard review; however, the evaluation will be under normal TFDA approval standards in safety, effectiveness, and quality. Under the priority review program, the review process may be completed within 240 days, commencing from the submission date of the NDA.

For the accelerated approval program, the qualifying criteria include that (i) the drug is NCE or new administration routes or new therapeutic compounds; (ii) the drug shall meet one of the following criteria: (a) A drug is intended to treat a serious condition and address unmet medical need; or (b) A drug is intended to address an unmet medical need and granted as orphan drug in US, UK, Japan, Switzerland, Canada, France, Australia, Germany, Belgium, and Sweden; or (c) A drug is not an orphan drug in Taiwan; however, it is intended to address an unmet medical need and with difficulties of manufacturing or importing. The drug in accelerated approval program may be approved on the basis of the effect on a surrogate endpoint to predict clinical benefit. It can shorten the time from R&D to marketing. In principle, post-marketing confirmatory trials are required to verify its clinical benefit. Under the accelerated approval program, the review process may be completed within 240 days, commencing from the submission date of the NDA.

For the breakthrough therapy program, the qualifying criteria include that (i) the drug is NCE or new administration routes or new therapeutic compounds; (ii) preliminary clinical evidence indicates substantial improvement over available therapies on one or more clinically significant endpoints; (iii) the applicant has conducted at least a clinical trial in Taiwan, especially clinical trials in the early phase. The applicant should report the implementation progress and the R & D plan to TFDA at least every 3 months after designation. If an applicant has any regulatory issue, they can request the consultation with TFDA. Under the breakthrough therapy program, the review process may be completed within 240 days, commencing from the submission date of the NDA.

For the pediatric and rare severe disease priority review voucher program, the qualifying criteria include that (i) the drug is NCE or new administration routes or new therapeutic compounds; (ii) the drug is intended to treat a serious condition; (iii) the disease is mainly prevalent in pediatric population or the prevalence of the disease is less than five per ten thousand; (iv) the drug is intended to address an unmet medical need. Under the pediatric and rare severe disease priority review voucher program, the review process may be completed within 240 days, commencing from the submission date of the NDA.

Taiwan Healthcare Regulation

Drug Price Regulations

Taiwan has been implementing a compulsory, universal, single-payer national health insurance system since 1995, with the overall coverage reaching 99.9%. The benefit package is comprehensive, covering inpatient, outpatient, and dental services, traditional Chinese medicine, and so on. Most drugs including orphan drugs, target therapy drugs, and many expensive drugs are covered. In Taiwan, the National Health Insurance Agency ("NHI"), one of the departments of the Ministry of Health and Welfare, imposes direct price controls on drugs by fixing the reimbursement prices product by product. Every one or two years, the NHI implements the price regulation to re-set (usually decrease) the reimbursement price of each product. According to NHI's Principles on Drug Reimbursement Price Approval, a new drug is defined as a newly applied pharmaceutical product that owns a new chemical entity, new dosage form, new administrated route or new therapeutic effect compound to the listed items in the pharmaceutical benefit scheme. New drugs are further categorized as breakthrough, generic, and line extension based on drug innovation. Different reimbursement price policies are applied in accordance with how drugs are categorized based upon these definitions.

National Health Insurance Reform

Due to the Taiwan healthcare system's accessibility, Taiwan's healthcare expenditures have increased steadily over the years, and there is currently a budget shortfall. During recent years, there have been calls to reform Taiwan's National Health Insurance to avoid bankruptcy of the healthcare system.

As a large portion of the healthcare expenditures arise from the drug reimbursement, one of the main targets in the reform plan is to utilize the healthcare budget more reasonably and to allocate more reimbursement on new drugs considering patients' benefits.

In order to achieve such goal, the National Health Insurance Agency has taken some reform measures since 2018. The National Health Insurance Agency has adopted the mechanism of managed entry agreement to set up an upper limit of drug expenditures in order to mitigate the financial impact caused by new drugs on the National Health Insurance. Though under the managed entry agreement mechanism, the price of the new drugs is subject to limitation, the National Health Insurance Agency have increased its budgets on new drug reimbursement during 2020 to 2021, to achieve a balance between including more new drugs in the medical insurance coverage and the financial impact it may cause to the healthcare system.

Other Healthcare Compliance Requirements

Though Taiwan does not enact a special law for the management of the healthcare fraud, healthcare fraud shall be prosecuted under the Criminal Code. In order to establish a clearer standard for the pharmaceutical firms and the doctors to follow, the TFDA has published the Rule of the Relationship Between the Doctors and the Pharmaceutical Firms. Though such rule does not have mandatory enforcement, the court may refer to such rule as the standard to judge whether the behavior of doctors or pharmaceutical firms constitute fraud as defined in the Criminal Code.

Regulations on Consumer Protection

In Taiwan, the main regulation governing the consumer protection is the Consumer Protection Act. Pursuant to the Consumer Protection Act, a manufacture shall be liable for any damage caused by its products, unless it is able to prove that the products have met and complied with the contemporary technical and professional standards of reasonably expected safety requirements prior to the launching of such products into the market. Furthermore, if the products may endanger consumers' lives, bodies, health or property, they shall be labelled in a conspicuous place with a warning and the methods for emergency handling of such danger. If an enterprise fails to perform its labelling obligations in this regard, it will be held liable for the damage caused thereby.

In addition to the Consumer Protection Act, Taiwan regulations also provide special liability regimes for medicinal products. Pursuant to the Drug Injury Relief Act, the pharmaceutical manufactures and importers are required to make contributions to the Drug Injury Relief Fund according to a certain percentage of their drug sales in the previous year. Under the Drug Relief Act, alleged victims or their heirs/legal guardians may apply for drug injury compensation for death, disability and serious illness. Violation of such provision may result in fines.

Regulations on Personal Data Protection

The Personal Data Protection Act is the main law in Taiwan governing personal data protection. Under the Personal Data Protection Act, unless otherwise specified, a company is generally required to give notice to and obtain consent from an individual before collecting, processing, or using any of the said individual's personal information, subject to certain exceptions.

Pursuant to the Personal Data Protection Act, the personal data pertaining to a natural person's medical records, healthcare, genetics, sex life, physical examination and criminal records is classified as sensitive personal data, which shall be subject to certain stricter obligations.

In addition to the Personal Data Protection Act, when conducting the clinical trial, the sponsor and the investigator shall also comply with other relative regulations or practices with regard to the protection of the subject's personal data, such as the Human Subjects Research Act and the Regulations on Human Trials.

Regulations on Environmental Protection

The bedrock of environmental protection in Taiwan is the Basic Environment Act. In addition to the Basic Environment Act, Taiwan regulations regulate each type of pollution by a different set of regulations, including the Soil and Groundwater Pollution Remediation Act, the Waste Disposal Act, the Air Pollution Control Act, the Water Pollution Control Act, and Toxic and Concerned Chemical Substances Control Act. The competent authority governing the environmental regulations is the Environmental Protection Agency (EPA). Failure to comply with such regulations may result in fines and other administrative sanctions.

Regulations on Foreign Currency Exchange

The principal regulation governing foreign currency exchange in Taiwan is the Foreign Exchange Regulation Act, amended on April 29, 2009. Pursuant to the Foreign Exchange Regulation Act, Taiwan Dollars amounting under the amount of NTD$500,000 are freely convertible no matter what transaction they are in relation with. On the other hand, the transactions involving NTD$500,000 or more or its equivalent in foreign currency shall fulfill certain obligations as provided in the Regulations Governing the Declaration of Foreign Exchange Receipts and Disbursements or Transactions.

Under the Regulations Governing the Declaration of Foreign Exchange Receipts and Disbursements or Transactions, for those foreign exchange transactions which amounts more than NTD$500,000 and relates to the sales of goods or provision of services, such transaction shall be declared through filing a declaration statement. For those foreign exchange transactions which are not related to the sales of goods or provision of services, ranging from NTD$500,000 to US$ 50 million, such transaction shall be declared through filing a declaration statement, and providing supporting documents, such as contracts or letters of approval, to the bank. For those foreign exchange transactions which are not related to the sales of goods or provision of services, amounting more than USD 50 million, such transaction shall be declared through filing a declaration statement, providing supporting documents to the bank, and obtaining the approval of the Central Bank of Taiwan.

Though Taiwan government has promulgated the Regulations Governing Foreign Exchange Control on July 2, 1997, pursuant to the Foreign Exchange Regulation Act, the requirements for the government to implement those foreign exchange control measures should be subject to either of the following conditions: (1) When the domestic or foreign economic disorder might endanger the stability of the domestic economy; and (2) When Taiwan suffers a severe balance of payments deficit. From the past history, the Taiwan government only implemented these foreign exchange control measures once, in 1997 during the Asian Financial Crisis.

Regulations on Dividend Distribution

The principal regulations governing dividend distribution is the Company Act. Pursuant to the Company Act, a Taiwan company shall not pay dividends unless its losses have been covered and statutory reserve funds has been set aside, which should be 10% of the company's after-tax net profits. However, in the event that the company's statutory reserve funds have reached the total amount of the company's capital, the company does not need to set aside any amounts for its statutory reserve funds. If the company has no net profits, in principle, it shall not pay dividends.

Regulations on Employee Stock Incentive Plan

The principal regulations governing dividend distribution is the Company Act. Pursuant to the Company Act, a Taiwan company may choose to implement the employee stock incentive plan in 5 ways: (1) employee stock compensation, (2) employee stock option certificates, (3) employee subscription of new shares using cash as consideration, (4) treasury shares transferred to employees, (5) employee restricted share units. After the amendment of the Company Act on August 1, 2018, transferring the company's stocks to the employees of the company's parent company or its subsidiaries under the employee stock incentive plan is also permitted by law.

Regulations on Employment and Social Insurance

The labor law in Taiwan is regulated mainly by the Labor Standards Act, amended in June 2020. The Labor Standards Act governs the terms and conditions of employment such as working hours, holidays, rest periods, wages, overtime, leave, and termination of employment. According to Labor Standard Act, an employer is required to reach an agreement on salary with the employees, in which the agreed salary shall meet with the minimum amount set by the competent authority. Violations of the Labor Standards Act may result in fines and other administrative sanctions, and serious violations may result in criminal liabilities.

In order to protect workers' safety and health and to prevent occupational accidents, employers in Taiwan are also required to comply with the Occupational Safety and Health Act. According to the Occupational Safety and Health Act, the employer shall arrange safety equipment to prevent any emergency. In addition, the employer shall provide safety education and training for employees which shall enable the employees to protect themselves when any accident occurs.

Taiwan governmental authorities have passed a variety of laws and regulations regarding social insurance and employee's pension from time to time, including, among others, the Labor Insurance Act, the National Health Insurance Act, the Labor Pension Act, and the Employment Insurance Act. Pursuant to these laws and regulations, Taiwan companies must make contributions at specified levels for their employees to the relevant social insurance and pension funds. Failure to comply with such laws and regulations may result in various fines and legal sanctions.

Regulations on Taxation

According to the Taiwan Income Tax Act, a company incorporated in Taiwan is a Taiwan tax resident and will be subject to 20% corporate income tax on its worldwide income. A non-resident company will be subject to 20% corporate income tax on its Taiwan-sourced income. If a resident company does not distribute its financial earnings generated in a year to its shareholders by the end of the following year, a surtax of 5% would be imposed on the undistributed earnings.

Effective from 2020, the Taiwan Statute for Industrial Innovation was amended, which extends the tax incentive by 10 years until December 31, 2029 for research and development ("R&D") expenditure. Under the tax incentive program, a company conducting qualifying R&D activities may select one of the following incentives: (i) up to 15% of qualifying R&D expenses may be credited against corporate income tax payable in the current year; or (ii) up to 10% of qualifying R&D expenses may be credited against corporate income tax payable in the year expenses incurred and carried forward for the next 2 years. In addition, if a company uses NTD 1 million or more of its undistributed earnings to construct or purchase buildings, software or hardware equipment, or technology for use in production or operation within 3 years from the year such earnings are derived, such investment amounts may be deducted from the undistributed earnings in calculation of the current year's undistributed earnings for assessment of surtax imposed on undistributed earnings from the year 2018.

The alternative minimum tax ("AMT") imposed under the Taiwan Income Basic Tax Act is a supplemental income tax which applies if the amount of regular income tax calculated pursuant to the Taiwan Income Tax Act and relevant laws and regulations is below the amount of basic tax prescribed under the Taiwan Income Basic Tax Act. The taxable income for calculating AMT includes most income that is exempt from income tax under various legislations, such as capital gains from qualified securities and future transactions. The prevailing AMT rate for business entities is 12%.

According to the Taiwan Income Tax Act, a withholding tax rate of 21% shall generally be applicable to dividends distributed to non-Taiwan resident enterprise/individual investors. The withholding tax on the dividends may be reduced pursuant to a tax treaty between Taiwan and the jurisdictions in which the non-Taiwan shareholders reside. Taiwan currently has a treaty network with 34 countries.

SINGAPORE

Regulations on Intellectual Property Rights

The Intellectual Property Office of Singapore administers the intellectual property legislative framework in Singapore, which includes copyrights, trademarks and patents. Singapore is a member of the main international conventions regulating intellectual property matters, and the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights.

Copyright

Pursuant to the Copyright Act 2021 of Singapore, authors of protected works enjoy various exclusive rights, including the rights of reproduction and communication to the public. Generally, an author will automatically enjoy copyright protection as soon as he creates and expresses an original work in a tangible form. Authors and performers also have a distinct right to be identified whenever their works or performances are used in public unless exceptions apply. For commissioned works, the copyright will be owned by the author by default, unless otherwise agreed by contract. On the other hand, employers by default own the copyright in all content created by their employees in the course of the employees' employment, unless otherwise agreed by contract.

There is no need to file for registration to obtain copyright protection. Copyright works sent over the internet or stored on web servers are treated in the same manner as copyright material in other media. Online games and computer programs would qualify for such copyright protection, for example, as literary works, artistic works and/or cinematograph films.

Trademarks

Singapore operates a first-to-file system in respect of registered trademarks under the Trade Marks Act 1988 of Singapore, and the registered proprietor is granted a statutory monopoly of the trademark in Singapore in relation to the product or service for which it is registered. In the event of any trademark infringement, the registered proprietor will be able to rely on the registered trademark as proof of his right to the mark, and the infringement of a trademark may give rise to civil and criminal liabilities. Statutory protection of a registered trademark can last indefinitely, as long as the registration is renewed every 10 years.

Patents

The Patents Act 1994 of Singapore confers protection on patentable inventions on a first-to-file basis in Singapore, provided that the invention satisfies the requirements of novelty, having an inventive step and industrial applicability. Patents are valid for 20 years from the date of filing, subject to the payment of annual renewal fees. During the life of the patent, the owner will have the exclusive right to exploit the invention that is the subject of the patent.

Regulations on Dividend Distributions

The governing legislation for the distribution of dividends in Singapore is the Companies Act 1967 of Singapore, or the Companies Act. Under Section 403 of the Companies Act, a Singapore company is only allowed to pay dividends out of profits and there are certain restrictions on the use of profits for the purposes of dividend declaration. Firstly, any profits of a company applied towards the purchase of its shares pursuant to the share buyback provisions under the Companies Act cannot be payable as dividends to the shareholders. However, the foregoing restriction does not apply to any part of the proceeds received by the company from a sale or disposal of its treasury shares where the sums that were utilized to purchase those treasury shares initially came out of profits in the first place. Finally, any gains derived from the sale of treasury shares cannot be payable as dividends to the shareholders of the company.

In addition to complying with the Companies Act, the payment of dividends must also be in accordance with the company's constitution and the generally acceptable accounting principles in Singapore.

Regulations on Anti-money Laundering and Prevention of Terrorism Financing

The primary anti-money laundering legislation in Singapore is the Corruption, Drug Trafficking and Other Serious Crimes (Confiscation of Benefits) Act 1992 of Singapore, or CDSA, provides for the confiscation of benefits derived from, and to combat, corruption, drug dealing and other serious crimes. Generally, the CDSA criminalizes the concealment or transfer of the benefits of criminal conduct as well as the knowing assistance of the concealment, transfer or retention of such benefits.

The Terrorism (Suppression of Financing) Act 2002 of Singapore, or TSOFA, is the primary legislation for the combating of terrorism financing. It was enacted to give effect to the International Convention for the Suppression of the Financing of Terrorism. Besides criminalizing the laundering of proceeds derived from drug dealing and other serious crimes and terrorism financing, the CDSA also requires suspicious transaction reports to be lodged with the Suspicious Transaction Reporting Office and the TSOFA requires information about any property belonging to any terrorist or terrorist entity to be reported to the Commissioner of Police. If any person fails to lodge the requisite reports under the CDSA and the TSOFA, it may be subject to criminal liability.

INTERNATIONAL REGULATION

In addition to regulations in the United States, the European Union and Taiwan, we will be subject to a variety of other regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States, Europe or Taiwan. The approval and reimbursement process varies from country to country and the time may be longer or shorter than that required to obtain U.S. FDA, EMA or NMPA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. In all cases the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles having their origin in the Declaration of Helsinki.

Anti-Corruption Laws

The FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. §201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities, prohibit any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. This could become relevant in the conduct of international clinical trials where the sites for such studies may be a government-owned hospital. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight and debarment from government contracts.

In the European Union, interactions between pharmaceutical companies and physicians are governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at the European Union level and in the individual European Union member states. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the European Union member states. Violation of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union member states also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her regulatory professional organization, and/or the competent authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the individual European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

C. Organizational Structure

See "— A. History and Development of the Company."

D. Property, Plants and Equipment

See "— B. Business Overview — Facilities."

Item 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion of our financial condition and results of operations is based upon and should be read in conjunction with our consolidated financial statements and their related notes included in this annual report. This annual report contains forward-looking statements. In evaluating our business, you should carefully consider the information provided under the caption "Item 3. Key Information — D. Risk Factors" and elsewhere in this annual report. in this annual report. We caution you that our businesses and financial performance are subject to substantial risks and uncertainties and that our actual results and the timing of events may differ materially from those anticipated in these forward-looking statements.

A. Operating Results

We are a science-driven biotechnology company based in Taiwan and are committed to developing and commercializing innovative and differentiated new drugs mainly specializing in the treatment of urinary system diseases, with an initial focus on the markets of the U.S., the EU and Asia.

Since our inception in 2002, we have built integrated capabilities that encompass all key functionalities of drug development, including early-stage drug discovery and development, clinical trials, regulatory affairs, manufacturing, and commercialization. Leveraging our strong research and development capabilities and proprietary platform, we have been developing a series of botanical drug candidates, including our primary botanical drug candidate of Botreso®, another clinical-stage botanical drug candidate of PCP, and other preclinical-stage botanical drug candidates.

In June 2025, we completed our IPO. In connection with our IPO, we issued and sold 2,666,667 ordinary shares, at a price to the public of $7.50 per share. As a result of the IPO, the Company received $17,771 thousand in net proceeds, after deducting underwriting discounts, commissions and offering costs.

Our pipeline features three innovative and differentiated new drug candidates, and we are developing them for (i) the treatment of benign prostate hyperplasia/lower urinary tract symptoms, or BPH/LUTS, (ii) prostate cancer prevention (PCP), and (iii) the treatment of interstitial cystitis, respectively.

- **Botreso®:** Botreso® is our new botanical drug candidate developed for treatment of BPH/LUTS. Botreso® is expected to be our core product in the future. Botreso® is a softgel capsule containing patented active pharmaceutical ingredients derived from botanical raw materials, specifically, Lycopersecum Esculentum. Botreso® contains, in the largest concentrations, five carotenoids including lycopene, phytoene, phytofluene, tocopherol and beta-carotene. We developed Botreso® using chylomicron technology to improve its bioavailability. Chylomicron is a type of lipoprotein particles consisting of triglycerides and phospholipids.

  We have conducted four Phase III clinical trials for Botreso® in the U.S. and Taiwan, including two pivotal trials (one in the US and one in Taiwan) and two open-label extension studies (one in the US and one in Taiwan), using API-1. Our pivotal Phase III clinical trial for Botreso® in the U.S. failed to show a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population.

We resubmitted an NDA for Botreso® using API-1 to the US FDA on December 17, 2021, the US FDA accepted our NDA for review "with issues identified." In the February 22, 2022 Filing Issues Identified letter, the US FDA identified, among other things, the lack of demonstrated difference between Botreso® and placebo for the primary efficacy endpoint in the MCS-2-US-a study. US FDA identified additional issues, including issues regarding pharmacology, toxicology, and our pharmacokinetic submission, statistical analyses, and the content and format of our proposed Prescribing Information. In a Mid-Cycle meeting and communication with the US FDA on May 24, 2022, the US FDA also identified the fact that API-1, the botanical drug substance used in our clinical trials and that was the basis for our NDA, was not available. Based upon these observations, we voluntarily withdrew our NDA on November 30, 2022, to develop more information about API-2 for the US FDA's review, to address the US FDA's concerns of a lack of demonstrated difference between Botreso® and placebo for the primary efficacy endpoint, and to resolve other issues the US FDA had previously identified (and discussed above). In the December 12, 2022 Acknowledge Withdrawal from the US FDA, the US FDA stated that "this withdrawal will not prejudice any future decisions on filing" if we decide to resubmit our NDA, and we can retain the application number (NDA 212872).

We have been conducting further research and development on Botreso® and identified an additional source for the botanical drug substance API-2. API-1 and API-2 are similar drug substances covered by the same patent owned by us; however, because they are sourced from raw materials manufactured in different locations, the US FDA considers them to be different botanical drug substances.

We submitted a meeting request to the US FDA on April 14, 2023 with our very preliminary comparative specifications of API-1 and API-2, and request that the agency provide a WRO to questions about our refiling of the NDA for Botreso® using API-2. The US FDA agreed to our request and responded in writing on June 26, 2023. The US FDA informed us that the information we provided on API-2 was not sufficient to demonstrate comparability with API-1. In addition to a lack of API source, US FDA explained that we had not demonstrated a statistically significant difference between Botreso® with API-1 and placebo in the primary efficacy endpoint in the MCS-2-US-a study. The US FDA stated that without new clinical information, any resubmission of the NDA for Botreso® would be at risk of the agency refusing to accept the application, a RTF action.

We submitted a Type D WRO meeting request to the US FDA on December 12, 2023. We asked that the US FDA provide a written response to questions focused on obtaining US FDA review and comments on a new, proposed Phase III clinical trial protocol for Botreso® with API-2 and a Phase I pharmacokinetic study. We proposed to address chemistry and manufacturing controls for Botreso® in a separate, future meeting. FDA granted our WRO meeting request but clarified that they viewed the meeting as a Type C meeting because it encompasses an entirely new drug development program, including Phase 1 PK study and Phase III clinical trial for Botreso® made from API-2, which the agency characterizes as a new product with a new active pharmaceutical ingredient.

If our new Phase 1 PK and Phase III studies are successful and we address the other deficiencies the US FDA has previously identified (including clinical, pharmacological, statistical, pharmaceutical manufacturing, validation, and other issues), we plan to resubmit our NDA for Botreso® under the same NDA number to the US FDA. The resubmission timeline is unclear at this point, depending on the comments from the US FDA.

BPH/LUTS is the most common urinary tract disease in the middle-aged male population.
According to Frost & Sullivan, the global prevalence of BPH increased from 88.4 million in 2017 to 94.2 million in 2020, representing an increase of 6.5%.

The global BPH drugs market increased from US$3.7 billion in 2017 to US$4.1 billion in 2020, representing a CAGR of 4.6%. We are establishing a strong sales and marketing team that is expected to consist of employees with experience in relevant areas and our target markets, and plan to work with both domestic and international business partners to seize the great market opportunities and to help more patients reduce their distress caused by BPH/LUTS and drug side effects caused by chemical drugs.

- **PCP:** PCP is our new botanical drug candidate developed for the prevention of prostate cancer. PCP, like Botreso®, contains patented active pharmaceutical ingredients derived from botanical raw materials, specifically, *Lycopersecum esculentum*. PCP contains, in the largest concentrations, five carotenoids including lycopene, phytoene, phytofluene, tocopherol and beta-carotene. PCP and Botreso® are essentially the same in terms of active ingredients, dosage form, strength and route of administration; however, they are different drug candidates targeting different indications. PCP has completed the data lock in May 2025, and statistical analysis was completed in September 2025.

  Prostate cancer begins when cells in the prostate gland start to grow out of control. In general, the more quickly prostate cells grow and divide, the more chances there are for mutations to occur. According to Frost & Sullivan, the global prevalence of prostate cancer increased from 10.0 million in 2017 to 11.2 million in 2020, representing a CAGR of 3.9%. The global prostate cancer market increased from US$9.7 billion in 2017 to US$12.6 billion in 2019, representing a CAGR of 9.1%. In addition, the prostate-specific antigen abnormal population, or PSA abnormal population, representing men over 40 years old with a prostate-specific antigen test value of 4.0 ng/ml or higher, is exposed to a high risk of prostate cancer. From 2015 to 2020, the total number of PSA abnormal populations in the U.S., Taiwan and China increased from 5.0 million to 5.3 million.

- **IC:** Interstitial Cystitis (IC) is our additional key new drug candidate which is composed of polysorbate loaded micelles as nanocarriers which can be used in the intravenous injection and intravesical instillation. The micelles enhance the bioavailability by prolonging the duration of stay in the bladder and increase the penetration of drug across the bladder wall. IC/BPS, refers to interstitial cystitis and bladder pain symptoms that is often associated with voiding symptomatology and other systemic chronic pain disorders.

Key Factors Affecting Our Results of Operations

Costs and Expenses Structure

Our results of operations are significantly affected by our cost structure, which primarily consists of research and development expenses and general and administrative expenses.

Research and development activities are central to our business operations. We believe our ability to successfully develop drug candidates will be the primary factor affecting our long-term competitiveness, as well as our future growth and development. Developing high-quality drug candidates requires a significant investment of resources over a prolonged period of time, and a core part of our strategy is to continue making sustained investments in this area. Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, and engaging in activities related to regulatory filings for our drug candidates. Clinical studies become increasingly more expensive from Phase I/II and onwards due to an increase in the number of subjects enrolled in such studies. Research and development costs are expensed as incurred. Costs for certain activities, such as activities performed by third-party contractors relating to the manufacturing and preclinical studies and clinical trials of our drug candidates, are generally accrued based on our estimates of the actual services performed for a given period. These estimates are based on our evaluation of the progress to completion of specific tasks to be performed using information and data provided to us by our third-party contractors and vendors.

At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our drug candidates. We expect research and development costs to continue to increase for the foreseeable future as we continue to support and advance the clinical trials of our drug candidates, including Botreso®, PCP and IC.

Our general and administrative expenses consist primarily of employee salaries and related benefit costs for personnel in executive, finance and administrative functions, professional fees for legal, audit and accounting services, and expenses for rental of facilities. We expect our employee salaries and related costs for personnel in executive to increase in the future to support our clinical program and research and development efforts, and the commercialization of our product candidates in the event approval is obtained. We also anticipate that our general and administrative expenses will increase as we operate as a public company.

Funding for Our Operations

During the periods presented, our operations have been primarily financed through the issuance and sale of ordinary shares in our initial public offering, as well as loans from banks, related parties, and third parties. As our business and drug candidate pipeline continue to expand, we anticipate the need for additional funding through public or private offerings, debt financing, collaborations, licensing arrangements, or other sources. Any fluctuations in our ability to secure financing may affect our development plans, operating strategies, and overall results of operations. Upon the successful development and commercialization of one or more of our drug candidates, we expect to partially fund our operations with revenue generated from sales of our commercialized products. Additionally, if we enter into out-licensing or collaboration arrangements, we expect to supplement our funding with revenue derived from such agreements.

Our Ability to Commercialize and/or Out-License Our Drug Candidates

Our business and results of operations depend on our ability to out-license our drug candidates or, in the event any of our drug candidates are approved for marketing by the respective regulatory authority in a country, commercialize such drug candidates. Our core drug candidate, Botreso®, is under further clinical development in the U.S. If our new Phase 1 PK and Phase III studies are successful and we address the other deficiencies the US FDA has previously identified (including clinical, pharmacological, statistical, pharmaceutical manufacturing, validation, and other issues), we plan to resubmit our NDA for Botreso® under the same NDA number to the US FDA. The resubmission timeline is unclear at this point, depending on the comments from the US FDA. Although we currently do not have any product approved for commercial sale and have not generated revenue from product sales, we expect to generate revenue either from sales of a drug candidate if we obtain regulatory approval and successfully commercialize Botreso®, or from out-licensing arrangements if we enter into an out-license and/or collaboration agreement for Botreso® and other drug candidates.

Key Components of Results of Operations

Revenue

As of the date of this annual report, we have not generated any revenue. Our ability to generate revenue and to become profitable will depend upon the successful commercialization of, and/or our successful entry into out-license and/or collaboration arrangements in connection with, one or more of our drug candidates. Because of the numerous risks and uncertainties associated with product development and regulatory approval, and out-license and/or collaboration arrangements, we are unable to predict the amount or timing of product revenue or out-license and/or collaboration revenue.

Research and Development Expenses

Research and development expenses consist of costs associated with planning and conducting clinical trials of our drug candidates. Our research and development expenses primarily consist of:

- payroll and other related costs of personnel engaged in research and development activities;
- costs for preclinical testing of our technologies and clinical trials such as payments to CROs, investigators and clinical trial sites that conduct the clinical studies;
- costs to develop our drug candidates, including raw materials and supplies, product testing, clinical trial equipment and its depreciation, and facility related expenses;
- costs incurred in seeking regulatory approval of our drug candidates; and
- other research and development expenses.

Clinical trial costs are a significant component of our research and development expenses. Our current research and development activities primarily related to the clinical development of the following drug candidates:

- **Botreso®.** Botreso® is our drug candidate being developed for BPH/LUTS treatment. Botreso® has been subjected various stages of regulatory review by US FDA or TFDA. We have conducted four Phase III clinical trials for Botreso® in the U.S. and Taiwan, including two pivotal trials and two open-label extension studies (one in the US and one in Taiwan), using API-1. Our pivotal Phase III clinical trial for Botreso® in the U.S. failed to show a difference between treatment groups for the primary efficacy endpoint in the intent-to-treat population. In a communication with the US FDA on May 24, 2022, the US FDA also identified the fact that API-1, the botanical drug substance used in our clinical trials and that was the basis for our pending NDA, was not available. Based upon these observations, we voluntarily withdrew our pending NDA on November 30, 2022, to develop more information about API-2 for the US FDA's review, to address the US FDA's concerns of a lack of demonstrated difference between Botreso® and placebo for the primary efficacy endpoint, and to resolve other issues the US FDA had previously identified. We submitted a Type D Written Response Only (WRO) meeting request to the US FDA on December 12, 2023. We asked that the US FDA provide a written response to questions focused on obtaining US FDA review and comments on a new, proposed Phase III clinical trial protocol for Botreso® with API-2 and a pharmacokinetic study. We proposed to address chemistry and manufacturing controls (CMC) data for our proposed drug product in a separate, future meeting. US FDA granted our WRO meeting request but clarified that they viewed the meeting as a Type C meeting because it encompasses an entirely new drug development program, including Phase 1 PK study and Phase III clinical trial for a new product with a new active pharmaceutical ingredient. On May 23, 2024, we received a denial notice from the FDA, stating that it is premature for this stage of drug development, and until the company can provide complete Chemistry, Manufacturing, and Controls (CMC) information on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2, the U.S. FDA is unable to reach agreement on protocols designed to establish the safety and efficacy of Botreso®. We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2, which was initially submitted to the U.S FDA in October 2024. We are currently updating the Module 3, stability data and other data, which will be submitted in Quarter 2 of 2026 to get any feedback from the U.S. FDA.

- **PCP.** PCP is our key drug candidate being developed for the prevention of prostate cancer. We received the investigation (IND) implication approval from the TFDA and initiated in November 2014. We have completed the phase II clinical trial, with data lock in May 2025 and statistical analysis completed in September 2025.The results indicated it met its primary endpoint, showing a positive trend in positive biopsy rates and incidence of higher-grade prostate cancer after 104 weeks of administration, and indicated a significant secondary potential therapeutic profile regarding metabolic regulation.

We incurred research and development expenses of approximately US$1,071 thousand, US$927 thousand, and US$813 thousand for the year ended December 31, 2023, 2024, and 2025, representing approximately 38%, 45%, and 31% of our total operating expenses for those periods, respectively. Our research and development expenses may vary substantially from period to period according to the status of our research and development activities. The timing of expenses is impacted by the commencement of clinical trials and enrollment of patients in clinical trials. We expect our research and development expenses to continue to increase for the foreseeable future, as we advance our core drug candidates, Botreso® and key drug candidate, PCP, toward later stages and continue to expand our operations.

General and Administrative Expenses

Our general and administrative expenses consist primarily of employee salaries and related benefit costs for personnel in executive, finance and administrative functions. General and administrative expenses include professional fees for legal, audit and accounting services, expenses for rental of facilities and litigation expenses. For the year ended December 31, 2023, 2024, and 2025, our general and administrative expenses amounted to approximately US$1,679 thousand, US$1,085 thousand, and US$1,749 thousand, respectively.

We anticipate that our general and administrative expenses will increase in the future to support ongoing and planned research and development of our core drug candidate and additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, investor relations activities and other administrative and professional services.

Selling and Marketing Expenses

Our selling and marketing expenses consist primarily of employee salaries and related benefit costs for personnel in selling and marketing functions. Other selling and marketing expenses include promotion costs. For the year ended December 31, 2023, 2024, and 2025, our selling and marketing expenses amounted to approximately US$47 thousand, US$44 thousand, and US$45 thousand, respectively.

We anticipate that our selling and marketing expenses will increase in the future to support commercial activities for the potential commercialization of drug candidates.

Interest Income (Expense)

Interest income consists primarily of interest income derived from our cash and loan to shareholder. Interest expense consists primarily of interest on borrowings under outstanding loan agreements and accrued interest incurred pursuant to loans due to related parties.

Other Gains and Losses

Other gains and losses consist primarily of foreign exchange gains and losses, contingent losses due to litigations, and non-operating gains or losses.

Taxation

Cayman Islands

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty or withholding tax applicable to us or to any holder of our ordinary shares. There are no other taxes likely to be material to us levied by the Government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within the jurisdiction of the Cayman Islands. No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies except those which hold interests in land in the Cayman Islands. Save and except that the Cayman Islands is a party to a double tax treaty entered into with the United Kingdom in 2010, the Cayman Islands are not party to any double tax treaties that are applicable to any payments made to or by the Company. There are no exchange control regulations or currency restrictions in the Cayman Islands. Payments of dividends and capital in respect of 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 ordinary shares, nor will gains derived from the disposal of ordinary shares be subject to Cayman Islands income or corporation tax.

Taiwan

Entities incorporated in Taiwan are subject to corporate income tax rate of 20% and a 5% surtax on undistributed earnings. Effective from 2020, Taiwan Statute for Industrial Innovation was amended, which extends the tax incentive by 10 years until December 31, 2029 for research and development (“R&D”) expenditure. Under the tax incentive program, a company conducting qualifying R&D activities may select one of the following incentives: (i) up to 15% of qualifying R&D expenses may be credited against corporate income tax payable in the current year; or (ii) up to 10% of qualifying R&D expenses may be credited against corporate income tax payable in the year expenses incurred and carried forward for the next 2 years. In addition, if a company uses NTD 1 million or more of its undistributed earnings to construct or purchase buildings, software or hardware equipment, or technology for use in production or operation within 3 years from the year such earnings are derived, such investment amounts may be deducted from the undistributed earnings in calculation of the current year’s undistributed earnings for assessment of surtax imposed on undistributed earnings from the year 2018. The alternative minimum tax (“AMT”) imposed under the Taiwan Income Basic Tax Act is a supplemental income tax which applies if the amount of regular income tax calculated pursuant to the Taiwan Income Tax Act and relevant laws and regulations is below the amount of basic tax prescribed under the Taiwan Income Basic Tax Act. The taxable income for calculating AMT includes most income that is exempt from income tax under various legislations, such as capital gains from qualified securities and future transactions. The prevailing AMT rate for business entities is 12%.

Our subsidiaries, Health Ever Bio-Tech Co., Ltd. and Genvace Biotechnology Co., Ltd. which are both incorporated in Taiwan, and are subject to corporate income tax at a rate of 20% and surtax on undistributed earnings at a rate of 5%. Both entities have no taxable income for the years ended December 31, 2023, 2024, and 2025; therefore, no provision for income taxes has been provided.

Singapore

Entities incorporated in Singapore are subject to corporate income tax rate of 17%. Our subsidiary, Jyong Biotech International Pte. Ltd., which was incorporated under the law of Singapore on September 29, 2022, and is subject to corporate income tax rate of 17%. The Singapore entity has no taxable income for the years ended December 31, 2023, 2024, and 2025.

Hong Kong

Entities incorporated in Hong Kong are subject to profits tax in Hong Kong at the rate of 16.5%. According to Tax (Amendment) (No. 3) Ordinance 2018 published by Hong Kong government, effective April 1, 2018, under the two-tiered profits tax rates regime, the profits tax rate for the first HKD2 million of assessable profits will be lowered to 8.25% (half of the rate specified in Schedule 8 to the Inland Revenue Ordinance (IRO)) for corporations.

Our subsidiary, Top ShunXing Bio-Tech Co., Limited is subject to Hong Kong profits tax at a tax rate of 8.25% for assessable profits on the first HKD2 million and 16.5% for any assessable profits in excess. No Hong Kong profit tax was provided as there was no estimated assessable profit that was subject to Hong Kong profits tax for the years ended December 31, 2023, 2024, and 2025.

PRC

Under the Enterprise Income Tax Laws of the PRC, or the EIT Laws, domestic enterprises and Foreign Investment Enterprises, or the FIEs, are usually subject to a unified 25% enterprise income tax rate, while preferential tax rates, tax holidays and tax exemption may be granted on case-by-case basis.

Our PRC subsidiary, Innovative Biotech Co., Ltd., is subject to the statutory rate of 25%, in accordance with the EIT Law. No provision for PRC corporate income tax has been made for the years ended December 31, 2023, 2024, and 2025, as Innovative Biotech Co., Ltd. had no such assessable profit.

Results of Operations

Comparison of the Fiscal Years Ended December 31, 2023 and 2024

The following table sets forth a summary of our consolidated results of operations for the years ended December 31, 2023 and 2024. This information should read together with our consolidated financial statements and related notes included elsewhere in this Annual Report. The operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Years Ended December 31,		Change	
	2023	2024	US$	%
	(amounts in US$ and in thousands)			
Expenses				
Research and development	US $1,071	US $927	(144)	(13)
Selling and marketing	47	44	(3)	(6)
General and administrative	1,679	1,085	(594)	(35)
Total operating expenses	2,797	2,056	(741)	(26)
Loss from operations	(2,797)	(2,056)	741	26
Other incomes (expenses):				
Interest income	56	7	(49)	(88)
Interest expenses	(757)	(1,035)	(278)	(37)
Other (losses) gains, net	(902)	65	967	107
Total other expense, net	(1,603)	(963)	640	40
Loss before income tax	(4,400)	(3,019)	1,381	31
Income tax expense	—	—	—	—
Net loss	US $(4,400)	US $(3,019)	1,381	31

Revenue

We did not generate any revenue for the years ended December 31, 2023 and 2024.

Research and Development Expenses

Our research and development expenses decreased by 13% from approximately US$1,071 thousand for the year ended December 31, 2023, to approximately US$927 thousand for the year ended December 31, 2024. The decrease was primarily attributable to a decrease in contracted research expenses and clinical trial expenses relating to our Phase II clinical trials for PCP and the preparation of the initial new drug application for Botreso® for submission to the US FDA. Additionally, there was a decrease in payroll and other headcount-related expense due to a reduction in the research and development office staff in our Taiwan subsidiary. We anticipate research and development expenses to increase in the future as we plan to initiate further clinical trials for PCP in Taiwan and apply for the necessary approvals to conduct the same clinical trials for PCP in other relevant jurisdictions. Further, given the withdrawal of our NDA from US FDA review for Botreso® with API-1, we anticipate further drug substance and drug product development and additional clinical trials for that key drug candidate with API-2. We have asked that the US FDA to provide a written response to questions focused on obtaining US FDA review and comments on a new, proposed Phase III clinical trial protocol for Botreso® with API-2 and a pharmacokinetic study. On May 23, 2024, we received a denial notice from the FDA, stating that it is premature for this stage of drug development, and until we can provide complete Chemistry, Manufacturing, and Controls (CMC) information on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2, the U.S. FDA is unable to reach agreement on protocols designed to establish the safety and efficacy of Botreso®. We have completed the CMC documentation on the active pharmaceutical ingredient-2 (API-2) and a plan to establish comparability between API-1 and API-2, which was initially submitted to the U.S FDA in October 2024. We are currently updating the Module 3, stability data and other data, which will be submitted in Quarter 2 of 2026 to get any feedback from the U.S. FDA.

The following table sets forth a breakdown of the major components of our research and development expenses in absolute amounts and as a percentage of our total research and development expenses for the years ended December 31, 2023 and 2024:

	Years ended December 31,			
	2023		2024	
(in US$ thousands, except percentages)	**US$**	**%**	**US$**	**%**
Contracted research expenses and clinical trial expenses	273	26	184	20
Payroll	453	42	436	47
Depreciation	110	10	103	11
Consultancy and professional service fees	6	1	11	1
Other expenses	229	21	193	21
Total	**1,071**	**100**	**927**	**100**

General and Administrative Expenses

Our general and administrative expenses decreased by approximately US$594 thousand from the year ended December 31, 2023, to the year ended December 31, 2024, which was primarily due to a US$534 thousand decrease in professional service expenses in connection with this offering and other consulting services and a US$5 thousand decrease in payroll and other headcount-related expense due to a decrease in headcount of the general and administrative office in the Taiwan subsidiary. We expect these costs to increase materially in the near future as we become a public company.

Interest Expense

Our interest expense increased by approximately US$278 thousand from the year ended December 31, 2023 to the year ended December 31, 2024, which was primarily due to an increase in the interest rate of bank loan and loan from related parties, partially offset by a decrease in the short-term and long-term borrowing for the year ended December 31, 2024.

Other Gain or Losses, net

Other gains and losses are primarily foreign exchange gains or losses, contingency loss due to litigations and other non-operating gains or losses. Other gains increased by approximately US$967 thousand from the year ended December 31, 2023 to the year ended December, 2024, primarily due to US$828 thousand of initial loss contingencies related to the penalty be paid to Taizhou Resource Bureau, which was recognized in 2023.

Comparison of the Fiscal Years Ended December 31, 2024 and 2025

The following table sets forth a summary of our consolidated results of operations for the years ended December 31, 2024 and 2025. This information should read together with our consolidated financial statements and related notes included elsewhere in this Annual Report. The operating results in any period are not necessarily indicative of the results that may be expected for any future period.

	Years Ended December 31,		Change	
	2024	2025	US$	%
	(amounts in US$ and in thousands)			
Expenses				
Research and development	US$ 927	US$ 813	(114)	(12)
Selling and marketing	44	45	1	2
General and administrative	1,085	1,749	664	61
Total operating expenses	2,056	2,607	551	27
Loss from operations	(2,056)	(2,607)	(551)	(27)
Other incomes (expenses):				
Interest income	7	610	603	8,614
Interest expenses	(1,035)	(2,539)	(1,504)	(145)
Other (losses) gains, net	65	(135)	(200)	(308)
Total other expense, net	(963)	(2,064)	(1,101)	(114)
Loss before income tax	(3,019)	(4,671)	(1,652)	(55)
Income tax expense	—	—	—	—
Net loss	US$ (3,019)	US$ (4,671)	(1,652)	(55)

Revenue

We did not generate any revenue for the years ended December 31, 2024 and 2025.

Research and Development Expenses

Our research and development expenses decreased by 12% from approximately US$927 thousand for the year ended December 31, 2024, to approximately US$813 thousand for the year ended December 31, 2025. This decrease was primarily driven by lower contracted research and clinical trial expenses for our PCP program; as the Phase II trials reached their final stages in the first half of 2025, the majority of significant milestone costs and clinical activities had already been recognized in 2024. Additionally, there was a decrease in depreciation and payroll and other headcount-related expense due to a reduction in the research and development office staff in our Taiwan subsidiary. We anticipate research and development expenses to increase in the future as we plan to initiate further clinical trials for PCP in Taiwan and apply for the necessary approvals to conduct the same clinical trials for PCP in other relevant jurisdictions. Further, given the withdrawal of our NDA from US FDA review for Botreso® with API-1, we anticipate further drug substance and drug product development and additional clinical trials for that key drug candidate with API-2.

The following table sets forth a breakdown of the major components of our research and development expenses in absolute amounts and as a percentage of our total research and development expenses for the years ended December 31, 2024 and 2025:

	Years ended December 31,			
	2024		2025	
(in US$ thousands, except percentages)	**US$**	**%**	**US$**	**%**
Contracted research expenses and clinical trial expenses	184	20	81	10
Payroll	436	47	422	52
Depreciation	103	11	82	10
Consultancy and professional service fees	11	1	28	3
Other expenses	193	21	200	25
Total	**927**	**100**	**813**	**100**

General and Administrative Expenses

Our general and administrative expenses increased by approximately US$664 thousand for the year ended December 31, 2025, from the year ended December 31, 2024. This increase was primarily attributable to a US$287 thousand increase in Nasdaq annual listing fees, US$181 thousand in professional service fees related to regulatory compliance and reporting obligations, and US$135 thousand in additional directors' and officers' liability insurance premiums. We expect these expenses to increase for the foreseeable future as we expand our headcount and infrastructure to support our operations as a public company.

Interest Income

Our interest income increased by approximately US$603 thousand from the year ended December 31, 2024 to the year ended December 31, 2025, was primarily attributable to interest earned on a new loan issued to shareholder during the year ended December 31, 2025.

Interest Expense

Our interest expense increased by approximately US$1,504 thousand from the year ended December 31, 2024 to the year ended December 31, 2025, which was primarily driven by a US$1,436 thousand upward adjustment in accrued interest on accrued liabilities - guarantee obligation arising from the share purchase agreement with Taizhou City Optimization and Upgrade Investment Partnership, following an updated assessment of legal claims and correspondence from its counsel. Furthermore, the increase was influenced by higher prevailing interest rates on bank and related-party loans, the effects of which were partially offset by a decrease in our average outstanding borrowings during 2025.

Other Losses, net

Other gains and losses are primarily foreign exchange gains or losses, contingency loss due to litigations and other non-operating gains or losses. Other losses increased by approximately US$200 thousand from the year ended December 31, 2024 to the year ended December, 2025, primarily due to an increase in the foreign exchange loss.

B. Liquidity and Capital Resources

As of the date of this annual report, we have not generated any revenue. We incurred net losses of approximately US$4,400, thousand, US$3,019 thousand, and US$4,671 thousand for the years ended December 31, 2023, 2024, and 2025, respectively. Our primary use of cash is funding our research and development expenses and professional services expenses. We used approximately US$2,601 thousand, US$3,624 thousand, and US$3,041 thousand in cash for our operating activities for the years ended December 31, 2023, 2024, and 2025, respectively. In addition, we are involved in several legal proceedings and the outcomes may be unfavorable to us. One of legal proceedings was resolved on August 21, 2024 and we returned RMB 10,952 thousand (US$1,507 thousand) of government subsidy to the New District Administrative Committee in 2024. The remaining subsidy and related interest expenses will be repaid in the future. As of December 31, 2024 and 2025, we have accrued liabilities of approximately US$22,727 thousand and US$25,112 thousand, respectively, and will require additional resources to settle these obligations. We have financed our operations primarily through the issuance of our ordinary shares and loan from banks, third parties, and related parties. As of December 31, 2024 and 2025, we had cash and cash equivalents of approximately thousand, US$98 thousand and US$1,175 thousand, respectively. Our cash consists primarily of bank deposits which are unrestricted as to withdrawal and use. Our ability to fund the operations is highly contingent on raising additional capital until we receive a regulatory approval that provides an ability to generate sufficient revenue, if ever. As such, we concluded that there is substantial doubt about our ability to continue as a going concern within one year after the issuance date of the consolidated financial statements.

We intend to pursue an additional offering to fund our future operations. However, there can be no assurance that we will be successful in completing such an offering on a timely basis or on terms acceptable to us. In the event that a public offering is not completed for a sufficient amount, our financing strategy includes obtaining credit facilities or bridge loans from related parties, in addition to pursuing other alternative such as third-party debt financing or strategic collaboration agreements. There can be no assurances, however, that the current operating plan will be achieved or that such related party funding or other financing will be available on commercially reasonable terms, or at all. If we are unable to obtain sufficient funding from by April 2027, we may have to delay our development efforts, limit activities and reduce research and development costs, which could adversely affect our business and the consolidated financial statements.

Although we conducted Phase III clinical trials for our core drug candidate, Botreso®, and filed a new drug application for Botreso® to the US FDA, the new drug application was subsequently withdrawn. We voluntarily withdrew our NDA on November 30, 2022, in order to develop more information about API-2 for the US FDA's review and to address ongoing questions regarding demonstrated difference between Botreso® and placebo for the primary efficacy endpoint in a clinical study for Botreso®, and to address other questions US FDA had previously identified in our NDA. Respecting our other drug candidates, PCP has just completed Phase II clinical trials and IC is under preclinical studies. We expect our expenses to increase substantially as compared to prior periods in connection with our ongoing activities, particularly as we continue the development of PCP and perform additional clinical trials and pursue regulatory approval for Botreso® and PCP. Furthermore, since the closing of our initial public offering, we have incurred additional costs associated with operating as a public company. Accordingly, we anticipate that we will need substantial additional funding in connection with our continuing operations. These factors raise substantial doubt about our ability to continue as a going concern. Our consolidated financial statements have been prepared assuming that we will continue as a going concern, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result from our possible inability to continue as a going concern.

We expect that our expenses will continue to increase substantially and that we will continue to incur significant operating losses and negative operating cash flows as we fund both ongoing research and development activities and new activities as well as working capital needs. 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 or on alternative uses. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development and commercialization of our drug candidates.

We believe that our cash and cash equivalents, together with our cash generated from our public offerings, will be sufficient to meet our current and anticipated needs for general corporate purposes for at least the next 12 months. However, we may consider to raise additional capital to fund future operations, and our future capital requirements will depend on many factors, including:

- the number and development requirements of the drug candidates we pursue;
- the scope, progress, timing, results and costs of discovering, researching and developing drug candidates, and conducting preclinical studies and clinical trials;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the cost of manufacturing our drug candidates and any products we commercialize, including costs associated with expanding our supply chain;
- the cost and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive regulatory approval;
- the cash received, if any, from commercial sales of any drug candidates for which we receive regulatory approval;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such collaborations and arrangements;
- the extent to which we acquire or in-license other drug candidates and technologies;
- our headcount growth and associated costs;
- the costs, timing and outcome of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- resources required to develop and implement policies and processes to promote ongoing compliance with applicable healthcare laws and regulations;
- the costs of operating as a public company in the United States.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. To the extent that we raise additional capital through the sale of equity, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to delay our future revenue streams or the development of drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings 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 drug candidates that we would otherwise prefer to develop and market ourselves. For additional information regarding the risks related to our need to obtain additional capital, see “Risk Factors — Risks Related to Our Business and Industry — We have recorded net cash outflow from operating activities since our inception and we expect to need to obtain additional financing to fund our operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our drug candidates.”

The following table summarizes the key components of our cash flows for the period indicated.

	Years ended December 31,		
	2023	2024	2025
	(amounts in US$ and in thousands)		
Net cash used in operating activities	US$ (2,601)	US$ (3,624)	US$ (3,041)
Net cash provided by (used in) investing activities	95	-	(13,507)
Net cash provided by financing activities	2,028	1,990	17,633
Effects of exchange rate changes on cash and restricted cash	(54)	(7)	(8)
Net (decreases) increase in cash and restricted cash	US$ (532)	US$ (1,641)	US$ 1,077

Operating Activities

Net cash used in operating activities was approximately US$2,601 thousand for the year ended December 31, 2023. This was primarily attributable to a net loss of US$4,400 thousand, adjusted for non-cash items of US$681 thousand and further impacted by changes in operating assets and liabilities, including an increase in accrued expenses of US$254 thousand, and an increase in other current liabilities of US$878 thousand, partially offset by a decrease in operating lease liabilities of US$128 thousand.

Net cash used in operating activities was approximately US$3,624 thousand for the year ended December 31, 2024. This primarily consisted of a net loss of US$3,019 thousand, adjusted for non-cash items of US$881 thousand, and was further impacted by a decrease in other current liabilities of US$1,542 thousand. This decrease was primarily associated with the repayment of a government subsidy to the New District Administrative Committee.

Net cash used in operating activities was approximately US$3,041 thousand for the year ended December 31, 2025. This result primarily reflected a net loss of US$4,671 thousand, adjusted for non-cash items of US$19,105 thousand, and changes in working capital, including an increase in prepayments and other assets of US$749 thousand, mainly due to interest receivable on a loan provided to a shareholder, a decrease in accrued expenses of US$159 thousand, and a decrease in operating lease liabilities of US$130 thousand. These uses of cash were partially offset by an increase in accrued liabilities of US$21,603 thousand and an increase in accrued expenses due to related parties of US$134 thousand.

Investing Activities

Net cash provided by investing activities was approximately US$95 thousand for the year ended December 31, 2023, which resulted from the proceeds from maturity of time deposits with original maturities more than three months.

No cash was provided by or used in investing activities during the year ended December 31, 2024.

Net cash used in investing activities was approximately US$13,507 thousand for the year ended December 31, 2025. This was primarily driven by loans provided to a shareholder and purchases of U.S. Treasury Bills, partially offset by proceeds from the partial collection of such loans and sale of U.S. Treasury Bills.

Financing Activities

Net cash provided by financing activities was approximately US$2,028 thousand for the year ended December 31, 2023, which consisted primarily of proceeds from short-term bank loans and loan from related parties of approximately US$11,829 thousand, partially offset by repayment of short-term, long-term bank loans and loan from related parties of approximately US$9,356 thousand.

Net cash provided by financing activities was approximately US$1,990 thousand for the year ended December 31, 2024, which consisted primarily of proceeds from short-term bank loans and loan from related parties of approximately US$11,668 thousand, partially offset by repayment of short-term and long-term bank loans of approximately US$9,465 thousand and an increase in payments of deferred offering costs of US$213 thousand.

Net cash provided by financing activities was approximately US$17,633 thousand for the year ended December 31, 2025. This was primarily attributable to $17,771 thousand in net proceeds from our initial public offering and US$24,472 thousand in proceeds from short-term bank loans and loans from related parties. These inflows were partially offset by US$24,496 thousand used for the repayment of short-term and long-term bank loans, as well as repayments of loans from related parties and third parties.

Material Cash Requirements

Contingencies

From time to time, we may have certain contingent liabilities that arise in the ordinary course of business activities. We accrue a liability for these matters when it is probable that a liability has been incurred and the amount can be reasonably estimated. As of the date of this annual report, we are not aware of any current pending legal matters or claims other than the litigation with Taizhou City Optimization and Upgrade Investment Partnership (Limited Partnership) and Taizhou Bay New Administrative Committee. See "Business — Legal Proceeding and Compliance".

Contractual Obligations and Commitments

In the course of normal business operations, we have agreements with contract service providers to assist in the performance of clinical trial activities. Such agreements are generally cancellable upon reasonable notice and payment of costs incurred. Upon such agreements, we need to pay expenditures related to clinical trial activities, which are based on actual costs incurred.

As of December 31, 2025, the future minimum payments under certain of our contractual obligations and commitments were as follows:

	Payments Due In				
	Total	**Less than 1 year**	**1-2 years**	**3-5 years**	**Thereafter**
Contractual obligations					
Operating leases	US$ 109	US$ 82	US$ 23	US$ 4	US$ —
Short-term loans	7,711	7,711	—	—	—
Long-term loans (including the current portion)	2,124	571	265	841	447
Loans from related parties	6,176	3,122	3,054	—	—
Loans from third parties	2,431	328	2,103	—	—
Total	US$ 18,551	US$ 11,814	US$ 5,445	US$ 845	US$ 447

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements between us and any other entity that have, or are reasonably likely to have, a current or future effect on our financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to shareholders. We have not entered into any financial guarantees or other commitments to guarantee the payment obligations of any third parties except for the guarantee mentioned in Note 18 of our audited consolidated financial statements included elsewhere in this annual report. In addition, we have not entered into any derivative contracts that are indexed to our shares and classified as shareholder's equity or that are not reflected in our consolidated financial statements included elsewhere in this annual report. Furthermore, we do not have any retained or contingent interest in assets transferred to an unconsolidated entity that serves as credit, liquidity or market risk support to such entity. We do not have any variable interest in any unconsolidated entity that provides financing, liquidity, market risk or credit support to us or engages in leasing, hedging or product development services with us.

C. Research and Development, Patents and Licenses, etc.

See "Item 4. Information on the Company — B. Business Overview — Intellectual Property."

D. Trend Information

Other than as disclosed elsewhere in this annual report, we are not aware of any trends, uncertainties, demands, commitments, or events that are reasonably likely to have a material effect on our net revenue, income from continuing operations, profitability, liquidity, or capital resources, or that would cause reported financial information not necessarily to be indicative of future operating results or financial condition. For a detailed discussion of trend information, see "— A. Operating Results —key Factors affecting our results of operations."

E. Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates. Our most critical accounting policies are summarized below. See Note 3 "Summary of Significant Accounting Policies" to our consolidated financial statements beginning on page F-8 of this annual report for a description of our other significant accounting policies.

Research and Development Expenses

Research and development expenses primarily include (1) payroll and other related costs of personnel engaged in research and development activities, (2) costs related to preclinical testing of our technologies and clinical trials such as payments to CROs, investigators and clinical trial sites that conduct the clinical studies; (3) costs to develop our drug candidates, including raw materials and supplies, product testing, clinical trial equipment and its depreciation, and facility related expenses, (4) other research and development expenses. Research and development expenses are charged to expenses as incurred when these expenditures relate to our research and development services and have no alternative future uses.

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses resulting from obligations under contracts with vendors, consultants and CROs, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which the services are provided under such contracts. We reflect research and development expenses in our consolidated financial statements by matching those expenses with the period in which services and efforts are expended. We account for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities and determine accrual estimates through review of the underlying contracts along with discussions with research and other key personnel as to the progress of studies, or other services being conducted. During the course of a study, we adjust our rate of expense recognition if actual results differ from our estimates. Estimates for accrued research and development expenses are classified as accrued expenses on the accompanying consolidated balance sheet.

Impairment of Long-lived Assets

We review our long-lived assets, including intangible assets with finite lives, for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount of the assets and fair value which is generally an expected present value cash flow technique. Our estimates of future cash flows attributable to our assets require significant judgment based on our historical and anticipated results and are subject to many factors. Factors we consider important which could trigger an impairment review include significant negative industry or economic trends, under-performance of a drug candidate in relation to expectations, and significant changes in the manner of our use of the acquired assets or the strategy for our overall business. If our assumptions are not correct, there could be an impairment loss in subsequent periods. For the years ended December 31, 2023, 2024, and 2025, no impairment loss of long-lived assets was recognized.

Guarantee Liabilities

We provided a joint and several guarantee for the performance of buyback shares obligation of the certain shareholders who transferred some of their shares in the Company to others. The guarantee of buyback shares obligation falls within the scope of ASC 460-10-15-4(b). The guarantee liability is recognized at the fair value at the inception of the guarantee and subsequently remeasured at each reporting period. Changes in the fair value of the guarantee liability are recorded as changes in guarantee liabilities in the consolidated statements of operations and comprehensive loss. When we settle the guarantee liability through the performance of the guarantee by making requisite payments to buy back shares, we record a corresponding deduction to the guarantee liability. When we are released from the guarantee obligation due to the buyback of shares performed by certain shareholders, it is recognized as a reversal of the deduction to the guarantee liability.

Loss contingencies

We are subject to certain legal proceedings and contingencies, the outcome of which are subject to significant uncertainty. We accrue for estimated losses if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred. We use judgment and evaluate whether a loss contingency arising from litigation or an unasserted claim should be disclosed or recorded. The outcome of legal proceedings and other contingencies is inherently uncertain and often difficult to estimate. Accrued legal contingencies are reported within other current liabilities or other non-current liabilities in the consolidated balance sheets based on the period in which we expect the contingency to be settled.

F. Recent Issued Accounting Pronouncements

A list of recently issued accounting pronouncements that are relevant to us is included in Note 3 “Summary of Significant Accounting Policies — Recent Accounting Pronouncements” of our consolidated financial statements beginning on page F-15 of this annual report.

G. JOBS Act

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards applicable to public companies. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. This transition period is only applicable under U.S. GAAP, which is the standard under which we prepare our consolidated financial statements.

We evaluated the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we intend to rely on all of these exemptions, including but not limited to, (i) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, 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 and (iii) complying with any new or revised financial accounting standards until such date that a private company is otherwise required to comply with such new or revised accounting standards. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of US$1.235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than US$1.0 billion in non-convertible debt during the previous three years; and (iv) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of the ordinary shares that are held by non-affiliates exceeds US$700.0 million as of the last business day of our most recently completed second fiscal quarter.

Item 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth information regarding our executive officers and directors as of the date of this annual report. Unless otherwise stated, the business address for our directors and executive officers is that of our principal executive offices at 23F-3, No. 95, Section 1, Xintai 5th Road, Xizhi District, New Taipei City, Taiwan, 221.

Directors and Executive Officers	Age	Position
Fu-Feng Kuo	68	Chairwoman of the Board of Directors and Chief Executive Officer
Wei Zhang	45	Chief Financial Officer
Fenglin Hsu	77	Director and Chief Technology Officer
Hung-Shu Fan	61	Independent Director
Pang-Chieh Chi	80	Independent Director
Ming Tsan Hsu	68	Independent Director

The following is a brief biography of each of our executive officers and directors:

Ms. Fu-Feng Kuo has been our director since December 2018. She currently serves as our chairwoman of the board of directors and chief executive officer. Ms. Kuo is the founder of Health Ever Bio-Tech Co., Ltd. She has also been serving as the Chairwoman and CEO of Genvace Biotechnology Co., Ltd. and Zhao Jian Fu Co., Ltd. since 2021 and 2011, respectively. Ms. Kuo has over 30 years of experience in the R&D of botanical products and new drugs and used to own multiple global patents in compositions. Since the establishment of Health Ever Bio-Tech Co., Ltd., or HEB, in 2002, Ms. Kuo has painstakingly researched and established CMC data, led HEB's conferences with regulatory authorities, and highly participated in preclinical studies as well as clinical trials of new drug candidates, such as Phase III clinical trials on Botreso® in the U.S. and Taiwan. Ms. Kuo had already initiated her research on natural medicine formulations before establishing HEB. During her study in the U.S., Ms. Kuo focused on developing new drugs for the treatment of urinary system diseases, formulated a preliminary blueprint, and began to explore active ingredients from plants. From 1996 to 1997, Ms. Kuo previously served as the guest lecturer on special nutritional foods in various hospitals in Taiwan. From 1987 to 1996, Ms. Kuo established Panatoz Corporation, a company engaging in international trade of health care products and plant raw materials and served as the Chairwoman as well as the general manager. Ms. Kuo received a master's degree in business management from Dominican University of California in 2000.

We believe Ms. Kuo is qualified to serve on the Board because of her substantial experience in executive leadership roles and her extensive knowledge of new drugs' R&D and corporate operations.

Ms. Wei Zhang has been the chief financial officer of Jyong Biotech Ltd. since February 2026. She served as the chief financial officer of Global Mofy AI Limited (formerly known as Global Mofy Metaverse Limited, Nasdaq: GMM) from May 2021 to January 2024, where she oversaw the Nasdaq initial public offering process, supervised all initial public-related activities, led fund-raising, implemented corporate strategy, and managed internal controls. She served as the investment director of Shenzhen Chuangdongfang Investment Co., Ltd. from March 2012 to December 2017 and Lenovo Capital and Incubator Group (LCIG) from January 2018 to December 2018, where she was mainly responsible for project investment and post-investment management in the fields of science and technology and greater consumer goods. Prior to that, she was an auditor at Shanghai Zhonghua Huyin Certified Public Accountants Co., Ltd. from June 2007 to April 2010 and supervised the audit and financial investigation during the overseas listing of Chinese enterprises. Ms. Zhang earned her master's degree in business administration from Oxford University in 2012 and her bachelor's degree in accounting from the University of South Australia in 2007.

Dr. Fenglin Hsu has been our director and chief technology officer since March 2025. Dr. Hsu has been serving as the chief technology officer of Health Ever Bio-Tech Co., Ltd. since July 2021. He is an expert in the research of natural medicinal chemistry, the R&D of Chinese herbal medicine, and the management of biotechnology medicine R&D. Prior to joining us, Dr. Hsu served as deputy editor-in-chief for Journal of Food and Drug Analysis, the director and consultant of NatureWise Biotech & Medicals Corporation from 2018 to 2021. Dr. Hsu served as the professor fellow for China Industrial & Commercial Research Institute and deputy editor-in-chief for Journal of Food and Drug Analysis from 2015 to 2018. Dr. Hsu served as a professor at Taipei Medical College (currently known as Taipei Medical University) from 1993 to 2014, and was awarded an Honorary Professorship in 2015. From 1993 to 2003, Dr. Hsu also served as the director of the Pharmacy Department of Taipei Medical College Hospital, where he engaged in drug management and clinical pharmacy. From 2000 to 2010, Dr. Hsu served as the director of Graduate Institute of Pharmacognosy at Taipei Medical College where he was responsible for the daily management of the Institute. Dr. Hsu received a Ph.D. in pharmaceutical sciences in 1985 and a master's degree in pharmaceutical sciences in 1982 from Kyushu University in Japan. Dr. Hsu has been a qualified pharmacist in Taiwan since 1949.

We believe Dr. Hsu is qualified to serve on the Board because of his extensive experience in the biotechnology field and his knowledge and expertise in drug development.

Mr. Hung-Shu Fan has been our independent director since March 2025. Mr. Fan has been serving as a professor in the Department of Accounting since 2010 and the associate dean of the College of Management at Fu Jen Catholic University in Taiwan since 2021. Mr. Fan currently serves as an independent director of Taiwan Semiconductor Co., Ltd. (Taipei Exchange: 5425) and a director of Tigerair Taiwan Co., Ltd. (Taipei Exchange: 6757). From 2018 to 2021, Mr. Fan served as a member of the Listing Review Committee of the Taiwan Stock Exchange and the OTC Listing Review Committee of The Taipei Exchange. From 2011 to 2021, Mr. Fan served as a member of the CPA Examination Review Committee of the Ministry of Examination. From 1994 to 2010, he successively served as the lecturer, associate professor, and head of the Department of Accounting at Fu Jen Catholic University. From 2015 to 2017, Mr. Fan worked as the director of TSC Venture Capital Co., Ltd. He also used to be the supervisor of Mega International Commercial Bank from 2016 to 2017, the independent supervisor of TSC Auto ID Technology Co., Ltd. from 2007 to 2010 and Para Light Co., Ltd. from 2004 to 2016, and the supervisor of Tidehold Development Co., Ltd. from 2002 to 2020. Mr. Fan received a master's degree in business administration and a Ph.D. degree in accounting from National Taiwan University in 1989 and 1997, respectively. From 2009 to 2022, Mr. Fan has been the moderator of 11 special research projects in accounting of the National Science and Technology Council. He was awarded the Special Outstanding Talent Award by the National Science and Technology Council in 2015 and 2017.

We believe Mr. Fan is qualified to serve on the Board due to his accounting background and lengthy experience in positions as a supervisor and independent director of publicly listed companies.

Mr. Pang-Chieh Chi has been our independent director since March 2025. Mr. Chi is the chief of Chi's Surgical Urology Medical Clinic in Taiwan. He has over 50 years of experience in the medical field and has expertise in urology, surgery, and family medicine. Mr. Chi has been serving as the physician-in-charge of the urology department at Taipei Tzuchi Hospital since 2007. From 1974 to 1981, Mr. Chi served as the director of the urology department at Zuoying Naval General Hospital. From 1981 to 1984, Mr. Chi served as the director of both the medical department and the surgical department at Shuntian Hospital in Taiwan. Mr. Chi received a bachelor's degree in medicine from National Defense Medical Center in 1971. During his years of practice, Mr. Chi has called on local doctors to conduct free clinics for disadvantaged groups and residents in undeveloped areas. He has also actively devoted himself to social medical welfare activities launched by the government in local communities. Mr. Chi has received numerous awards in Taiwan, such as "Outstanding Medical Staff" in 2002, "Eight Virtues Award" in 2012, "Medical Contribution Award" in 2017, and "National Medical Exemplary Award" in 2021.

We believe Mr. Chi is qualified to serve on the Board because of his successful practice in the treatment of urinary system disease as well as other medical fields.

Mr. Ming Tsan Hsu has been our independent director since March 2025. Mr. Hsu has been serving as the deputy chairman of the board of directors at Joyear Construction Co., Ltd. since April 2008 and the supervisor of Duennien Construction Co., Ltd since June 2008. From 2017 to 2018, Mr. Hsu previously served as the independent director of Health Ever Bio-Tech Co., Ltd. He served as the deputy general manager of Joyear Construction Co., Ltd. from 2003 to 2008 and Duennien Construction Co., Ltd. from 1989 to 2002. He served as the assistant manager of the Engineering Department at Chang Shen Construction Co., Ltd from 1988 to 1989, and the site director of Guang Ji Construction Co., Ltd. from 1982 to 1987. Mr. Hsu received a master's degree in business management from Dayeh University in Taiwan in 1999, a Ph.D. degree in management from Xi'an Jiaotong University in China in 2009, and a Ph.D. degree in law from China University of Political Science and Law in 2015. He previously served as the deputy director of Taiwan Innovative Business Management Association from 2018 to 2014.

We believe Mr. Hsu is qualified to serve on the Board because of his experience in corporate management, as well as his combined professional academic background in law and management.

Family Relationships

None of our directors or executive officers has a family relationship as defined in Item 401 of Regulation S-K.

B. Compensation

For the year ended December 31, 2023, 2024 and 2025 we paid an aggregate of approximately US$405,198, $399,400, and $396,967 in cash to our executive officers and directors, respectively. We have not set aside or accrued any amount to provide pension, retirement or other similar benefits to our executive officers and directors. We did not grant any stock options or restricted stock units to our named executive officers or directors in 2023, 2024 and 2025. Our Taiwan subsidiaries are required by Taiwan laws to make contributions equal to certain percentages of its employee's salary for his or her labor insurance, medical insurance, employment service insurance, occupational accident insurance and labor pension. Our PRC subsidiary is required by the PRC law to make contributions equal to certain percentages of each employee's salary for his or her pension insurance, medical insurance, unemployment insurance and other statutory benefits and a housing provident fund.

C. Board Practices

Board of Directors

Our board of directors is consist of five directors, including two executive directors and three independent directors. The powers and duties of our directors include convening general meetings and reporting our board's work at our shareholders' meetings, declaring dividends and distributions, determining our business and investment plans, appointing officers and determining the term of office of the officers, preparing our annual financial budgets and financial reports, formulating proposals for the increase or reduction of our authorized capital as well as exercising other powers, functions and duties as conferred by our articles of association. A director may exercise all the powers of our company to borrow money, mortgage its business, property and uncalled capital and issue debentures or other securities whenever money is borrowed or as security for any obligation of our company or of any third party. A director who is in any way, whether directly or indirectly, interested in a contract or proposed contract with our company is required to declare the nature of his interest at a meeting of our directors. A director may vote in respect of any contract or proposed contract or arrangement notwithstanding that he may be interested therein and if he does so his vote shall be counted and he may be counted in the quorum at any meeting of the directors at which any such contract or proposed contract or arrangement is considered. A general notice given to the directors by any director to the effect that he is a member or officer of any specified company or firm and is to be regarded as interested in any contract or arrangement with that company or firm or a specified person who is connected with him shall be deemed a sufficient declaration of interest for the purposes of voting on a resolution in respect to a contract or transaction in which he has an interest, provided that no such notice shall be effective unless either it is given at a meeting of the board of directors or the director takes reasonable steps to secure that it is brought up and read at the next board meeting after it is given.

None of our directors has a service contract with us that provides for benefits upon termination of service.

Committees of the Board of Directors

We have established an audit committee, a compensation committee and a nominating and corporate governance committee under the board of directors. We have adopted a charter for each of the three committees prior to the completion of our IPO. Each committee's members and functions are described below.

Audit Committee. Our audit committee is consist of Mr. Hung-Shu Fan, Mr. Pang-Chieh Chi and Mr. Ming Tsan Hsu, and is chaired by Mr. Hung-Shu Fan. Mr. Hung-Shu Fan, Mr. Pang-Chieh Chi and Mr. Ming Tsan Hsu satisfy the "independence" requirements of Rule 5605(c)(2) of the Listing Rules of the Nasdaq and meet the independence standards under Rule 10A-3 under the Securities Exchange Act of 1934, as amended. We have determined that Mr. Hung-Shu Fan qualifies as an "audit committee financial expert." The audit committee oversees our accounting and financial reporting processes and the audits of the financial statements of our company. The audit committee is responsible for, among other things:

- selecting the independent registered public accounting firm and pre-approving all auditing and non-auditing services permitted to be performed by the independent registered public accounting firm;

- reviewing with the independent registered public accounting firm any audit problems or difficulties and management's response;
- reviewing and approving all proposed related party transactions, as defined in Item 404 of Regulation S-K under the Securities Act;
- discussing the annual audited financial statements with management and the independent registered public accounting firm;
- reviewing major issues as to the adequacy of our internal controls and any special audit steps adopted in light of material control deficiencies;
- annually reviewing and reassessing the adequacy of our audit committee charter;
- meeting separately and periodically with management and the independent registered public accounting firm; and
- reporting regularly to the board of directors.

Compensation Committee. Our compensation committee is consist of Mr. Hung-Shu Fan, Mr. Pang-Chieh Chi and Mr. Ming Tsan Hsu, and is chaired by Mr. Pang-Chieh Chi. Mr. Hung-Shu Fan, Mr. Pang-Chieh Chi and Mr. Ming Tsan Hsu satisfy the "independence" requirements of Rule 5605(c)(2) of the Listing Rules of the Nasdaq. The compensation committee will assist the board of directors in reviewing and approving the compensation structure, including all forms of compensation, relating to our directors and executive officers. Our executive officers may not be present at any committee meeting during which their compensation is deliberated upon. The compensation committee is responsible for, among other things:

- reviewing the total compensation package for our executive officers and making recommendations to the board of directors with respect to it;
- approving and overseeing the total compensation package for our executives other than the three most senior executives;
- reviewing the compensation of our directors and making recommendations to the board of directors with respect to it; and
- periodically reviewing and approving any long-term incentive compensation or equity plans, programs or similar arrangements, annual bonuses, and employee pension and welfare benefit plans.

Nominating and Corporate Governance Committee. Our nominating and corporate governance committee is consist of Mr. Hung-Shu Fan, Mr. Pang-Chieh Chi and Mr. Ming Tsan Hsu and is chaired by Mr. Ming Tsan Hsu. Mr. Hung-Shu Fan, Mr. Pang-Chieh Chi and Mr. Ming Tsan Hsu satisfy the "independence" requirements of Rule 5605(c)(2) of the Listing Rules of the Nasdaq. The nominating and corporate governance committee will assist the board of directors in selecting individuals qualified to become our directors and in determining the composition of the board of directors and its committees. The nominating and corporate governance committee is responsible for, among other things:

- recommending nominees to the board of directors for election or re-election to the board of directors, or for appointment to fill any vacancy on the board of directors;
- reviewing annually with the board of directors the current composition of the board of directors with regards to characteristics such as independence, age, skills, experience and availability of service to us;
- selecting and recommending to the board of directors the names of directors to serve as members of the audit committee and the compensation committee, as well as of the nominating and corporate governance committee itself; and
- monitoring compliance with our code of business conduct and ethics, including reviewing the adequacy and effectiveness of our procedures to ensure proper compliance.

Duties of Directors

Under Cayman Islands law, our directors have a fiduciary duty to our company act honestly, in good faith and with a view to our best interests. Our directors also owe to our 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. In fulfilling their duty of care to us, our directors must ensure compliance with our memorandum and articles of association, as amended and restated from time to time. Our company has the right to seek damages if a duty owed by our directors is breached. In limited exceptional circumstances, a shareholder may have the right to seek damages in our name if a duty owed by our directors is breached.

Terms of Directors and Officers

Our officers are elected by and serve at the discretion of the board of directors. Pursuant to our second amended and restated memorandum and articles of association, our board of directors has 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 or as an addition to the existing board (subject to the maximum size limit, if any). Our directors are subject to retirement from office at least once every three years under our second amended and restated memorandum and articles of association. A director will be removed from office automatically if, among other thing, the director (i) becomes of unsound mind or dies; (ii) becomes bankrupt or makes any arrangement or composition with his creditors generally; (iii) is absent from meeting of the board for three consecutive meetings without special leave of absence form the board; (iv) resigns his office by notice in writing to our company; (v) is prohibited by law from being a director; and (vi) is removed from the office pursuant to any other provisions of our amended and restated memorandum and articles of association.

Employment Agreement and Indemnification Agreements

We have entered into employment agreements with each of our executive officers. Under these agreements, each of our executive officers is employed for a specified time period. We may terminate employment for cause, at any time, without advance notice or remuneration, for certain acts of the executive officer, such as conviction or plea of guilty to a felony or any crime involving moral turpitude, negligent or dishonest acts to our detriment, or misconduct or a failure to perform agreed duties. We may also terminate an executive officer's employment without cause upon advance written notice. In such case of termination by us, we will provide severance payments to the executive officer as expressly required by applicable law of the jurisdiction where the executive officer is based. The executive officer may resign at any time with an advance written notice.

Each executive officer has agreed to hold, both during and after the termination or expiry of his or her employment agreement, in strict confidence and not to use, except as required in the performance of his or her duties in connection with the employment or pursuant to applicable law, any of our confidential information or trade secrets, any confidential information or trade secrets of our clients or prospective clients, or the confidential or proprietary information of any third party received by us and for which we have confidential obligations. The executive officers have also agreed to disclose in confidence to us all inventions, designs and trade secrets which they conceive, develop or reduce to practice during the executive officer's employment with us and to assign all right, title and interest in them to us, and assist us in obtaining and enforcing patents, copyrights and other legal rights for these inventions, designs and trade secrets.

In addition, each executive officer has agreed to be bound by non-competition and non-solicitation restrictions during the term of his or her employment and typically for two years following the last date of employment. Specifically, each executive officer has agreed not to (i) approach our suppliers, clients, customers or contacts or other persons or entities introduced to the executive officer in his or her capacity as a representative of us for the purpose of doing business with such persons or entities that will harm our business relationships with these persons or entities; (ii) assume employment with or provide services to any of our competitors, or engage, whether as principal, partner, licensor or otherwise, any of our competitors, without our express consent; or (iii) seek directly or indirectly, to solicit the services of any of our employees who is employed by us on or after the date of the executive officer's termination, or in the year preceding such termination, without our express consent.

We will also enter into indemnification agreements with each of our directors and executive officers. Under these agreements, we agree to indemnify our directors and executive officers against certain liabilities and expenses incurred by such persons in connection with claims made by reason of their being our director or officer.

D. Employees

See "Item 4. Information on the Company — B. Business Overview — Employees."

E. Share Ownership

The following table sets forth information with respect to the beneficial ownership, within the meaning of Rule 13d-3 under the Exchange Act, of our ordinary shares as of the date of this annual report:

- each of our directors and executive officers; and
- each person known to us to beneficially own more than 5% of our ordinary shares.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC. In computing the number of ordinary shares beneficially owned by a person and the percentage ownership of that person, we have included ordinary shares that the person has the right to acquire within sixty (60) days, including through the exercise of any option, warrant, or other right or the conversion of any other security. These ordinary shares, however, are not included in the computation of the percentage ownership of any other person. The percentage of beneficial ownership of our ordinary shares is based on 76,027,667 ordinary shares outstanding as of the date of this annual report. Unless otherwise noted, the business address for each of our directors and executive officers is 23F-3, No. 95, Section 1, Xintai 5th Road, Xizhi District, New Taipei City, Taiwan, 221.

	Ordinary shares beneficially owned prior to our IPO†		Ordinary shares beneficially owned after our IPO		
	Number of ordinary shares	Percentage of beneficial ownership**	Number of ordinary shares	Percentage of beneficial ownership	Percentage of total voting power after this offering***
Directors and Executive Officers**					
Fu-Feng Kuo[(1)]	25,349,500	34.6%	25,349,500	33.3%	33.3%
Fenglin Hsu[(2)]	*	*	*	*	*
Hung-Shu Fan	—	—	—	—	—
Pang-Chieh Chi	—	—	—	—	—
Ming Tsan Hsu	—	—	—	—	—
Wei Zhang	—	—	—	—	—
All Directors and Executive Officers as a Group	**25,353,500**	**34.6%**	**25,353,500**	**33.3%**	**33.3%**
Principal Shareholders:					
Perfect Minds Co., Ltd.[(1)]	25,349,500	34.6%	25,349,500	33.3%	33.3%
Laxton Investments Company Limited[(3)]	7,631,200	10.4%	7,631,200	10.0%	10.0%
Linkage Gladden Enterprise Ltd.[(4)]	6,863,548	9.4%	6,863,548	9.0%	9.0%
Honest Dynasty Ltd.[(5)]	2,343,610	3.2%	2,343,610	3.1%	3.1%
Peak Valley International Co., Ltd.[(6)]	5,098,000	7.0%	5,098,000	6.7%	6.7%

Notes:

† Beneficial ownership information disclosed herein represents direct and indirect holdings of entities owned, controlled or otherwise affiliated with the applicable holder as determined in accordance with the rules and regulations of the SEC.

* Represents less than 1% of the total number of shares outstanding as of the date of this annual report.

** For each person and group included in this table, percentage ownership is calculated by dividing the number of shares beneficially owned by such person or group by the sum of the total number of shares outstanding as of the date of this annual report.

*** For each person or group included in this column, percentage of total voting power is calculated by dividing the voting power beneficially owned by such person or group by the voting power of all of our ordinary shares as a single class.

(1) Represents 25,349,500 ordinary shares held of record by Perfect Minds Co., Ltd., a Seychelles company. Perfect Minds is a wholly owned subsidiary of Innovation Global Group Limited, a BVI company ("IGGL"). IGGL is a wholly owned subsidiary of the Innovation Trust, a family discretionary trust for which Unity Trust Limited acts as professional trustee. Ms. Fu-Feng Kuo is the settlor of The Innovation Trust and serves as the sole director of Perfect Minds and as the Chief Executive Officer and Chairwoman of the Board of Directors of the Company. The registered address of Perfect Minds Co., Ltd. is No.4, Franky Building, Providence Industrial Estate, Mahe, Seychelles.

(2) Represents 3,000 ordinary shares held by Fenglin Hsu.

(3) Represents 3,471,000 ordinary shares held of record by, Laxton Investments Company Limited ("Laxton"), a British Virgin Islands company wholly owned by Shuai Shao, and 4,160,200 ordinary shares mortgaged by Honest Dynasty Ltd. to Laxton in 2018. According to the Mortgage Agreement entered between Honest Dynasty Ltd. and Laxton on April 15, 2018 ("2018 Mortgage Agreement"), an event of default has occurred on December 31, 2018 and Laxton may, following an event of default, enforce all of the 4,160,200 mortgaged shares. On March 31, 2023, Laxton enforced all of the 4,160,200 mortgaged shares. The registered address of Laxton Investments Company Limited is Kingston Chambers, PO Box 173, Road Town, Tortola, British Virgin Islands.

(4) Represents 6,863,548 ordinary shares held of record by Linkage Gladden Enterprise Ltd., a Belize company wholly owned by I-Hsien Huang. The registered address of Linkage Gladden Enterprise Ltd. is 25 Guzman Street Belama Phase 1, Belize City, Belize, C.A.

(5) Represents 6,503,810 ordinary shares held of record by Honest Dynasty Ltd., a Seychelles company wholly owned by Wen-Tsai Peng. The registered address of Honest Dynasty Ltd. is No. 4, Franky Building, Providence Industrial Estate, Mahe, Seychelles. According to the 2018 Mortgage Agreement, Honest Dynasty Ltd. mortgaged 4,160,200 ordinary shares to Laxton and on December 31, 2018, an event of default has occurred, thus Laxton may, following an event of default, enforce all such shares. On March 31, 2023, Laxton enforced all of the 4,160,200 mortgaged shares. The number of shares beneficially owned by Honest Dynasty Ltd. was 2,343,610, representing 3.2% of our 73,361,000 ordinary shares outstanding as of the date of this annual report.

(6) Represents 5,098,000 ordinary shares held of record by Peak Valley International Co., Ltd., a Seychelles company wholly owned by Chun-Ko Chen. The registered address of Peak Valley International Co., Ltd. is No. 4, Franky Building, Providence Industrial Estate, Mahe, Seychelles.

As of the date of this annual report, of our issued and outstanding ordinary shares are held by record holders in the United States, representing approximately 0.01% of our total outstanding shares on an as-converted basis. None of our shareholders has informed us that it is affiliated with a registered broker-dealer or is in the business of underwriting securities. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

F. Disclosure of a Registrant's Action to Recover Erroneously Awarded Compensation

Not applicable.

Item 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

See "Item 6. Directors, Senior Management and Employees — E. Share Ownership."

B. Related Party Transactions

Employment Agreements

See "Item 6. Directors, Senior Management and Employees — C. Board Practices-Employment Agreements and Indemnification Agreements."

Material Transactions with Related Parties

Set forth below are our material related party transactions that occurred during the fiscal years ended December 31, 2023, 2024, and 2025. The "related party transactions" are transactions identified in accordance with the rules prescribed under Part I, Item 7B of Form 20-F. Please see "Note 17 Related Party Balances and Transactions" from page F-24 to F-26 for more details.

		For the years ended December 31,		
Related Parties	**Nature**	**2023**	**2024**	**2025**
			US$ thousand	
Rental Expenses				
Panatoz Corporation	Significantly influenced by Fu-Feng Kuo, CEO of the Company	83	80	83
Zhao Jian Fu Co., Ltd.	Significantly influenced by Fu-Feng Kuo, CEO of the Company	48	47	48
Fu-Feng Kuo	CEO and Chairwoman of the Company	2	2	2

		As of December 31,	
Related Parties	**Nature**	**2024**	**2025**
		US$ thousand	
Loan from related parties			
Nobel Consumer Corporation	Managed by Xue-Juan Chen, a related party of the Company	1,706	2,558
Fu-Feng Kuo	CEO and Chairwoman of the Company	2,018	1,383
Panatoz Corporation	Significantly influenced by Fu-Feng Kuo, CEO of the Company	1,336	1,760
Zhao Jian Fu Co., Ltd	Significantly influenced by Fu-Feng Kuo, CEO of the Company	455	475
Operating lease liabilities due to related parties (including current and non-current)			
Panatoz Corporation	Significantly influenced by Fu-Feng Kuo, CEO of the Company	65	21
Zhao Jian Fu Co., Ltd	Significantly influenced by Fu-Feng Kuo, CEO of the Company	110	79
Fu-Feng Kuo	CEO and Chairwoman of the Company	—	7
Other non-current liabilities due to related parties			
Fu-Feng Kuo[(1)]	CEO and Chairwoman of the Company	62	62
Ju-Ting Chen[(1)]	The shareholder of the Company	566	566
Loan to related party			
Linkage Gladden Enterprise Ltd	Shareholder of the Company, see also "Item 6. Directors, Senior Management and Employees — E. Share Ownership"		

Notes:

(1) The balance of other non-current liabilities due to related parties resulted from the transaction with Fu-Feng Kuo and Ju-Ting Chen that they paid securities exchange tax and bridge loan fees on behalf of us during 2018 and 2019.

Nobel Consumer Corporation, Panatoz Corporation, Fu-Feng Kuo, and Ju-Ting Chen provided guarantees of short-term and long-term loans from Shanghai Commercial & Savings Bank, Ltd. and long-term loans from Taiwan Cooperative Bank to HEB. As of December 31, 2024, and 2025, the amount of borrowing guaranteed were US$9,314 thousand and US$9,835 thousand, respectively.

On June 24, 2025, we, as lender, entered into the a loan agreement with Linkage Gladden Enterprise Ltd., one of our shareholders, as borrower, pursuant to which we extended a loan in the principal amount of US$15,000 thousand at a fixed annual interest rate of 8.0%. Under the terms of the loan agreements, the principal, together with all accrued interest, was due in one single lump-sum payment upon maturity on June 23, 2027. In September and October 2025, we received aggregate repayments of approximately US$1,490 thousand. As of December 31, 2025, the outstanding loan receivable was approximately US$13,510 thousand and the related accrued interest receivable was approximately US$602 thousand. For the year ended December 31, 2025, interest income recognized from this loan was approximately US$602 thousand. In the subsequent period through May 12, 2026, we received an aggregate repayment of approximately US$12,328 thousand. As of the date of this annual report, the outstanding loan amount is approximately US$1,182 thousand, which will be fully repaid by Linkage Gladden Enterprise Ltd. no later than May 31, 2026. See also "Item 10. Additional Information — C. Material Contracts."

C. Interests of Experts and Counsel

Not applicable.

Item 8. FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

We have appended consolidated financial statements filed as part of this annual report. See "Item 18. Financial Statements."

Legal Proceedings

See "Item 4. Information on the Company-B. Business Overview-Legal Proceedings and Compliance."

Dividend Policy

Our board of directors has discretion on whether to distribute dividends, subject to certain restrictions under Cayman Islands law, namely that our Company may only pay dividends out of profits or share premium, and provided always that we are able to pay our debts as they become due in the ordinary course of business. Even if our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that the board of directors may deem relevant.

We have never declared or paid dividends on our ordinary shares. We do not have any present plan to declare any cash dividends on our ordinary shares in the foreseeable future after our IPO. We currently intend to retain most, if not all, of our available funds and any future earnings to operate and grow our business.

Jyong Biotech Ltd. is a holding company incorporated in the Cayman Islands. We have not received and do not have any present plan to receive dividends paid by our U.S., Taiwan, Singapore, Hong Kong and PRC subsidiaries, but we have discretion as to whether such dividends are paid, subject to applicable statutory and contractual restrictions, including PRC regulations which may govern the ability of our PRC subsidiary to pay dividends to us.

B. Significant Changes

Except as disclosed elsewhere in this annual report, we have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report.

Item 9. THE OFFER AND LISTING

A. Offer and Listing Details.

Our ordinary shares have been listed on the Nasdaq Global Market since June 17, 2025 under the symbol "MENS."

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares have been listed on the Nasdaq Global Market since June 17, 2025 under the symbol "MENS."

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

We incorporate by reference into this annual report the description of our Memorandum and Articles of Association, Exhibit 3.1, and the description of differences in corporate laws contained in our registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the SEC on August 17, 2023.

C. Material Contracts

Other than as described below and in "Item 4. Information on the Company" or elsewhere in this annual report, we have not entered into any material contracts other than in the ordinary course of business.

Loan Agreement with Linkage Gladden Enterprise Ltd.

On June 24, 2025, we, as lender, entered into the a loan agreement with Linkage Gladden Enterprise Ltd., one of our shareholders, as borrower, pursuant to which we extended a loan in the principal amount of US$15,000 thousand at a fixed annual interest rate of 8.0%. Under the terms of the loan agreements, the principal, together with all accrued interest, was due in one single lump-sum payment upon maturity on June 23, 2027. In September and October 2025, we received aggregate repayments of approximately US$1,490 thousand. As of December 31, 2025, the outstanding loan receivable was approximately US$13,510 thousand and the related accrued interest receivable was approximately US$602 thousand. For the year ended December 31, 2025, interest income recognized from this loan was approximately US$602 thousand. In the subsequent period through May 12, 2026, we received an aggregate repayment of approximately US$12,328 thousand. As of the date of this annual report, the outstanding loan amount is approximately US$1,182 thousand, which will be fully repaid by Linkage Gladden Enterprise Ltd. no later than May 31, 2026.

D. Exchange Controls

The Cayman Islands currently has no exchange control regulations or currency restrictions. For exchange control regulations or currency restrictions in Taiwan, see "Item 4 Information of the Company — B. Business Overview — Regulation — Regulations on Foreign Currency Exchange."

E. Taxation

TAIWAN TAXATION

The following is a general summary of the principal Taiwan tax consequences of the ownership and disposition of our ordinary shares by and to a non-resident individual or non-resident entity holder (referred to herein as a "Non-Taiwan Holder"). As used in the preceding sentence, a "non-resident individual" is generally a foreign national who owns our ordinary shares and is not physically present in Taiwan for 183 days or more during any calendar year, and a "non-resident entity" is a corporation or a non-corporate body that owns our ordinary shares and is organized under the laws of a jurisdiction other than Taiwan.

Holders should consult their tax advisors concerning the Taiwan tax consequences of holding our ordinary shares and the laws of any relevant taxing jurisdiction to which they are subject.

Capital gains from the sale or disposal of our ordinary shares

Sale or disposal of the ordinary shares of a Cayman Islands company is generally not regarded as the sale of Taiwan securities; thus, any gains generated therefrom by Non-Taiwan Holders are not subject to Taiwan income tax.

Securities Transaction Tax

Sale of the ordinary shares of a Cayman Islands company by Non-Taiwan Holders is generally not subject to Taiwan securities transaction tax.

CAYMAN ISLANDS TAXATION

The Cayman Islands currently levies no taxes on individuals or corporations based upon profits, income, gains or appreciations and there is no taxation in the nature of inheritance tax or estate duty or withholding tax applicable to us or to any holder of our ordinary shares. There are no other taxes likely to be material to us levied by the Government of the Cayman Islands except for stamp duties which may be applicable on instruments executed in, or after execution brought within the jurisdiction of the Cayman Islands. No stamp duty is payable in the Cayman Islands on transfers of shares of Cayman Islands companies except those which hold interests in land in the Cayman Islands. Save and except that the Cayman Islands is a party to a double tax treaty entered into with the United Kingdom in 2010, the Cayman Islands are not party to any double tax treaties that are applicable to any payments made to or by the Company. There are no exchange control regulations or currency restrictions in the Cayman Islands.

Payments of dividends and capital in respect of 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 ordinary shares, nor will gains derived from the disposal of ordinary shares be subject to Cayman Islands income or corporation tax.

U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a discussion of the material U.S. federal income tax considerations relevant to the acquisition, ownership, and disposition of our ordinary shares by U.S. Holders (as defined below) that will hold our ordinary shares as "capital assets" (generally, property held for investment) under the U.S. Internal Revenue Code of 1986, as amended, or the "Code"). This discussion is based upon applicable provisions of the Code, U.S. Treasury regulations promulgated thereunder, pertinent judicial decisions, interpretive rulings of the U.S. Internal Revenue Service, or the IRS, and such other authorities as we have considered relevant, all of which are subject to change, possibly with retroactive effect. This discussion does not address all aspects of U.S. federal income taxation that may be important to particular investors in light of their individual investment circumstances, including investors subject to special tax and/or reporting rules (for example, certain financial institutions; insurance companies; broker-dealers; pension plans; regulated investment companies; real estate investment trusts; tax-exempt organizations (including private foundations); holders who are not U.S. Holders (as defined below); holders who own (directly, indirectly, or constructively) 10% or more of the voting power or value of our stock; investors that will hold their ordinary shares as part of a straddle, hedge, conversion, constructive sale, or other integrated transaction for U.S. federal income tax purposes; investors that are traders in securities that have elected the mark-to-market method of accounting; or investors that have a functional currency other than the U.S. dollar), or holders that acquire ordinary shares through the exercise of options or other convertible instruments or in connection with the provision of services, all of whom may be subject to tax rules that differ significantly from those discussed below.

In addition, this discussion does not address tax considerations relevant to U.S. Holders under any non-U.S., state or local tax laws, the Medicare tax on net investment income, the one-percent excise tax on stock repurchases, estate or gift tax, or the alternative minimum tax. Each U.S. Holder is urged to consult its tax advisors regarding the U.S. federal, state, local, and non-U.S. income and other tax considerations of an investment in ordinary shares.

The discussion below of U.S. federal income tax consequences applies to you if you are a "U.S. Holder." You are a U.S. Holder if you are a beneficial owner of our ordinary shares and you are: (i) an individual who is a citizen or resident of the United States for U.S. federal income tax purposes; (ii) a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created in, or organized under the law of any state of the United States, or the District of Columbia; (iii) an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or (iv) a trust (A) the administration of which is subject to the primary supervision of a U.S. federal or state court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (B) that has otherwise validly elected to be treated as a U.S. person under the Code.

If you are a partner in a partnership (including any entity or arrangement treated or elects to be treated as a partnership for U.S. federal income tax purposes) that holds our ordinary shares, your tax treatment generally will depend on your status and the activities of the partnership (or any such entity or arrangement treated as or elects to be treated as a partnership for U.S. federal income tax purposes). Partners in a partnership (or any such entity or arrangement treated as or elects to be treated as a partnership for U.S. federal income tax purposes) holding our ordinary shares should consult their tax advisors regarding the tax consequences of an investment in the ordinary shares.

We are a corporation organized under the laws of the Cayman Islands. As such, we believe that we are properly classified as a non-U.S. corporation for U.S. federal income tax purposes. Under certain provisions of the Code and U.S. Treasury regulations, however, if pursuant to a plan (or a series of related transactions), a non-U.S. corporation (such as our company) acquires substantially all of the properties constituting a trade or business of a U.S. corporation or partnership, and after the acquisition 80% or more of the stock (by vote or value) of the non-U.S. corporation (excluding stock issued in a public offering related to the acquisition) is owned by former stockholder or partners of the U.S. corporation or partnership by reason of their holding stock or a capital or profits interest in the U.S. corporation or partnership, the non-U.S. corporation will be considered a U.S. corporation for U.S. federal income tax purposes. You are urged to consult your tax advisor concerning the income tax consequences of purchasing, holding or disposing of ordinary shares if we were to be treated as a U.S. corporation for U.S. federal income tax purposes. The remainder of this discussion assumes that our company is treated as a non-U.S. corporation for U.S. Federal income tax purposes.

Dividends

Subject to the PFIC rules discussed below, any cash distributions (including the amount of any other tax withheld) paid on our ordinary shares out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, will generally be includible in your gross income as dividend income on the day actually or constructively received by you. Because we do not intend to determine our earnings and profits under U.S. federal income tax principles, any distribution paid will generally be treated as a dividend for U.S. federal income tax purposes by us. Dividends received by corporations on our ordinary shares may be eligible for the dividends received deduction allowed to U.S. corporations under the Code.

Considering that the U.S. has not entered into an income tax treaty with Taiwan, in the event that we are deemed to be a Taiwan tax resident enterprise under Taiwan Tax Law, you may be subject to Taiwan withholding taxes on dividends paid on our ordinary shares, as described under "— Taiwan Taxation."

A non-corporate U.S. Holder generally may be subject to tax at preferential tax rates applicable to "qualified dividend income," provided that certain conditions are satisfied, including that (1) our stock is readily tradable on an established securities market in the United States, (2) we are neither a PFIC nor treated as such with respect to a U.S. Holder (as discussed below) for the taxable year in which the dividend was paid and the preceding taxable year, and (3) certain holding period requirements are met. U.S. holders are urged to consult their own tax advisors regarding the availability of the preferential rate for any dividends paid with respect to our ordinary shares.

For U.S. foreign tax credit purposes, dividends generally will be treated as income from foreign sources and generally will constitute "passive" category income. Depending on your particular circumstances, you may be eligible, subject to a number of complex limitations, to claim a foreign tax credit in respect of any foreign withholding taxes imposed on dividends received on our ordinary shares. If you do not elect to claim a foreign tax credit for foreign tax withheld, you may instead claim a deduction, for U.S. federal income tax purposes, for the foreign tax withheld, but only for a year in which you elect to do so for all creditable foreign income taxes. The rules governing the foreign tax credit are complex. You are urged to consult your tax advisor regarding the availability of the foreign tax credit under your particular circumstances.

Sale or Other Disposition of Ordinary Shares

Subject to the PFIC rules discussed below, you generally will recognize capital gain or loss upon the sale or other disposition of our ordinary shares in an amount equal to the difference, if any, between the amount realized upon the disposition and your adjusted tax basis in such ordinary shares. Any capital gain or loss will be long-term capital gain or loss if you have held the ordinary shares for more than one year, and will generally be U.S.-source gain or loss for U.S. foreign tax credit purposes. In the event that we are deemed to be a Taiwan tax resident enterprise under Taiwan Tax Law, gain from the disposition of the ordinary shares may be subject to tax in the PRC, as described under "— Taiwan Taxation." If such income were treated as U.S.-source income for foreign tax credit purposes, you might not be able to use the foreign tax credit arising from any tax imposed on the sale, exchange, or other taxable disposition of our ordinary shares unless such credit could be applied (subject to applicable limitations) against tax due on other income derived from foreign sources. The deductibility of a capital loss may be subject to limitations. You are urged to consult your tax advisor regarding the tax consequences if a foreign tax is imposed on a disposition of our ordinary shares, including the availability of the foreign tax credit under your particular circumstances.

PFIC Rules

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, 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 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. For this purpose, cash is categorized as a passive asset and the company's goodwill associated with active business activity is taken into account as an active asset. We will be treated as owning our proportionate share of the assets and income of any other corporation in which we own, directly or indirectly, more than 25% (by value) of the stock.

Based on the projected composition of our assets and income, we were not classified as a PFIC for our taxable year ending December 31, 2025. While we were not classified as a PFIC, because the value of our assets for purposes of the PFIC asset test will generally be determined by reference to the market price of our ordinary shares, fluctuations in the market price of our ordinary shares may cause us to become a PFIC for any subsequent taxable year. The determination of whether we will become a PFIC will also depend, in part, on the composition of our income and assets, which will be affected by how, and how quickly, we use our liquid assets and the cash raised in our IPO. Whether we are a PFIC is a factual determination and we must make a separate determination each taxable year as to whether we are a PFIC (after the close of each taxable year). Accordingly, we cannot assure you that we will not be classified as a PFIC for any future taxable year. If we are classified as a PFIC for any taxable year during which you hold our ordinary shares, we generally will continue to be treated as a PFIC, unless you make certain elections, for all succeeding years during which you hold our ordinary shares even if we cease to qualify as a PFIC under the rules set forth above.

If we are a PFIC for any taxable year during which you hold our ordinary shares, you will be subject to special tax rules with respect to any "excess distribution" that you receive and any gain you realize from a sale or other disposition (including a pledge) of our ordinary shares, unless you make a "mark-to-market" election as discussed below. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the ordinary shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period for the ordinary shares;
- amounts allocated to the current taxable year and any taxable years in your holding period prior to the first taxable year in which we are classified as a PFIC (a "pre-PFIC year") will be taxable as ordinary income; and
- amounts allocated to each prior taxable year, other than the current taxable year or a pre-PFIC year, will be subject to tax at the highest tax rate in effect applicable to you for that year, and such amounts will be increased by an additional tax equal to interest on the resulting tax deemed deferred with respect to such years.

If we are classified as a PFIC for any taxable year during which you hold our ordinary shares and any of our non-U.S. subsidiaries is also a PFIC, you will be treated as owning a proportionate amount (by value) of the shares of each such non-U.S. subsidiary classified as a PFIC for purposes of the application of these rules.

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 tax treatment discussed in the two preceding paragraphs. If you make a valid mark-to-market election for the ordinary shares, you will include in income each year an amount equal to the excess, if any, of the fair market value of the ordinary shares as of the close of your taxable year over your adjusted basis in such ordinary shares. You will be allowed a deduction for the excess, if any, of the adjusted basis of the ordinary shares over their fair market value as of the close of the taxable year. However, deductions will be allowable only to the extent of any net mark-to-market gains on the ordinary shares included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of the ordinary shares, will be treated as ordinary income. Ordinary loss treatment will also apply to the deductible portion of any mark-to-market loss on the ordinary shares, as well as to any loss realized on the actual sale or disposition of the ordinary shares, to the extent that the amount of such loss does not exceed the net mark-to-market gains previously included for such ordinary shares. Your basis in the ordinary shares will be adjusted to reflect any such income or loss amounts. If you make a mark-to-market election, tax rules that apply to distributions by corporations which are not PFICs would apply to distributions by us (except that the preferential rates for qualified dividend income would not apply).

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 U.S. Treasury regulations. The ordinary shares will be listed on the Nasdaq Global Market, which is a qualified exchange for these purposes. If the ordinary shares are regularly traded, and the ordinary shares qualify as "marketable stock" for purposes of the mark-to-market rules, then the mark-to-market election might be available to you if we were to become a PFIC.

Because, as a technical matter, a mark-to-market election cannot be made for any lower-tier PFICs that we may own, you may continue to be subject to the PFIC rules with respect to your indirect interest in any investments held by us that are treated as an equity interest in a PFIC for U.S. federal income tax purposes.

We do not currently intend to provide 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.

If you own our ordinary shares during any taxable year that we are a PFIC, you must file an annual report with the IRS, subject to certain exceptions based on the value of the ordinary shares held. You are urged to consult your tax advisor concerning the U.S. federal income tax consequences of purchasing, holding, and disposing of our ordinary shares if we are or become a PFIC, including the possibility of making a mark-to-market election.

Information Reporting and Backup Withholding

You may be required to submit to the IRS certain information with respect to your beneficial ownership of our ordinary shares, if such ordinary shares are not held on your behalf by certain financial institutions. Penalties also may be imposed if you are required to submit such information to the IRS and fail to do so.

Dividend payments with respect to ordinary shares and proceeds from the sale, exchange or redemption of ordinary shares may be subject to information reporting to the IRS and possible U.S. backup withholding. Backup withholding will not apply, however, to a U.S. Holder who furnishes a correct taxpayer identification number and makes any other required certification or who is otherwise exempt from backup withholding. U.S. Holders who are required to establish their exempt status generally must provide such certification on IRS Form W-9 or by otherwise establishing an exemption.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against your U.S. Federal income tax liability, and you may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the IRS and furnishing any required information. You are urged to consult your tax advisors regarding the application of the U.S. information reporting and backup withholding rules.

The U.S. federal income tax discussion set forth above is included for general information only and may not be applicable depending upon a holder's particular situation. Holders are urged to consult their tax advisors with respect to the tax consequences to them of the acquisition, ownership and disposition of our ordinary shares and warrants, including the tax consequences under state, local, estate, foreign and other tax laws and tax treaties and the possible effects of changes in U.S. or other tax laws.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We have previously filed with the SEC our registration statements on Form F-1 (File No. 333-277725), as amended.

We are subject to the periodic reporting and other informational requirements of the Exchange Act. Under the Exchange Act, we are required to file reports and other information with the SEC. Specifically, we are required to file annually a Form 20-F within four months after the end of each fiscal year. The SEC maintains a website at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding registrants that make electronic filings with the SEC using its EDGAR system. As a foreign private issuer, we are exempt from the rules of the Exchange Act prescribing the furnishing and content of proxy statements to shareholders under the federal proxy rules contained in Sections 14(a), (b) and (c) of the Exchange Act, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. Effective March 18, 2026, our executive officers and directors will be required, pursuant to the Holding Foreign Insiders Accountable Act, to file the Section 16(a) reports with the SEC to disclose their beneficial ownership of, and transactions in, our securities. Our 10% shareholders who are not officers or directors, however, will remain exempt from Section 16(a) reporting requirements.

I. Subsidiary Information

For a listing of our subsidiaries, see "Item 4. Information on the Company — A. History and Development of the Company."

J. Annual Report to Security Holders

No applicable.

Item 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest and Credit Risk

Our interest rate risk arises primarily from bank borrowing bearing interest based on floating rates. We currently do not have any interest rate hedging policy and have not historically used any derivative financial instruments to manage our interest risk exposure. As of December 31, 2024 and 2025, it is estimated that a general increase of 100 basis points in interest rate, with all other variables held constant, would have increased our pre-tax loss for the year by US$21 thousand and US$21 thousand, respectively.

Our credit risk is primarily attributable to cash. We mainly place or invest cash with reputable financial institutions in the jurisdictions where we and our subsidiaries are located. We do not believe that our cash has significant risk of default or illiquidity, and we will continually monitor the credit worthiness of these financial institutions. While we believe our cash does not contain excessive risk, future investments may be subject to adverse changes in market value.

Assets that potentially subject us to significant concentration of credit risk primarily consist of cash. We expect that there is no significant credit risk associated with our cash, which were held by reputable financial institutions in the jurisdictions where we and our subsidiaries are located. We believe that it is not exposed to unusual risks as these financial institutions have high credit quality.

Liquidity Risk

We manage liquidity risk by monitoring and maintaining a level of cash deemed adequate to finance its operations and mitigate the effects of fluctuations in cash flows. In addition, management monitors the utilization of bank borrowings and ensures compliance with loan covenants.

Foreign Currency Exchange Rate Risk

Fluctuations in exchange rates may adversely affect our financial results. Our functional currency is the U.S. dollar, but the functional currency for each of our foreign subsidiaries is the local currency. As a result, certain of our assets and liabilities which were not denominated in U.S. dollar are sensitive to foreign currency exchange rate fluctuations. As of December 31, 2025, substantially all of our total assets and liabilities were denominated in the NTD and RMB.

Item 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Not applicable.

Part II

Item 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

None.

Item 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

See "Item 10. Additional Information" for a description of the rights of securities holders, which remain unchanged.

Use of Proceeds

Registration Statement on Form F-1, as amended (File Number 333-277725)

The following "Use of Proceeds" information relates to the registration statement on Form F-1, as amended (File Number 333-277725) for our IPO, which was declared effective by the SEC on June 16, 2025. In June 2025, we completed our IPO and issued and sold an aggregate of 2,666,667 ordinary shares, at a price of $7.50 per share for gross proceeds of US$ 20,000 thousand, before deducting underwriting discounts and other related expenses. The Company received net proceeds of approximately US$17,771 thousand. Joseph Stone Capital, LLC was the representative of the underwriters of our IPO.

We incurred approximately US$2,229 thousand in expenses in connection with our IPO, which included approximately US$1,400 thousand in underwriting discounts, approximately US$480 thousand in expenses paid to or for underwriters, and approximately US$349 thousand in other expenses. None of the transaction expenses included payments to directors or officers of our Company or their associates, persons owning more than 10% or more of our equity securities, or our affiliates. None of the net proceeds we received from the IPO were paid, directly or indirectly, to any of our directors or officers or their associates, persons owning 10% or more of our equity securities, or our affiliates.

We received net proceeds of approximately US$17,771 thousand after the deduction of approximately US$2,229 thousand of offering costs. As of the date of this annual report, we have used US$15,000 thousand for a loan to Linkage Gladden Enterprise Ltd., US$2,495 thousand towards researching and developing new drugs and clinical trials, with the remaining funds used for general corporate purposes. As of the date of this annual report, Linkage Gladden Enterprise Ltd has repaid US$13,817,950 of the loan amount and the outstanding amount of the loan is US$1,182,050. We intend to use the remaining proceeds from our IPO in the manner disclosed in our registration statement on Form F-1, as amended (File Number 333-277725).

Item 15. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we carried out an evaluation of the effectiveness of our disclosure controls and procedures, which is defined in Rules 13a-15(e) of the Exchange Act, as of December 31, 2025. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of December 31, 2025 were ineffective.

Our conclusion is based on the fact that we lack accounting staff and resources with appropriate knowledge of U.S. GAAP and SEC reporting and compliance requirement and deficiency of IT policy and control procedures. Our management is currently in the process of evaluating the steps necessary to remediate the ineffectiveness, such as (i) working closely with external highly qualified accountants with relevant U.S. GAAP and SEC reporting experience and qualifications to strengthen the financial reporting function, establish a financial and system control framework, and arrange regular training programs on U.S. GAAP accounting for our accounting and financial reporting personnel; (ii) strengthening and improving the overall internal control function by employing an external consulting firm to assist us in assessing the compliance requirements of the Sarbanes Oxley Act; and (iii) strengthen corporate governance; and (iv) making an internal control report to the Audit Committee every quarter to report the progress and improvement in internal control, which is well monitored by the Audit Committee.

Management's Annual Report on Internal Control over Financial Reporting

This annual report on Form 20-F does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm, as permitted by the transition period established by rules of the SEC for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This annual report on Form 20-F does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC where domestic and foreign registrants that are non-accelerated filers, which we are, and "emerging growth companies," which we also are, are not required to provide the auditor attestation report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the period covered by this annual report on Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [RESERVED]

Item 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Mr. Hung-Shu Fan qualifies as an "audit committee financial expert" as defined in Item 16A of Form 20-F. Mr. Hung-Shu Fan satisfies the "independence" requirements of Section 5605(a)(2) of the NASDAQ Listing Rules as well as the independence requirements of Rule 10A-3 under the Exchange Act.

Item 16B. CODE OF ETHICS

Our board of directors has adopted a code of business conduct and ethics, which is applicable to all of our directors, officers, and employees. Our code of business conduct and ethics is publicly available on our website.

Item 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered and billed by WWC, P.C., our independent registered public accounting firm for the periods indicated.

	For the Years Ended December 31,	
	2025	**2024**
Audit fees[(1)]	$ 266,000	$ 264,000
Audit-related fees[(2)]	$ —	$ —
Tax fees[(3)]	$ —	$ —
All other fees	$ 7,682	$ 7,266
Total	**$ 273,682**	**$ 271,266**

(1) Audit fees include the aggregate fees billed for each of the fiscal years for professional services rendered by our independent registered public accounting firm for the audit of our annual financial statements or for the audits of our financial statements and review of the interim financial statements in connection with our IPO in 2025.
(2) Audit-related fees include the aggregate fees billed for related services by our principal accountant that are reasonably related to the performance of the audit or review of our financial statements and are not reported under audit fees.
(3) Tax fees represent the aggregated fees billed for professional services rendered by our independent registered public accounting firm for tax compliance, tax advice, and tax planning.

Item 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

Item 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

Item 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

None.

Item 16G. CORPORATE GOVERNANCE

As a Cayman Islands company listed on the Nasdaq Capital Market, we are subject to the Nasdaq corporate governance listing standards. The Nasdaq rules permit a foreign private issuer like us to follow the corporate governance practices of its home country. Certain corporate governance practices in the Cayman Islands, which is our home country, may differ significantly from the Nasdaq corporate governance listing standards.

We intend to follow the home country practices for the required quorum in lieu of Nasdaq Listing Rule 5620(c). A quorum required for any general meeting of shareholders consists of, at the time when the meeting proceeds to business, two shareholders holding shares which carry in aggregate (or representing by proxy) not less than one-third in nominal value of the total issued and outstanding voting shares in our company entitled to vote at such general meeting throughout the meeting.

Other than as described above, there are no significant differences between our corporate governance practices and those followed by U.S. domestic companies under Nasdaq corporate governance listing standards. We may in the future decide to use the foreign private issuer exemption with respect to some or all the other Nasdaq corporate governance rules. As a result, our shareholders may be afforded less protection than they otherwise would under the Nasdaq corporate governance listing standards applicable to U.S. domestic issuers. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

Item 16H. MINE SAFETY DISCLOSURE

Not applicable.

Item 16I. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

Item 16J. INSIDER TRADING POLICIES

Our board of directors has adopted insider trading policies and procedures governing the purchase, sale, and other dispositions of our securities by directors, senior management, and employees that are reasonably designed to promote compliance with applicable insider trading laws, rules, and regulations, and any listing standards applicable to us.

Item 16K. CYBERSECURITY

We have established cybersecurity risk management to identify, assess, and mitigate cybersecurity risks alongside other business risks. The process is in alignment with our strategic objectives and risk appetite. We may engage assessors, consultants, auditors, or other third parties to enhance our cyber security risk management processes. Any cybersecurity incidents are closely monitored for their potential impact on our business strategy, operations, and financial condition.

Our board of directors is collectively responsible for oversight of risks from cybersecurity threats. The Company's executive officers oversee the overall processes to safeguard data and comply with relevant regulations and will report material cybersecurity incidents to the board. The Company's executive officers have limited experience in the area of cybersecurity, but where necessary in the view of the Company's executive officers, the Company will consult with external advisers to manage and remediate any cybersecurity incidents. For material cybersecurity incidents, the Company's executive officers will promptly inform, update, and seek the instructions of the board of directors.

As of the date of this annual report, we have not experienced any cybersecurity incidents that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. We continuously adapt our business strategy to enhance resilience, strengthen defenses and ensure the sustainability of our operations.

Part III

Item 17. FINANCIAL STATEMENTS

We have elected to provide financial statements pursuant to Item 18.

Item 18. FINANCIAL STATEMENTS

The consolidated financial statements of Jyong Biotech Ltd., and its operating subsidiaries are included at the end of this annual report.

Item 19. EXHIBITS

EXHIBIT INDEX

Exhibit No.	Description
1.1	Memorandum and Articles of Association (incorporated herein by reference to Exhibit 3.1 of our Registration Statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on August 17, 2023)
2.1	Specimen Certificate for Ordinary Shares (incorporated herein by reference to Exhibit 4.1 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on March 7, 2024)
2.2*	Description of Securities
4.1	Form of Employment Agreement by and between executive officers and the Registrant (incorporated herein by reference to Exhibit 10.1 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on March 7, 2024)
4.2	Form of Director Agreement by and between directors and the Registrant (incorporated herein by reference to Exhibit 10.2 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on March 7, 2024)
4.3	Form of Indemnification Agreement with the Registrant's directors and officers (incorporated herein by reference to Exhibit 10.3 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on March 7, 2024)
4.4	English Translation of Share Purchase Agreement, dated May 15, 2019, among Taizhou City Optimization Upgrading Partnership (Limited) Corporation, Medi-life Co. Limited, Sira View Corp., Jyong Biotech Ltd., Health Ever Bio-Tech Co., Ltd., and Fu-Feng Guo (incorporated herein by reference to Exhibit 10.4 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on March 7, 2024)
4.5	English Translation of Supplementary Agreement to Share Purchase Agreement, dated July 2, 2019, among Taizhou City Optimization Upgrading Partnership (Limited) Corporation, Medi-life Co. Limited, Sira View Corp., Jyong Biotech Ltd., Health Ever Bio-Tech Co., Ltd., and Fu-Feng Guo (incorporated herein by reference to Exhibit 10.5 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on March 7, 2024)
4.6	English Translation of Agreement of Cooperation Framework, dated December 21, 2018, among Taizhou High-tech Industrial Park Management Committee, Taizhou Infrastructure Investment Group Co., Ltd., and Jyong Biotech Ltd. (incorporated herein by reference to Exhibit 10.6 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on March 7, 2024)
4.7	English Translation of Jianyong Biotechnology Herbal Medicine Project Investment Cooperation Agreement, dated September 12, 2019, between Management Committee of Aggregating Area of Taizhou Bay Circulating Economic Productions Industries (Gaoxin Zone and Luxin Resort Zone) and Chuang-Yao Biotech Pharmaceutical Co., Ltd. (incorporated herein by reference to Exhibit 10.7 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on March 7, 2024)
4.8	Loan and Mortgage Agreement, dated May 20, 2019, between Taiwan Cooperative Bank Co., Ltd. and Health Ever Bio-Tech Co., Ltd (incorporated herein by reference to Exhibit 10.8 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on May 8, 2024)
4.9*	English Translation of Loan Agreement, dated June 24, 2025, between Jyong Biotech Ltd. and Linkage Gladden Enterprise Ltd.
8.1*	List of subsidiaries of the Registrant
11.1	Code of Business Conduct and Ethics of the Registrant (incorporated herein by reference to Exhibit 99.1 to the registration statement on Form F-1 (File No. 333-277725), as amended, initially filed with the Securities and Exchange Commission on August 17, 2023)
11.2*	Insider Trading Compliance Manual of the Registrant
12.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2**	Certification of Chief 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*	Compensation Recovery Policy of the Registrant
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed with this annual report on Form 20-F

** Furnished with this annual report on Form 20-F

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Jyong Biotech Ltd.

By: */s/ Fu-Feng Kuo*
Name: Fu-Feng Kuo
Title: Chief Executive Officer

Dated: May 14, 2026

JYONG BIOTECH LIMITED
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WWC, P.C. CERTIFIED PUBLIC ACCOUNTANTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To: The Board of Directors and Shareholders of
Jyong Biotech Ltd. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Jyong Biotech Ltd. and subsidiaries (collectively the "Group") as of December 31, 2024 and 2025, and the related consolidated statement of operations and comprehensive loss, change in shareholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Group as of December 31, 2024 and 2025, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of Matter — Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Group will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Group has a significant working capital deficiency, has incurred significant losses, and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Group's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding those matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Basis for Opinion

These consolidated financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on our consolidated 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 Group 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 consolidated financial statements are free of material misstatement, whether due to error or fraud. The Group 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 its 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ WWC, P.C.
WWC, P.C.
Certified Public Accountants
PCAOB ID No.1171

We have served as our auditor since 2023.
San Mateo, California
May 14, 2026

JYONG BIOTECH LIMITED
CONSOLIDATED BALANCE SHEETS
(in thousand US Dollars, except share and per share data)

	As of December 31,	
	2024	2025
ASSETS		
Current Assets		
Cash	$ 98	$ 1,175
Restricted cash	3	3
Prepayments and other current assets	105	854
Loan receivable from shareholder	-	13,510
Total current assets	206	15,542
Property and equipment, net	3,049	3,088
Operating right-of-use assets	137	66
Deferred offering costs	934	-
Restricted asset	2,034	2,076
Other non-current assets	6	6
Total non-current assets	6,160	5,236
TOTAL ASSETS	$ 6,366	$ 20,778
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities		
Short-term bank loans	$ 7,225	$ 7,711
Notes and accounts payable	3	2
Accrued expenses	1,203	1,044
Accrued expenses due to related parties	147	281
Current portion of long-term bank loans	57	571
Operating lease liabilities due to related parties-current	159	81
Accrued liabilities - guarantee obligation	-	21,603
Other current liabilities	3,292	3,449
Other current liabilities due to related parties	41	68
Total current liabilities	12,127	34,810
Long-term loan from related parties	5,515	6,176
Long-term loan from third parties	3,131	2,431
Long-term bank loans, net of current portion	2,032	1,553
Operating lease liabilities due to related parties – non-current	16	26
Other non-current liabilities	58	60
Other non-current liabilities due to related parties	628	628
Guarantee liabilities	19,378	-
Total non-current liabilities	30,758	10,874
TOTAL LIABILITIES	42,885	45,684
Commitments and contingencies (Note 18)		
Shareholders' deficit		
Ordinary shares, $0.00001 par value; 5,000,000 thousand shares authorized; 73,361 thousand and 76,028 thousand shares issued and outstanding as of December 31, 2024 and 2025, respectively	1	1
Additional paid-in capital	11,805	28,528
Treasury shares, 1,794 thousand shares as of December 31, 2024 and 2025, respectively	(16,366)	(16,366)
Accumulated deficit	(33,080)	(37,751)
Accumulated other comprehensive income	1,121	682
Total shareholders' deficit	(36,519)	(24,906)
TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT	$ 6,366	$ 20,778

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

JYONG BIOTECH LIMITED
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousand US Dollars, except share data in thousands and per share data)

	For the years ended December 31,		
	2023	2024	2025
Operating expenses			
Research and development	$ (1,071)	$ (927)	$ (813)
Selling and marketing	(47)	(44)	(45)
General and administrative	(1,679)	(1,085)	(1,749)
Total operating expenses	(2,797)	(2,056)	(2,607)
Loss from operations	(2,797)	(2,056)	(2,607)
Other incomes (expenses):			
Interest income	56	7	610
Interest expenses	(757)	(1,035)	(2,539)
Other (losses) gains, net	(902)	65	(135)
Total other expenses, net	(1,603)	(963)	(2,064)
Loss before income tax	(4,400)	(3,019)	(4,671)
Income tax expense	-	-	-
Net loss	(4,400)	(3,019)	(4,671)
Other comprehensive (loss) income			
Foreign currency translation adjustments, net of nil tax	(42)	573	(439)
Total comprehensive loss	$ (4,442)	$ (2,446)	$ (5,110)
Net loss per share:			
Basic and Diluted	$ (0.06)	$ (0.04)	$ (0.06)
Weighted average shares outstanding (in thousands):			
Basic and Diluted	71,567	71,567	73,011

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

JYONG BIOTECH LIMITED
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' DEFICIT
(In thousand US Dollars, except share data in thousands)

	Ordinary Shares		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Treasury Shares	Total Shareholders' Deficit
	Shares	Amount					
Balance as of January 1, 2023	**73,361**	**$ 1**	**$ 11,805**	**$ 590**	**$ (25,661)**	**$ (16,366)**	**$ (29,631)**
Net loss	**-**	**-**	**-**	**-**	**(4,400)**	**-**	**(4,400)**
Foreign currency translation adjustment	**-**	**-**	**-**	**(42)**	**-**	**-**	**(42)**
Balance as of December 31, 2023	**73,361**	**$ 1**	**$ 11,805**	**$ 548**	**$ (30,061)**	**$ (16,366)**	**$ (34,073)**
Net loss	**-**	**-**	**-**	**-**	**(3,019)**	**-**	**(3,019)**
Foreign currency translation adjustment	**-**	**-**	**-**	**573**	**-**	**-**	**573**
Balance as of December 31, 2024	**73,361**	**$ 1**	**$ 11,805**	**$ 1,121**	**$ (33,080)**	**$ (16,366)**	**$ (36,519)**
Issuance of shares upon initial public offering, net	**2,667**	**-**	**16,723**	**-**	**-**	**-**	**16,723**
Net loss	**-**	**-**	**-**	**-**	**(4,671)**	**-**	**(4,671)**
Foreign currency translation adjustment	**-**	**-**	**-**	**(439)**	**-**	**-**	**(439)**
Balance as of December 31, 2025	**76,028**	**$ 1**	**$ 28,528**	**$ 682**	**$ (37,751)**	**$ (16,366)**	**$ (24,906)**

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

JYONG BIOTECH LIMITED
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousand US Dollars)

	For the years ended December 31,		
	2023	2024	2025
Cash flows from operating activities			
Net loss	$ (4,400)	$ (3,019)	$ (4,671)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	127	120	100
Noncash operating lease expenses	175	170	176
Fair value changes in the guarantee liabilities	379	591	(19,378)
Gain on disposal of short-term investments	-	-	(3)
Changes in operating assets and liabilities:			
Prepayments and other current assets	(2)	(8)	(749)
Notes and accounts payable	(2)	1	(1)
Accrued liabilities – guarantee obligation	-	-	21,603
Accrued expenses	254	76	(159)
Accrued expenses due to related parties	42	92	134
Operating lease liabilities due to related parties	(128)	(124)	(130)
Other current liabilities	878	(1,542)	10
Other current liabilities due to related parties	17	20	27
Other non-current liabilities	59	(1)	-
Net cash used in operating activities	(2,601)	(3,624)	(3,041)
Cash flows from investing activities			
Purchases of short-term investments	-	-	(16,870)
Proceeds from disposal of short-term investments	-	-	16,873
Proceeds from maturity of time deposits	95	-	-
Loan to a shareholder	-	-	(15,000)
Repayment from shareholder	-	-	1,490
Net cash provided by (used in) investing activities	95	-	(13,507)
Cash flows from financing activities			
Payments of deferred offering costs	(445)	(213)	(114)
Proceeds from short-term bank loans	9,803	9,241	23,096
Repayment of short-term bank loans	(9,113)	(9,394)	(22,936)
Proceeds from issuance of ordinary shares	-	-	17,771
Proceeds of loan from related parties	2,026	2,427	1,376
Repayments of loan from related parties	(120)	-	(800)
Repayment of loan from third party	-	-	(700)
Repayments of long-term bank loans	(123)	(71)	(60)
Net cash provided by financing activities	2,028	1,990	17,633
Effects of exchange rate changes on cash and restricted cash	(54)	(7)	(8)
NET (DECREASE)INCREASE IN CASH AND RESTRICTED CASH	(532)	(1,641)	1,077
CASH AND RESTRICTED CASH AT BEGINNING OF THE YEAR	2,274	1,742	101
CASH AND RESTRICTED CASH AT END OF THE YEAR	$ 1,742	$ 101	$ 1,178
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Income taxes paid	$ -	$ -	$ -
Interest paid	$ 104	$ 223	$ 337
Reconciliation to amount on consolidated balance sheets			
Cash	$ 177	$ 98	$ 1,175
Restricted cash	1,565	3	3
TOTAL CASH AND RESTRICTED CASH	$ 1,742	$ 101	$ 1,178

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

1. ORGANIZATION AND BUSINESS OPERATION

Health Ever Biotech Co., Ltd., was incorporated under the laws of Taiwan in August 2002 to research and develop new drugs for today's great unmet medical needs and planned to manufacture and sell new drugs after receiving regulatory approval. In January 2018, HEB incorporated Jyong Biotech Ltd., ("Jyong" or the "Company") under the laws of the Cayman Islands and was reorganized into the Company's subsidiary in December 2018. After the reorganization, HEB was wholly owned by the Company in April 2019.

The Company and its subsidiaries' (the "Group") product candidates are led by "Botreso" (also known as Botreso®) and PCP. Botreso is a drug candidate in the clinic, developed for unmet medical needs of benign prostate hyperplasia/lower urinary tract symptoms (BPH/LUTS). The Group has completed four Phase III clinical trials in Taiwan and the U.S. and submitted a new drug application for Botreso to the U.S. Food and Drug Administration ("US FDA") for review in December 2021, using Active Pharmaceutical Ingredient (API)-1, but voluntarily withdrew it in November 2022, in order to develop more information about API-2 for the U.S. FDA's review. The Group is still in the process of providing the information required by the U.S. FDA and has not yet successfully demonstrated the comparability of API-1 and API-2. "PCP" is the other key new drug candidate developed for the prevention of prostate cancer. Similar to Botreso®, PCP works through its mechanism of antioxidant and anti-inflammatory. PCP contains several types of patented medical-grade active pharmaceutical ingredients that reduce oxidative stress and inflammatory cytokines (IL-6), both of which are causes of many chronic inflammatory diseases. The Group just completed phase II clinical trials of PCP in Taiwan. PCP has completed the data lock in May 2025, and statistical analysis of primary endpoint was completed in September 2025.

Initial Public Offering

On June 17, 2025, the Company consummated its initial public offering ("IPO") of 2,666,667 ordinary shares at a public offering price per share of $7.5. The gross proceeds from IPO, before deducting the underwriting discounts and commissions and offering expenses were $20,000 with net proceeds of $17,771.

As of December 31, 2025, the Company's subsidiaries are as follows:

Subsidiaries	Date of incorporation	Place of incorporation	Ownership	Principal activities
Health Ever Biotech Co., Ltd. ("HEB")	August 1, 2002	Taiwan	100% owned by the Company	Research, development, manufacturing
Genvace Biotechnology ("GB")	September 14, 2021	Taiwan	100% owned by HEB	Research and development
Top ShunXing Bio-Tech Co., ("TSB")	March 4, 2019	Hong Kong	100% owned by the Company	Investment holding
Innovative Biotech Co., ("IB")	July 1, 2019	People's Republic of China ("China")	100% owned by TSB	Research, development, manufacturing
Jyong Biotech International Pte. Ltd.	September 29, 2022	Singapore	100% owned by the Company	Leasing of non-financial intangible assets

2. LIQUIDITY RISKS AND GOING CONCERN

In accordance with Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Group has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Group's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

As of December 31, 2025 and as of April 30, 2026, the Group had cash of approximately $1,175 and $428, respectively. The Group has incurred recurring negative cash flows since inception and has funded its operations primarily from equity and debt financing. The Group had accumulated deficit of approximately $30,061, $33,080 and $37,751 as of December 31, 2023, 2024 and 2025, respectively and net losses of approximately $4,400, $3,019 and $4,671 for the years ended December 31, 2023, 2024, and 2025. In addition, the Group incurred negative cash flows in operating activities for the approximate amount of $2,601, $3,624 and $3,041 for the years ended December 31, 2023, 2024, and 2025, respectively. The Group's ability to fund its operations is highly contingent on raising additional capital until a regulatory approval that provides an ability to generate sufficient revenue, if ever. As such, the Group's management concluded that there is substantial doubt about the Group's ability to continue as a going concern within one year after the issuance date of the consolidated financial statements.

The Group intends to pursue an additional public offering to fund future operations. However, there can be no assurance that the Group will be successful in completing such an offering on a timely basis or on terms acceptable to the Group. In the event that a public offering is not completed for a sufficient amount, the Group's financing strategy includes obtaining credit facilities or bridge loans from related parties, in addition to pursuing other alternative such as third-party debt financing or strategic collaboration agreements. There can be no assurances, however, that the current operating plan will be achieved or that such related party funding or other financing will be available on commercially reasonable terms, or at all. If the Group is unable to obtain sufficient funding by April 2027, it will be required to significantly delay, limit, or terminate its research and development efforts and implement further cost-reduction measures. Such circumstances would have a material adverse effect on the Group's business, financial condition, and its ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Group will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC").

Principle of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated on consolidation.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect certain reported amounts and disclosures. Significant accounting estimates reflected in the Group's consolidated financial statements include, but are not limited to, useful lives for property and equipment, impairment of long-live assets, determination of incremental borrowing rate for lease, research and development expense recognition, other contingency liabilities, and valuation allowance for deferred income tax assets. Management evaluates the estimates based on historical experience 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. Accordingly, actual results could differ from those estimates.

Risk and uncertainties

The product candidates developed by the Group require approvals from the US FDA or foreign regulatory agencies prior to commercial sales. There can be no assurance that the Group's current and future product candidates will receive the necessary approvals or be commercially successful. If the approval is denied or delayed, it will have a material adverse impact on the business and consolidated financial statements of the Group.

Generally, the industry in which the Group operates subjects the Group to a number of other risks and uncertainties that can affect its operating results and financial condition. Such factors include, but are not limited to: the timing, costs and results of clinical trials and other development activities versus expectations; the ability to manufacture products successfully; competition from products sold or being developed by other companies; the price of, and demand for products once approved; the ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products.

Emerging Growth Company Status

The Group is an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, (the "Securities Act"), as modified by the Jumpstart The Company's Business Startups Act of 2012, (the "JOBS Act"), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. The Group has elected not to opt out of such extended transition periods which means that when a standard is issued or revised and it has different application dates for public or private companies, the Group, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of the Group's consolidated financial statements with another public company difficult because of the potential differences in accounting standards used.

Fair value measurements

The Group applies ASC 820, Fair Value Measurements and Disclosures. ASC 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements.

ASC 820 requires disclosures to be provided for fair value measurements. ASC 820 establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 — Observable inputs such as quoted prices for identical instruments in active markets;

Level 2 — Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly;

Level 3 — Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

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.

The carrying amount of the Group's financial instruments, including cash, short-term bank loans, notes and accounts payable, other current liabilities due to related parties, approximates fair value due to the short-term maturity of the instruments. The Group's long-term liabilities approximate their fair values as they contain interest rates that vary according to market interest rates.

Cash

Cash consists of cash and demand deposits placed with banks. All cash is unrestricted to withdrawal and use.

Restricted cash

Restricted cash mainly consists of the bank deposits held as collateral for the credit of a business credit card and bank deposits with time deposits having original maturities of more than three months.

Short-term investments

The short-term investments consist of U.S. Treasury Bills with contractual maturities of 12 months or less. The Group classifies these investments as available-for-sale. These investments are stated at fair value within current assets. Unrealized gains and losses on investment are recorded within accumulated other comprehensive income.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and impairment if applicable. Significant additions, renewals and betterments are capitalized, while maintenance and repairs are expenses as incurred. Depreciation is computed on a straight-line basis over estimated useful lives that range as follows:

	Useful life
Buildings	50 years
Building improvements	3 to 15 years
Laboratory equipment	3 to 5 years
Transportation equipment	5 years
Office equipment	2 to 8 years
Other equipment	2 to 10 years
Leasehold improvements	the shorter of the estimated useful life or the lease term, which is 3 to 5 years

Retirements, sale and disposals of assets are recorded by removing the cost and accumulated depreciation with any resulting gain or loss reflected in the consolidated statements of operations and comprehensive loss.

Leases

The Group determines if an arrangement is a lease at inception. The Group classifies the lease as a finance lease if it meets certain criteria or as an operating lease when it does not. The Group leases several properties for offices, research and development centers, and manufacturing factories in mainland China and Taiwan, which are all classified as operating leases with fixed lease payments, as contractually stated in the lease agreements. The Group's leases do not contain any material residual value guarantees or material restrictive covenants.

At the commencement date of a lease, the Group recognizes a lease liability for future fixed lease payments and a right-of-use ("ROU") asset representing the right to use the underlying asset during the lease term. The lease liability is initially measured as the present value of the future fixed lease payments that will be made over the lease term. The future fixed lease payments are discounted using the rate implicit in the lease, if available, or the incremental borrowing rate ("IBR") based on the information available at the commencement date of the lease. The Group has elected not to record leases with an initial term of 12 months or less on the consolidated balance sheets.

The ROU asset is measured at the amount of the lease liability with adjustments, if applicable, for lease prepayments made prior to or at lease commencement, initial direct costs incurred by the Group and lease incentives. Under ASC 842, land use rights agreements are also considered to be operating lease contracts. The Group will evaluate the carrying value of ROU assets if there are indicators of impairment and review the recoverability of the related asset group. If the carrying value of the asset group is determined to not be recoverable and is in excess of the estimated fair value, the Group will record an impairment loss in other expenses in the consolidated statements of operations. ROU assets for operating leases are included in operating lease right-of-use assets in the consolidated balance sheets.

Operating leases are included in operating lease right-of-use assets and operating lease liabilities in the consolidated balance sheets. Operating lease liabilities that become due within one year of the balance sheet date are classified as current operating lease liabilities.

Lease expense is recognized on a straight-line basis over the lease term.

In addition, IB, the Company's subsidiary, acquired land use rights from the Bureau of Natural Resources and Planning in Taizhou, China ("Taizhou Resources Bureau") in December 2019 for 50 years and paid RMB 16,494 thousand ($2,528). All land in mainland China is owned by the China government. The China government may sell land use rights for a specified period of time. The purchase price of land use rights represents the operating lease prepayments for the rights to use the land in mainland China under ASC 842 and is recorded as operating ROU assets on the consolidated balance sheets, which is amortized over the lease term.

Restricted asset

Restricted asset mainly consists of the land use rights from the Taizhou Resources Bureau have been seized by the Taizhou Intermediate People's Court as asset preservation for the Taizhou Bay New District Administrative Committee. See Note 18 — Commitments and Contingencies for further detail.

Intangible assets

Intangible assets consist of costs incurred to acquire computer software, which are considered finite live assets and recorded at cost less accumulated amortization and accumulated impairment. Amortization is recorded using the straight-line basis over estimated useful lives that range from 3 years.

Impairment of long-lived assets

The Group evaluates the recoverability of long-lived assets, including finite-lived intangible assets, whenever events or changes in circumstances indicate the carrying value may not be fully recoverable. When these events occur, the Group evaluates the recoverability of long-lived assets by comparing the carrying amount of the assets to the future undiscounted cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected undiscounted cash flows is less than the carrying amount of the assets, the Group recognizes an impairment loss based on the excess of the carrying amount of the assets over their fair value. Fair value is generally determined by discounting the cash flows expected to be generated by the assets when the market prices are not readily available. The adjusted carrying amount of the assets becomes a new cost basis and is depreciated over the assets' remaining useful lives. No impairment loss was recorded for the years ended December 31, 2023, 2024, and 2025.

Deferred offering costs

Deferred offering costs consist of underwriting, legal, accounting and other expenditures incurred through the balance sheet date that are directly related to the Company's initial public offering and that will be charged to shareholder's deficit upon the completion of the initial public offering. Should the initial public offering prove to be unsuccessful, the deferred offering costs, will be charged to operating expense in the consolidated statement of operations and comprehensive loss. As of December 31, 2024 and 2025, the Company recorded $934 and nil of offering costs, respectively. Total deferred offering cost of $1,048 reclassified to additional paid-in capital upon the completion of IPO in June 2025.

Guarantee liabilities

The Company provided a joint and several guarantee for the performance of buyback shares obligation of the certain shareholders who transferred some of their shares in the Company to others. The guarantee of buyback shares obligation falls within the scope of ASC 460-10-15-4(b). The guarantee liability is recognized at the fair value at the inception of the guarantee and subsequently remeasured at each reporting period. Changes in the fair value of the guarantee liability are recorded as changes in guarantee liabilities in the consolidated statements of operations and comprehensive loss. When the Company settles the guarantee liability through the performance of the guarantee by making requisite payments to buy back shares, the Company records a corresponding deduction to the guarantee liability. When the Company is released from the guarantee obligation due to the buyback of shares performed by certain shareholders, it is recognized as a reversal of the deduction to the guarantee liability. See Commitment with the Taizhou Company in Note 18 — Commitments and Contingencies for further detail.

Loss contingencies

The Group is subject to certain legal proceedings and contingencies in addition to those related to guarantee liabilities discussed above in this Note, the outcome of which are subject to significant uncertainty. The Group accrues for estimated losses if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred. The Group uses judgment and evaluates whether a loss contingency arising from litigation or an unasserted claim should be disclosed or recorded. The outcome of legal proceedings and other contingencies is inherently uncertain and often difficult to estimate. Accrued legal contingencies are reported within other current liabilities or other non-current liabilities in the consolidated balance sheets based on the period in which the Group expects the contingency to be settled.

Segment reporting

ASC 280, Segment Reporting, establishes standards for reporting information about operating segments on a basis consistent with the Group's internal organizational structure. The Group's chief operating decision maker ("CODM") has been identified as the Chief Executive Officer, who reviews the financial information of each separate operating segment when making decisions about allocating resources and assessing the performance of the segment. The Group operates and manages its business as a single segment—in the research and development of novel therapeutics targeting significant unmet needs. Refer to Note 19 — Segment Reporting for the Group's segment reporting disclosure.

Research and development expenses

Research and development expenses primarily include (1) payroll and other related costs of personnel engaged in research and development activities, (2) costs related to preclinical testing of the Group's technologies and clinical trials such as payments to contract research organizations ("CRO"), investigators and clinical trial sites that conduct the clinical studies, (3) costs to develop the product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses, and (4) other research and development expenses. Research and development expenses are charged to expense as incurred when these expenditures relate to the Group's research and development services and have no alternative future uses.

The Group is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants and CROs, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which the services are provided under such contracts. The Group reflects research and development expenses in the consolidated financial statements by matching those expenses with the period in which services and efforts are expended. The Group accounts for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities and determines accrual estimates through reviewing the underlying contracts along with discussions with research and other key personnel as to the progress of studies, or other services being conducted. During the course of a study, the Group adjusts its expense recognition if actual results differ from its estimates.

Income tax

The Group accounts for income taxes under the liability method in accordance with the regulations of the relevant tax jurisdictions. Under the liability method, deferred income tax assets and liabilities are determined based on the differences between the financial reporting and income tax bases of assets and liabilities and are measured using the enacted income tax rates expected to apply when the differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period including the enactment date. A valuation allowance is recorded if it is more likely than not that some portion or all of a deferred income tax assets will not be realized in the foreseeable future.

The Group evaluates its uncertain tax positions using the provisions of ASC 740-10, Income Taxes, which prescribes a recognition threshold that a tax position is required to meet before being recognized in the consolidated financial statements. The Group recognizes in the consolidated 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 Group's policy to recognize interest and penalties related to unrecognized tax benefits, if any, as a component of income tax expense.

For years ended December 31, 2023, 2024 and 2025, the Group did not have any material interest or penalties associated with tax positions nor did the Group have any significant uncertain tax benefits.

Earnings (loss) per share

Basic earnings (loss) per ordinary share is computed by dividing net income (loss) attributable to ordinary shareholders by weighted average number of ordinary shares outstanding during the period.

Diluted earnings (loss) per ordinary share reflects the potential dilution that could occur if securities were exercised or converted into ordinary shares. The Company did not have potential ordinary shares (e.g., stock options, non-vested restricted shares and other securities), which could potentially convert into ordinary shares and dilute basic earnings (loss) per share in the future.

Foreign currency transactions

The functional currency of the Company is the U.S. dollar. The Company's subsidiaries determined their functional currency to be the local currency of the respective entities except for TSB which determined its functional currency to be the U.S. dollar based on the criteria of ASC 830, Foreign Currency Matters. Gains or losses, resulting from the application of different foreign exchange rates when cash in foreign currency is converted into the entities' functional currency, or when foreign currency receivable and payable are settled, are credited or charged to income in the period of conversion or settlement. At year-end, the balances of foreign currency monetary assets and liabilities are recorded based on prevailing exchange rates and any resulting gains or losses are credited or charged to non-operating income or loss.

Translation of foreign currency financial statements

The reporting currency of the Group is the US dollar. Assets and liabilities are translated from each entity's functional currency to the reporting currency at the exchange rate on the balance sheet date. Equity amounts, except for the change in accumulated deficits, are translated at historical exchange rates at the date of entry to shareholders' equity; the change in accumulated deficits uses historical exchange rates of each period's statement of operations. Translation adjustments are reported as accumulative translation adjustments and are shown as a separate component of other comprehensive income in the consolidated statements of changes in shareholders' deficit.

Translation of amounts into USD has been made at the following exchange rates from Board of Governors of the Federal Reserve System:

Balance sheet items, except for equity accounts

December 31, 2025	RMB6.9931 to $1; NTD31.3700 to $1
December 31, 2024	RMB7.2993 to $1; NTD32.7900 to $1

Statement of operations and comprehensive loss, and cash flows items

For the year ended December 31, 2025	RMB7.1875 to $1; NTD31.1663 to $1
For the year ended December 31, 2024	RMB7.1957 to $1; NTD32.1064 to $1
For the year ended December 31, 2023	RMB7.0809 to $1; NTD31.1525 to $1

Comprehensive loss

Comprehensive loss consists of two components, net loss and other comprehensive income (loss). The foreign currency translation gain or loss resulting from translation of the consolidated financial statements expressed in USD is reported in other comprehensive loss in the consolidated statements of operations and comprehensive loss.

Concentration of risks

Concentration of suppliers

The following suppliers accounted for 10% or more of research and development expenses for the years ended December 31, 2023, 2024, and 2025:

	Years ended December 31,		
	2023	2024	2025
Supplier			
A	-	-	44%
B	*	*	31%
C	*	*	*
D	24%	27%	*
E	-	24%	-
F	22%	10%	*
G	15%	-	-
H	10%	-	-

* Represents less than 10% of research and development expenses for the years ended December 31, 2023, 2024, and 2025.

Concentration of credit risk

Financial instruments that potentially subject the Group to significant concentration of credit risk consist primarily of deposits and time deposits with original maturities more than three months.

In China, the insurance coverage of each financial institution is RMB 500 thousand. As of December 31, 2024 and 2025, all deposits at the financial institution incorporated in China were covered by the insurance, respectively.

In Taiwan, the insurance coverage of each financial institution is NTD 3,000 thousand. As of December 31, 2024 and 2025, the Group had $13 and $931 in uninsured deposits at the financial institutions incorporated in Taiwan, respectively.

In Hong Kong, the insurance coverage of each financial institution is HKD 800 thousand. As of December 31, 2024 and 2025, all deposits at the financial institution incorporated in Hong Kong were covered by the insurance, respectively.

In the United States of America, the insurance coverage of each financial institution is provided by the Federal Deposit Insurance Corporation (FDIC) up to USD 250 thousand and by the Securities Investor Protection Corporation (SPIC) up to a total of USD 500 thousand (including a USD 250 thousand limit for cash). As of December 31, 2024 and 2025, all deposits at the financial institution incorporated in the United States of America were covered by SPIC, respectively.

While management believes that these financial institutions are of high credit quality, it also continually monitors their credit worthiness.

Recent adopted and issued accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses among other disclosure requirements. The amendment is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The amendments will be applied retrospectively to all prior periods presented in the financial statements. The adoption of this standard has not had a material impact on the Group's consolidated financial statements and disclosures (See Note19).

In October 2023, the FASB issued ASU 2023-06, "Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative." This amendment incorporates certain U.S. Securities and Exchange Commission (SEC) disclosure requirements into the FASB Accounting Standards Codification. The amendments in the ASU are expected to clarify or improve disclosure and presentation requirements of a variety of Codification Topics, allow users to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the requirements, and align the requirements in the Codification with the SEC's regulations. For entities subject to the SEC's existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each amendment will be the date on which the SEC removes that related disclosure from its rules. For all other entities, the amendments will be effective two years later. However, if by June 30, 2027, the SEC has not removed the related disclosure from its regulations, the amendments will be removed from the Codification and not become effective for any entity. The Group does not expect the adoption of ASU 2023-06 to have a material impact on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) — Improvements to Income Tax Disclosures. The amendment requires that entities on an annual basis (1) disclose specific categories in the rate reconciliation and (2) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate. The amendment also requires disclosure of, on an annual basis, the year-to-date amount of income tax paid (net of refunds received) disaggregated by disaggregated by federal, state, and foreign jurisdictions, including additional disaggregated information on income taxes paid (net of refunds received) to an individual jurisdiction equal to or greater than 5% of total income taxes paid (net of refunds received). This amendment is effective for the Group's consolidated financial statements issued for annual periods beginning after December 15, 2024. Early adoption is permitted. The Group adopted this standard on January 1, 2025. There was no material impact to the Group's consolidated financial statements (See Note 13).

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. The amendment requires that entities disclose the amounts of purchases of inventory, employee compensation, depreciation and intangible asset amortization, as applicable, included in certain expense captions in the consolidated statements of operations, as well as qualitatively describe remaining amounts included in those captions. The amendment also requires the entities disclose both the amount and their definition of selling expenses. In January 2025, the FASB issued ASU 2025-01, Clarifying the Effective Date. The amendments, as clarified by ASU 2025-01, are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendment is effective for fiscal years beginning after December 15, 2026 and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendment should be applied either prospectively to financial statements issued for reporting periods after the effective date of this amendment or retrospectively to any or all prior periods presented in the financial statements. The Group is currently evaluating the impact of adopting this amendment.

In December 2025, the FASB issued ASU 2025-12, Codification Improvements. This amendment revises and supplements existing literature, addressing minor changes and corrections across 33 Accounting Standards Codification topics. The amendment is effective for fiscal years beginning after December 15, 2026. The Group is currently assessing the potential impact of adoption.

Except as mentioned above, the Group does not believe other recently issued but not yet effective accounting standards, if currently adopted, would have a material effect on the Group's consolidated balance sheets, statements of operations and comprehensive loss and statements of cash flows.

4. CASH AND RESTRICTED CASH

	As of December 31,	
	2024	2025
Cash in hand	$ 1	$ 1
Deposits in banks	97	1,174
Total cash	$ 98	$ 1,175
Collateral for the credit of a business credit card	3	3
Total restricted cash	$ 3	$ 3
Total cash and restricted cash	$ 101	$ 1,178

5. SHORT-TERM INVESTMENT

Short-term investments consisted of U.S. Treasury Bills with contractual maturities of 12 months or less and were classified as available-for-sale. The Group's short-term investments are categorized as Level 1 instruments, as the Group uses quoted market prices in active markets when determining the fair value of these securities. During the year ended December 31, 2025, the Company purchased U.S. Treasury Bills for $16,870 and sold all such securities for $16,873 prior to year-end. As of December 31, 2024 and 2025, the Group had no short-term available-for-sale investment securities. For the years ended December 31, 2023, 2024, and 2025, a realized gain of nil, nil and $3 were recorded within other income related to these investment securities, respectively.

6. PROPERTY AND EQUIPMENT, NET

Property and equipment consist of the following:

	As of December 31,	
	2024	2025
Land	$ 952	$ 995
Buildings	2,334	2,440
Buildings improvements	142	148
Laboratory equipment	741	775
Office equipment	112	117
Transportation equipment	21	22
Other equipment	48	50
Leasehold improvements	140	146
Construction in progress	135	140
	4,625	4,833
Less: accumulated depreciation	(1,576)	(1,745)
Property and equipment, net	$ 3,049	$ 3,088

Depreciation expenses recognized during the years ended December 31, 2023, 2024 and 2025 were approximately $127, $120 and $100, respectively.

7. LEASES

The Group leased facilities for office, research and development and manufacturing facilities in China and Taiwan. Most of the lease facilities in Taiwan were leased from the related parties. In December 2019, the land use right of gross value of RMB 16,494 thousand ($2,528) for 50 years was acquired from Taizhou Resource Bureau in China. As of December 31, 2024 and 2025, the net carrying values of the acquired Taizhou land use rights were RMB 14,845 thousand ($2,034) and RMB 14,515 thousand ($2,076), respectively. This asset was reclassified as restricted assets after the Taizhou Intermediate People's Court seized the land use right in January 2024 due to litigation with the Taizhou Bay New District Administrative Committee. See Notes 18 for the detail. In February 2024, May 2024, January 2025 and December 2025, the Group renewed the lease agreement with the related party, Zhao Jian Fu Co., Ltd. and Ms. Kuo to lease an office in Taiwan, continuously. Lease terms vary based on the nature of operations and the market dynamics; however, all leased facilities are classified as operating leases with remaining lease terms between 0.17 to 4 years except for the land use rights acquired from the Bureau of Land and Resources in Taizhou, China with remaining lease terms of 44 years. See Note 17 for related party lease obligations due and related party lease costs.

Supplemental information related to leases was as follows:

	Years ended December 31,		
	2023	2024	2025
Operating fixed lease cost	$ 180	$ 175	$ 179

Supplemental cash flow information related to leases was as follows:

	Years ended December 31,		
	2023	2024	2025
Cash paid for amounts included in measurement of lease liabilities	$ 133	$ 129	$ 133
Non-cash operating lease liabilities arising from obtaining operating right-of-use assets	43	113	52

The maturities of lease liabilities as of December 31, 2025 were as follows:

	Amount
2026	$ 82
2027	23
2028	2
2029	2
2030	-
Thereafter	-
Total lease payments	109
Less: imputed interest	(2)
Present value of minimum operating lease payments	$ 107

Weighted-average remaining lease terms and discount rates are as follows:

	2024	2025
Weighted-average remaining lease term	1.15 years	1.73 years
Weighted-average discount rate	3.20%	3.05%

8. LOAN RECEIVABLE FROM SHAREHOLDERS

On June 24, 2025, the Company entered into a loan agreement with Linkage Gladden Enterprise Ltd., a shareholder holding less than 10% of the Company's voting interest. The loan was extended with a principal amount of $15,000, carrying a fixed interest rate of 8.0% per annum. Under the payment terms, the principal and all accrued interest are due in a single lump-sum payment upon maturity. In September and October 2025, the Company received aggregate repayments of $1,490. As of December 31, 2025, the outstanding loan receivable from the shareholder was $13,510, classified as a current asset since it is not due within one year. As of December 31, 2025, the interest receivable related to this loan amounted to $602, which was reclassified as a current asset. For the year ended December 31, 2025, interest income recognized from this loan was $602. In the subsequent period, the Company received an aggregate repayment of US$12,328 from Linkage Gladden Enterprise Ltd. as of May 12, 2026. The residual amount of US$1,182 will be fully repaid by Linkage Gladden Enterprise Ltd. no later than May 31, 2026.

9. SHORT-TERM BANK LOANS

The following table presents short-term bank loan as of December 31, 2024 and 2025:

	As of December 31,	
	2024	2025
Shanghai Commercial & Savings Bank	$ 6,389	$ 6,838
Taipei Fubon Bank	836	873
Total	$ 7,225	$ 7,711

Morgan Stanley Bank N.A.

Since May 2025, the Company has maintained a revolving margin loan facility with Morgan Stanley Bank N.A. to provide flexible working capital. The loan carried a variable interest rate, had no fixed maturity date, and was payable on demand by Morgan Stanley Bank N.A. It was secured by U.S. Treasury Bills held in the Company's investment account with Morgan Stanley Bank N.A. The Company borrowed an aggregate principal of $15,335, incurred interest expenses of $30, and fully repaid the loan in 2025. As of December 31, 2025, the facility had no outstanding principal balance.

Shanghai Commercial & Savings Bank loan

On September 23, 2023, HEB entered into a one-year loan agreement with Shanghai Commercial and Savings Bank, Ltd., increasing its credit limit from NTD 200,000 thousand to NTD 300,000 thousand. The loan carried a variable interest rate and had a maturity date of September 23, 2024. The agreement was subsequently renewed on September 23, 2024 and again on September 30, 2025, extending the maturity date to September 23, 2026.

Under this agreement, HEB borrowed NTD 227,800 thousand ($7,312), NTD 214,500 thousand ($6,681), and NTD 214,500 thousand ($6,882) in 2023, 2024, and 2025, respectively, and made repayments of NTD 206,300 thousand ($6,622), NTD 208,000 thousand ($6,479), and NTD 209,500 thousand ($6,722) in the same respective years.

As of December 31, 2024 and 2025, the outstanding borrowings under this agreement amounted to NTD 209,500 thousand ($6,389) at an interest rate of 2.19% per annum and NTD 214,500 thousand ($6,838) at an interest rate of 1.90% per annum, respectively. The borrowing was guaranteed by Panatoz Corporation, Nobel Consumer Corporation, Fu-Feng Kuo, and Ju-Ting Chen, related parties.

In the subsequent period, HEB had repaid an aggregate amount of NTD 51,400 thousand ($1,639) for this loan as of April 30, 2026.

Taipei Fubon Bank loan

On December 16, 2021, HEB entered into a short-term loan agreement with Taipei Fubon Bank, providing a credit limit of NTD 38,800 thousand with a variable interest rate. The Company subsequently rolled over and renewed this facility through 2022 and 2023.

On November 21, 2024, HEB entered into a new short-term loan agreement with Taipei Fubon Bank, providing a credit limit of NTD 27,400 thousand with a variable interest rate.

Under these agreements, HEB borrowed aggregate amounts of NTD 77,600 thousand ($2,491), NTD 82,200 thousand ($2,560), and NTD 27,400 thousand ($879) in 2023, 2024, and 2025, respectively, and made aggregate repayments of NTD 77,600 thousand ($2,491), NTD 93,600 thousand ($2,915), and NTD 27,400 thousand ($879) in the same years.

As of December 31, 2024 and 2025, the outstanding borrowings under this agreement amounted to NTD 27,400 thousand ($836), which were due on December 15, 2025, at an interest rate of 2.85% per annum, and NTD 27,400 thousand ($873), which were due on June 12, 2026, at an interest rate of 2.96% per annum, respectively. These borrowings were guaranteed by Panatoz Corporation, Fu-Feng Kuo, and Ju-Ting Chen, the related parties.

10. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
	2024	2025
Clinical trial	$ 248	$ 260
Interest expenses	343	320
Professional service fees	433	295
Payroll	145	137
Other	34	32
Total accrued expenses	$ 1,203	$ 1,044
Accrued government subsidy repayment obligations (Note 18)	$ 2,878	$ 3,004
Repayment of government subsidies (Note 18)	413	437
Other	1	8
Total other current liabilities	$ 3,292	$ 3,449

11. LOANS FROM THIRD PARTIES

On September 10, 2019, the Company entered into a loan facility with Medi-life Co., Limited (“Medi-life), a minority shareholder, for $600. This loan had a one-year term with a 2% interest rate per annum. Before the maturity date, the Company renewed the loan agreement with Medi-life to extend the maturity date to September 10, 2026. On December 3, 2020, the Company also entered into a new loan facility with Medi-life for $100, which had a two-year term with a 2% interest rate per annum. Before the maturity date, the Company renewed the loan agreement with Medi-life to extend the maturity date to December 2, 2026. In July 2025, the Company repaid an aggregate amount of $700 to Medi-life.

On August 5, 2019, TSB entered a loan facility with Medi-life for RMB 16,003 thousand ($2,273), which had a two-year term with a 2% interest rate per annum. On June 1, 2021, TSB repaid $250 to Medi-life. Before the maturity date, TSB renewed the loan agreement with Medi-life to extend the maturity date to May 31, 2027.

On January 10, 2020 and December 7, 2020, TSB also entered two loan facilities with Medi-life for an aggregate amount of $408, which had a two-year term with a 2% interest rate per annum. Before the maturity date, TSB renewed the loan agreement with Medi-life, totaling $80 and $328, extending the maturity date to January 9, 2027 and December 6, 2026, respectively.

Loans from third parties were $3,131 and $2,431 as of December 31, 2024 and 2025, and accrued interests were $334 and $311 as of December 31, 2024 and 2025, respectively.

The future principal payments for the Group's loans from third parties as of December 31, 2025 were as follows:

	Amount
2026	$ 328
2027	2,103
2028	-
2029	-
2030	-
Thereafter	-
Total loans from third parties	$ 2,431

12. LONG-TERM BANK LOANS

	As of December 31,	
	2024	2025
Secured bank loans	$ 2,089	$ 2,124
Less: Current portion	(57)	(571)
Long-term bank loans	$ 2,032	$ 1,553

	As of December 31,	
	2024	2025
Loan content		
Annual interest rate	2.72%~3.38%	2.72%~3.30%
Maturity date	Due by June 2032	Due by June 2032

Taiwan Cooperative Bank loan

On June 5, 2014, HEB entered into a loan agreement with Taiwan Cooperative Bank for NTD 73,200 thousand. This loan had an 18-year term with a variable interest rate per annum. HEB started repaying the principal from June 2015. HEB suspended principal repayments under the COVID-19 emergency relief program provided by Taiwan Cooperative Bank. As of December 31, 2024, the outstanding loan was NTD 55,012 thousand ($1,677) with an interest rate of 2.72% per annum. On March 18, 2025, HEB reached an agreement with Taiwan Cooperative Bank to postpone principal repayments, and subsequently repaid NTD 200 thousand ($6) on March 28, 2025. As a result, HEB will pay only interest until principal repayments resume in April 2026. As of December 31, 2025, the outstanding loan balance was NTD 54,812 thousand ($1,747) at an interest rate of 2.72% per annum.

On August 20, 2019, HEB also entered into a new loan agreement with Taiwan Cooperative Bank for NTD 15,000 thousand. This loan had a 5-year term with a variable interest rate per annum. Similar to the above, principal repayments were suspended from 2020 through March 2023 under the COVID-19 emergency relief program. On February 19, 2024, HEB reached an agreement with Taiwan Cooperative Bank to postpone principal repayments, with interest-only payments until March 2025. As of December 31, 2024, the outstanding loan balance was NTD 12,328 thousand ($376) at an interest rate of 2.88% per annum. On March 18, 2025, HEB further agreed with Taiwan Cooperative Bank to extend the maturity date to August 20, 2026 and postpone principal repayments until February 2026. In addition, HEB repaid NTD 500 thousand ($16) on March 28, 2025. As of December 31, 2025, the outstanding loan balance was NTD 11,828 thousand ($377) at an interest rate of 2.88% per annum.

HEB provided land and buildings located in Yilan, Taiwan as collateral for these loans from Taiwan Cooperative Bank. These loans were also guaranteed by Fu-Feng Kuo, CEO of the Company, and Ju-Ting Chen, the shareholder of the Company. The carrying amount of pledged land, buildings, and building improvements was $2,817 and $2,895 as of December 31, 2024 and 2025, respectively.

In the subsequent period, HEB had repaid an aggregate amount of NTD 4,598 thousand ($147) for this loan as of April 30, 2026.

Shanghai Commercial & Savings Bank loan

On August 25, 2020, HEB entered into a loan agreement with Shanghai Commercial & Saving Bank for NTD 16,000 thousand. This loan had a 5-year term with a variable interest rate per annum. For the years ended December 31, 2023, 2024, and 2025, HEB repaid NTD 1,770 thousand ($57), NTD 1,770 thousand ($55), and NTD 1,180 thousand ($38) for this loan, respectively. HEB had fully repaid the amount as of December 31, 2025. As of December 31, 2024 and 2025, the outstanding loan was NTD 1,180 thousand ($36) and nil with an interest rate of 3.38% and nil, respectively. This loan was also guaranteed by Fu-Feng Kuo, CEO of the Company with the fixed asset located in Xinbei, Taiwan owned by Panatoz Corporation.

The future principal payments for the Group's long-term bank loans as of December 31, 2025 were as follows:

	Amount
2026	$ 571
2027	265
2028	273
2029	280
2030	288
Thereafter	447
Total long-term bank loans	$ 2,124

13. INCOME TAX

The Group is subject to income taxes on an entity basis on income arising in or derived from the tax jurisdiction in which each entity is domiciled.

Cayman Islands

The Company is incorporated in the Cayman Islands. Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gain. Additionally, the Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

Taiwan

HEB and GB are incorporated in Taiwan and are subject to corporate income tax at a rate of 20%. Both of them have no taxable income for all periods presented, therefore, no provision for income taxes is required.

Hong Kong

TSB is incorporated in Hong Kong and is subject to Hong Kong profits tax on the taxable income as reported in the respective statutory financial statements adjusted in accordance with the relevant Hong Kong tax laws. The applicable tax rate in Hong Kong is 8.25% for assessable profits on the first HKD2 million and 16.5% for any assessable profits in excess.

China

IB is incorporated in China and is subject to China statutory income tax rate of 25% on the assessable income in accordance with relevant PRC enterprise income tax legislation, interpretations and practices.

No provision for PRC corporate income tax has been made for the years ended December 31, 2023, 2024, and 2025 as IB had no such assessable profit for the years ended December 31, 2023, 2024, and 2025.

Singapore

Entities incorporated in Singapore are subject to corporate income tax rate of 17%. Jyong Biotech International Pte. Ltd., which was incorporated under the law of Singapore on September 29, 2022, and is subject to corporate income tax rate of 17%. No provision for Singapore corporate income tax has been made for the years ended December 31, 2023, 2024, and 2025 as Jyong Biotech International Pte. Ltd., had no such assessable profit.

The Company and its subsidiaries file separate income tax returns. The applicable statutory income tax rate in the Cayman Islands was zero for the Company for the years being reported. For purpose of reconciling the provision for income at the statutory rate to the provision for income taxes at the effective tax rate, the Group applies the 20% Taiwan statutory income tax rate, as the main operation of Group is located in Taiwan. A reconciliation of the Group's effective income tax rate for the years ended December 31, 2025 are as follows:

	Year ended December 31, 2025	
	Amount	**Percentage**
Statutory income tax rate	$ (934)	20.00%
Foreign tax effect:		
Cayman Island:		
Statutory tax rate difference between Cayman Island and Taiwan	602	(12.89)%
Other foreign jurisdictions	29	(0.62)%
Changes in valuation allowances	300	(6.42)%
Others	3	(0.07)%
Effective tax rate	$ -	0.00%

Reconciliations of the differences between the Taiwan statutory income tax rate and the Group's effective income tax rate for the years ended December 31, 2023 and 2024 are as follows:

	Years ended December 31,	
	2023	**2024**
Statutory income tax rate	20.00%	20.00%
Non-deductible expenses	(0.09)%	(0.07)%
Changes in valuation allowances	(19.91)%	(19.93)%
Effective tax rate	0.00%	0.00%

The deferred income tax assets and liabilities as of December 31, 2024 and 2025 consisted of the following:

	As of December 31,	
	2024	2025
Deferred income tax assets		
Net operating loss carryforwards	$ 6,919	$ 6,529
Research and development credits	10,089	10,534
Others	36	40
	17,044	17,103
Valuation allowance	(17,044)	(17,103)
Total net deferred income tax assets	$ -	$ -

Realization of the net deferred income tax assets is dependent on factors including future reversals of existing taxable temporary differences and adequate future taxable income, exclusive of reversing deductible temporary differences and tax loss carry forwards. The Group evaluates the potential realization of deferred tax assets on an entity-by-entity basis. As of December 31, 2024 and 2025, valuation allowances were provided against deferred tax assets in entities where it was determined it was more likely than not that the benefits of the deferred tax assets will not be realized.

As of December 31, 2024 and 2025, HEB had Taiwan research and development credit carryforwards of approximately $10,089 and $10,534, respectively. The Act for the Development of Biotech and New Pharmaceuticals Industry in Taiwan provided HEB the research and development credit for a period of five years from the time it is subject to the profit-seeking enterprise income tax.

As of December 31, 2025, the Group had net operating loss carryforward available to offset future taxable income, shown below by jurisdictions.

	Amount	Expiring year
Jurisdiction		
Taiwan	$ 30,617	2026-2035
China	1,623	2026-2030

14. ORDINARY SHARES

As of December 31, 2024 and 2025 the Company was authorized to issue 5,000,000 thousand shares. As of December 31, 2024 and 2025, 73,361 thousand and 76,028 thousand shares were issued and outstanding, respectively, $0.00001 par value ordinary shares. Holders of the Company's ordinary shares are entitled to dividends, if and when, declared by the board of directors of the Company. The holder of each ordinary share is entitled to one vote. As of December 31, 2025, no dividends were declared.

15. LICENSE AGREEMENTS

In April 2016, HEB entered into a licensing agreement with Chhak Kamponngsaon Sez Co., Ltd to grant an exclusive right to sell and market Botreso in the Kingdom of Cambodia until April 2036 in exchange for an upfront payment of $100 thousand, a certain amount in milestone payments for applying the regulatory approval of Botreso and obtaining the regulatory approval of Botreso in the Kingdom of Cambodia, and a certain percent on net sales in royalty payments. HEB has no other performance obligation in addition to the license, and Chhak Kamponngsaon Sez Co., Ltd is responsible for assisting HEB to obtain initial and all subsequent regulatory approvals of Botreso in the Kingdom of Cambodia. HEB recognized the upfront payment of $100 thousand as revenue in 2016 since HEB has no other performance obligation in addition to the licenses. As of April 30, 2026, HEB has not achieved any milestones.

16. NET LOSS PER SHARE

Basic and diluted net loss per share for the years ended December 31, 2023, 2024, and 2025 are calculated as follows:

	Years ended December 31,		
	2023	2024	2025
Numerator:			
Net loss attributable to ordinary shareholders	$ (4,400)	$ (3,019)	$ (4,671)
Denominator:			
Weighted average number of ordinary shares outstanding – basic and diluted (in thousands)	71,567	71,567	73,011
Net loss per share – basic and diluted	$ (0.06)	$ (0.04)	$ (0.06)

17. RELATED PARTY TRANSACTIONS

Intercompany balances and transactions between the Company and its subsidiaries, which are related parties of the Company, have been eliminated upon consolidation; therefore, those items are not disclosed in this note. The table below sets forth the major related parties and their relationships with the Group as of December 31, 2024 and 2025:

Name of related parties	Relationship with the Group
Fu-Feng Kuo	CEO and Chairwoman of the Company
Ju-Ting Chen	The shareholder of the Company
Xue-Juan Chen	The fourth degree of kinship to CEO
Panatoz Corporation	Significantly influenced by Fu-Feng Kuo, CEO of the Company
Zhao Jian Fu Co., Ltd.	Significantly influenced by Fu-Feng Kuo, CEO of the Company
Nobel Consumer Corporation	Managed by Xue-Juan Chen, a related party of the Company

From February 2021 to November 2021, the Company entered into several loan agreements with Nobel Consumer Corporation for an aggregate amount of $ 300, which had a 2-year term with a 2% interest rate per annum. Before the maturity date, the Company renewed the loan agreements with Nobel Consumer Corporation to extend the maturity date of the loans. An amount of $100 will be due on February, June and November 2027, respectively.

From March 2022 to December 2022, the Company entered additional loan agreements with Nobel Consumer Corporation and Fu-Feng Kuo for an aggregate amount of $595 and $342, respectively, which had two-year term with a 2% interest rate per annum. Before the maturity date, the Company renewed the loan agreements to extend the maturity date of the loans due on March 2026 to December 2026. From July 2025 to October 2025, the Company repaid an aggregate amount of $280 to Fu-Feng Kuo.

From January 2023 to December 2023, the Company and HEB entered additional loan agreements with Nobel Consumer Corporation, Fu-Feng Kuo, and Panatoz Corporation for an aggregate amount of $480, $963, and NTD 13,500 thousand ($433) and $30, respectively, which had two-year term with a 2% interest rate per annum. Before the maturity date, the Company renewed several loan agreements to extend the maturity date of the loans due in January 2027 to December 2027, with an agreement amount of $1,906. From July 2025 to December 2025, the Company repaid an aggregate amount of $520 to Fu-Feng Kuo.

From January 2024 to December 2024, the Company and HEB entered additional loan agreements with Nobel Consumer Corporation, Fu-Feng Kuo, Panatoz Corporation, and Zhao Jian Fu Co., Ltd. for an aggregate amount of $14 and NTD 10,400 thousand ($324), $656 and NTD 1,836 thousand ($57), NTD 25,600 thousand ($797) and $114, and NTD 14,913 thousand ($465), respectively, which had two-year term with a 2% interest rate per annum.

From January 2025 to December 2025, the Company and HEB entered additional loan agreements with Nobel Consumer Corporation, Fu-Feng Kuo and Panatoz Corporation for an aggregate amount of $405 and NTD 13,590 thousand, $128 and NTD 1,106 thousand ($35), and $41 and NTD 10,300 thousand ($330), respectively, which had two-year term with a 2% interest rate per annum.

As of December 31, 2025, the accrued interest expenses to Nobel Consumer Corporation, Fu-Feng Kuo, Panatoz Corporation and Zhao Jian Fu Co., Ltd. were $115, $92, $55, and $18 respectively.

The future principal payments for the Group's loans from related parties as of December 31, 2025 were as follows:

	Amount
2026	$ 3,122
2027	3,054
2028	-
2029	-
2030	-
Thereafter	-
Total loans from related parties	$ 6,176

In the subsequent period, the Company repaid an aggregate amount of $1,278, $862, and $185 to Nobel Consumer Corporation, Fu-Feng Kuo, and Panatoz Corporation as of April 30, 2026, respectively.

HEB leased the facilities for office, research and development, and manufacturing facilities in Taiwan from Panatoz Corporation, Zhao Jian Fu Co., Ltd., and Fu-Feng Kuo, respectively. See Note 7.

During 2018 and 2019, Fu-Feng Kuo and Ru-Ting Chen paid securities exchange tax and bridge loan fees on behalf of the Company, respectively. As of December 31, 2024 and 2025, the aggregate balance of due to Fu-Feng Kuo and Ju-Ting Chen were $628 and $628, respectively.

Nobel Consumer Corporation, Panatoz Corporation, Zhao Jian Fu Co., Ltd., Fu-Feng Kuo, and Ju-Ting Chen provided guarantees of short-term and long-term loans from Shanghai Commercial & Savings Bank, Ltd., short-term loan from Taipei Fubon Bank loan, and long-term loans from Taiwan Cooperative Bank to HEB. As of December 31, 2024 and 2025, the amount of borrowing guaranteed were $9,314 and $9,835, respectively.

The related party balances and transactions were summarized as follows:

(a) Related party balances

	As of December 31,	
	2024	2025
Loan from related parties		
Nobel Consumer Corporation	$ 1,706	$ 2,558
Fu-Feng Kuo	2,018	1,383
Panatoz Corporation	1,336	1,760
Zhao Jian Fu Co., Ltd.	455	475
	$ 5,515	$ 6,176
Accrued expenses		
Nobel Consumer Corporation	$ 64	$ 116
Fu-Feng Kuo	53	92
Panatoz Corporation	21	55
Zhao Jian Fu Co., Ltd.	9	18
	$ 147	$ 281
Operating lease liabilities due to related parties (including current and non-current)		
Panatoz Corporation	$ 65	$ 21
Zhao Jian Fu Co., Ltd.	110	79
Fu-Feng Kuo	-	7
	$ 175	$ 107
Other non-current liabilities due to related parties		
Ju-Ting Chen	$ 566	$ 566
Fu-Feng Kuo	62	62
	$ 628	$ 628

(b) Related party transactions

During the years ended December 31, 2023, 2024 and 2025, related party transactions of rental expenses consisted of the following:

	Years ended December 31,		
	2023	2024	2025
Zhao Jian Fu Co., Ltd.	$ 83	$ 80	$ 83
Panatoz Corporation	48	47	48
Fu-Feng Kuo	2	2	2
	$ 133	$ 129	$ 133

18. COMMITMENTS AND CONTINGENCIES

Clinical Research Organization (CRO)

The Group has agreements with contract service providers to assist in the performance of phase II clinical trial activities for PCP, one of the Group's key drug candidates. One CRO is mainly responsible for the data management, biostatistical analysis, and clinical study report writing; while the other CRO is responsible for the subjects' enrollment and serving as study coordinator (SC) at each study site. Such agreements are generally cancellable upon reasonable notice and payment of costs incurred.

Commitment and Litigation with the Taizhou Company

In May 2019, two of Jyong's shareholders, Medi-life Co., Limited and Sira View Corp. (collectively, the "Transferring Shareholders"), entered into a share purchase agreement (the "Share Purchase Agreement) with Taizhou City Optimization and Upgrade Investment Partnership (Limited Partnership) (the "Taizhou Company") to sell 1,794 thousand shares of Jyong's ordinary shares held by the Transferring Shareholders to the Taizhou Company at RMB 112,500 thousand ($16,366) (the "Share Purchase Transaction"). Under the Share Purchase Agreement, the Taizhou Company would have a right to request the Transferring Shareholders to repurchase the shares if Jyong would not accomplish the "Qualified Issuance and Listing" (defined as Jyong's public filing of shares and listing on the main board of the Stock Exchange of Hong Kong Limited, or the HKEX) within 5 years after the closing of the Share Purchase Transaction, or any other commitments were breached, such as not changing the primary control-person of Jyong, not changing the main operation of HEB, etc. and the repurchase payment is determined by the principal investment plus the interest based on the loan benchmark interest rate of People's Bank of China when the payment is made. In addition, Jyong provided the Taizhou Company a joint and several guarantee for the performance of the repurchase shares obligation of the Transferring Shareholders and pledged 100% of its equity interest in IB to the Taizhou Company as collateral pursuant to the Share Purchase Agreement. The above commitments and guarantees shall be automatically terminated after the Company completes the qualified issuance and listing.

In the event of any liquidation, dissolution, bankruptcy or winding up of Jyong, either voluntary or involuntary, or any deemed liquidation event as defined in the agreement, the Taizhou Company is entitled to receive, prior to any distribution to the holders of ordinary shares, an amount per share equal to the original issue price, plus accrued interest. This right enjoyed by the Taizhou Company shall be automatically suspended when the Company submits its A1 application proof to go public on the main board of the HKEX, which never occurred. If the Company fails to pass the hearing procedure or withdraws the application, this right will automatically resume its validity and has retrospective rights to the rights and interests of the Taizhou Company during the period of expiration.

On November 15, 2022, the Group received a complaint for civil suit filed by the Taizhou Company to the Taizhou Intermediate People's Court (the "Taizhou Court") against the Transferring Shareholders, Jyong, HEB, TSB, IB and Ms. Kuo, Fu Feng (collectively, the "Defendants"), requesting, among other claims: (i) redemption by the Transferring Shareholders for all shares purchased by the Taizhou Company under the Share Purchase Agreement for the original purchase price of RMB112,500 thousand ($16,366) and corresponding interests from July 29, 2019 to the date of actual payment calculated at the loan prime rate in China (the "Redemption"); (ii) the Taizhou Court to hold Jyong, HEB and Ms. Kuo, Fu Feng jointly liable for the Redemption; (iii) the Taizhou Court to confirm Taizhou Company's right to liquidate all equity interest in IB held by TSB that was pledged to the Taizhou Company; and (iv) the Taizhou Court to hold IB for the obligations of other Defendants within the scope of the benefits it received from the investment made under the Share Purchase Agreement. The dispute went on trial in the Taizhou Court on March 16, 2023 and November 29, 2023, respectively.

On March 25, 2024, the Taizhou Court issued a judgment (the "Judgment") partially in favor of the Taizhou Company, requiring Medi-life Co., Limited and Sira View Corp. to pay the redemption price of RMB 112,500 thousand ($16,366) and corresponding interests from August 20, 2019, to the date of actual payment calculated at the Loan Prime Rate published by the National Inter-bank Funding Center in China, and Jyong, HEB, and Ms. Fu Feng Kuo to be jointly liable for such obligation. The Taizhou Court also ruled that the Taizhou Company is entitled to liquidate all equity interest in Innovative Biotech pledged to it in order to realize the payment of the aforementioned obligations. Additionally, the lawyer service fees of RMB 420 thousand ($59) incurred by the Taizhou Company and litigation fees of RMB 684 thousand ($97) should be paid by Medi-life Co., Limited, Sira View Corp., Jyong, HEB, or Ms. Fu Feng Kuo. In April 2024, Nobel Consumer Corporation, the Company's related party, paid the litigation fees of RMB 684 thousand ($95) on behalf of Sira View Corp. Additionally, other than the guarantee liabilities under the Share Purchase Agreement as set forth below, the Company recognized an additional contingency liability of RMB 420 thousand ($58) for litigation fees in 2023, which will be due by the end of appeal process. The Company filed an appeal with the High People's Court of Zhejiang Province on April 29, 2024. The High Court held a hearing on August 9, 2024. On September 12, 2024, the High Court issued a judgment rejecting the Company's petition and affirming the Taizhou Court's ruling in its entirety. As a result, Medi-life Co., Limited and Sira View Corp., the Transferring Shareholders, shall pay the redemption price of RMB 112,500 thousand ($16,366) and corresponding interests to buy back the Company's shares from the Taizhou Company, and Jyong, HEB, and Ms. Fu Feng Kuo are jointly liable for this obligation. The judgment is final and non-appealable.

On November 19, 2025, the Judgment was registered with the Court of First Instance of the High Court of Hong Kong. As of that registration date, the total outstanding obligation, including interest and legal fees, amounted to RMB 149,458 thousand (approximately $21,372 thousand). The Transferring Shareholders were formally notified of this registration on December 11, 2025. The Transferring Shareholders did not an appeal against this registration prior to December 31, 2025. On December 17, 2025, the Shilin District Court in Taipei recognized the Judgment. While HEB filed an appeal against this recognition prior to December 31, 2025. On March 10, 2026, the Financial Services Division of the Grand Court of the Cayman Islands recognized the Judgment. The Company filed a defense in the Grand Court of the Cayman Islands opposing enforcement of the Judgment on May 5, 2026.

As of the date these consolidated financial statements were issued, the Transferring Shareholders are in settlement negotiations with Taizhou Company regarding the repurchase obligation and the Taizhou Company has initiated enforcement procedure before competent courts respectively in Taiwan, Hong Kong and Cayman Islands, however, the concerned parties are actively engaged in negotiation to reach a settlement and thus postpone or suspend the enforcement procedure.

The Group considered the guarantee provided under this Share Purchase Agreement was accounted for as an equity transaction between Jyong and shareholders to buy back Jyong's shares. Therefore, the Group estimated the fair value of guarantee liabilities at the fair value of the shares at the inception of this guarantee and recorded $16,366 of guarantee liabilities and corresponding treasury shares at the inception date, as well as subsequently measured the fair value of guarantee liabilities determined by the interest expense which will be paid when repurchasing the shares under the Share Purchase Agreement and recognized interest expense for the fair value change of guarantee liabilities. The Group reclassified the guarantee liabilities to accrued liabilities – guarantee obligation since the Judgment is final and non-appealable, and the Group expects this accrued liabilities to be settled within the next twelve months. The amount of interest expenses recognized were $438, $657, and $2,093 for the years ended December 31, 2023, 2024, and 2025, and the amount of guarantee liabilities were $19,378 as of December 31, 2024 and the amount of accrued liabilities was $21,603 as of December 31,2025, respectively. In addition, the negative net book value of IB's equity pledged was $1,197 and $1,317 as of December 31, 2024 and 2025, respectively.

Commitments with Taizhou Resources Bureau

On November 29, 2019, IB, our PRC subsidiary, entered into the land use right agreement with Taizhou Resources Bureau (the "Land Use Right Agreement"). Under the Land Use Right Agreement, IB shall commence construction on the industrial land granted by May 28, 2020 and complete the construction by November 28, 2022, otherwise, IB shall pay the liquidated damages to Taizhou Resources Bureau for each day of delay, being 0.1% of the total amount of the land use right grant price of approximately RMB16,000 thousand plus tax.

On November 23, 2022, Taizhou Resources Bureau (the "Bureau") issued a formal notice of reminder of default, requiring IB to pay the liquidated damages of RMB13,080 thousand, with the amount of damages accruing from November 24, 2022 to the date of actual construction to be calculated separately. In addition, under the Land Use Right Agreement, apart from the liquidated damages, IB is obliged to pay a land idling fee if the land is left idle for more than one year but less than two years, and the Bureau has the right to take back the land use right if the land is left idle for more than two years. IB submitted the application to the People's Government of Zhejiang Province (the "Zhejiang Government") for seeking its approval for construction on March 18, 2023.

On September 26, 2024, the Bureau issued a notice to reclaim the land use rights of IB without compensation. Although IB initially requested an administrative hearing, it subsequently decided to forgo the hearing process in accordance with the notice.

On February 8, 2025, the Bureau issued a formal Decision Letter confirming the reclamation of IB's land use rights without compensation. IB timely filed an application for administrative reconsideration with the Taizhou Municipal People's Government. On June 26, 2025, the Municipal Government issued its decision upholding the Bureau's reclamation order. Dissatisfied with the outcome, IB initiated an administrative lawsuit with the Taizhou Intermediate People's Court of Zhejiang Province on July 23, 2025.

On January 19, 2026, the Court rendered a judgment dismissing IB's claims and ordering IB to bear the litigation costs of RMB 50. Although IB filed an appeal against this judgment on February 2, 2026, management, based on the advice of our local legal counsel, assesses that there is a high probability that the unfavorable judgment will be upheld on appeal. As of the date of these consolidated financial statements, the appellate process remains ongoing.

As of December 31, 2024 and 2025, IB had accrued a sufficient contingent liability for penalties estimated through January 16, 2024. No additional contingent loss needs to be accrued for the years ended December 31, 2024 and 2025. Additionally, as of the issuance of consolidated financial statements, IB has not yet received the Zhejiang Government's approval and has not paid the penalty of RMB13,080 thousand. IB accrued RMB 21,005 thousand ($2,878) and RMB 21,005 thousand ($3,004) of other liabilities for the liquidated damages as of December 31, 2024 and 2025, and recorded RMB 5,860 thousand ($828), nil, and nil of other loss for the years ended December 31, 2023, 2024, and 2025, respectively.

Litigation

From time to time, the Group may have certain contingent liabilities that arise in the ordinary course of business activities or may be a party to certain legal proceedings, as well as certain asserted and un-asserted claims. The Group accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. Amounts accrued, as well as the total amount of reasonably possible losses with respect to such matters, individually and in the aggregate, are not deemed to be material to the consolidated financial statements. As of the issuance of consolidated financial statements, the Group is not aware of any current pending legal matters or claims except for the litigation with the Taizhou Company discussed above and as set forth below:

Innovative Biotech Co. v. Taizhou Bay New District Administrative Committee. On November 29, 2022, the Taizhou Bay New District Administrative Committee (the "Plaintiff" or "New District Administrative Committee"), the successor of the Taizhou Industry District Committee, filed a civil complaint to the Taizhou Court (the "Court") against the Company's PRC subsidiary, IB, claiming that IB has materially breached the Jyong Biotechnology Herbal Medicine Project Investment Cooperation Agreement (the "2019 Taizhou Agreement") by failing to initiate and conclude the construction of the Factory Project in accordance with the schedule stipulated by the 2019 Taizhou agreement and the Land Use Right Agreement. The Plaintiff requested the Court to terminate the 2019 Taizhou Agreement, and to order IB to return the government subsidy of RMB12.0 million ($1,690) IB previously received under the 2019 Taizhou Agreement, and to pay corresponding interests calculated at the Loan Prime Rate published by the National Inter-bank Funding Center. On December 1, 2022, the Court issued an order of preliminary asset preservation, freezing the RMB 10,708 thousand ($1,477) deposit in IB's bank account. This dispute went on trial on February 13, 2023, and two hearings were held on May 6, 2023 and August 17, 2023, respectively. On September 8, 2023, the Court entered into a judgement in favor of the Plaintiff, terminating the 2019 Taizhou Agreement and ordering IB to return the government subsidy of RMB12.0 million ($1,690) and corresponding interest and expenses to the Plaintiff. On September 14, 2023, IB filed an appeal with the High People's Court of Zhejiang Province (the "High Court") regarding each of the Court's rulings described above. The High Court held a hearing for this case on October 24, 2023. On December 12, 2023, the High Court issued a judgment against IB to affirm the Taizhou Court's ruling in its entirety. In addition, IB is required to pay litigation fees of RMB 94 thousand ($13) to the Taizhou Administrative Committee, and security fees of RMB 5 thousand ($1) and execution fees of RMB 79 thousand ($11) to the High Court. IB filed a petition for retrial to the Supreme People's Court of the People's Republic of China (the "Supreme Court") on December 27, 2023 and it was accepted by the Supreme Court on January 9, 2024.

On January 5 and 10, 2024, the Taizhou Court issued an order of enforcement, stipulating, among other things, freezing and assignment of IB's deposit in its bank account or withholding of IB's income up to RMB 12.0 million ($1,690) and corresponding interests, and the seizure, attachment and freezing of IB's property valued at RMB 12.0 million ($1,690) and corresponding interests, and restrictions on making certain high expenses by IB and related personnel. On January 16, 2024, the industrial land acquired by IB was seized by the Taizhou Court, and corresponding RMB15,010 thousand ($2,065) of operating right-of-use assets as of June 30, 2024. On February 22, 2024, RMB 11,129 thousand ($1,547) of IB's bank deposit was transferred to the Taizhou Court to repay litigation fees, security fees, and execution fees, and to the New District Administrative Committee to return a government subsidy. On July 7, 2024, the Taizhou Court issued a ruling of execution, notifying IB that it had repaid RMB 10,952 thousand ($1,522) to the Taizhou Administrative Committee by enforcing the transfer of its bank deposit and the Taizhou Administrative Committee agreed to terminate the execution as IB had no available assets to repay the remaining government subsidy of RMB 1,048 thousand ($144) and corresponding interest expenses. On August 21, 2024, the Supreme Court issued a decision to reject IB's petition for retrial and this lawsuit was concluded. As a result, shall return government subsidy of RMB 12.0 million and corresponding interest expenses to the Taizhou Administrative Committee.

As of December 31, 2024 and 2025, IB accrued an aggregate amount of RMB 3,021 thousand ($413) and RMB 3,058 thousand ($437) of other liabilities for this litigation and recorded an aggregate amount of RMB 609 thousand ($86) in other losses and litigation expenses for the year ended December 31, 2023, as well as RMB 175 thousand ($24) in other gains for reversing overestimated other liabilities and RMB 32 thousand ($5) in other losses for the year ended December 31, 2024, and RMB 37 thousand ($5) for the year ended December 31, 2025.

As of the issuance of consolidated financial statements, IB returned RMB 10,952 thousand ($1,566) of government subsidy to the New District Administrative Committee and the remaining subsidy of RMB 1,048 thousand ($150) and corresponding interest expenses shall be repaid when IB has assets to pay in the future.

19. SEGMENT

The Group operates and manages its business as a single reportable segment—in the research and development of novel therapeutics targeting significant unmet needs.

The accounting policies of the segment are the same as those described in "Note 3 — Summary of Significant Accounting Policies and Practices". The Group's CODM uses net loss to measure segment loss and assesses performance against expectations to make resource allocation decisions. Additionally, the CODM reviews and uses functional expenses included in net loss to manage the Group's operations and assess operating profitability. The Group operates as one operating and reportable segment, and as such the significant segment expenses regularly provided to the CODM are those presented on the consolidated statements of operations, including research and development, selling and marketing and general and administrative. Other segment items that presented on the consolidated statements of operations include interest income, interest expenses and other (losses) gains, net.

20. SUBSEQUENT EVENTS

The Group evaluated all events and transactions that occurred after December 31, 2025 up through May 14, 2026, which is the date that these consolidated financial statements are available to be issued, other than the events disclosed above, no other subsequent events have occurred that would require recognition or disclosure in the Group's consolidated financial statements.

Exhibit 2.2

DESCRIPTION OF SECURITES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED (the "Exchange Act")

The following is a summary of material provisions of our currently effective second amended and restated memorandum and articles of association ("amended and restated articles of association"), as well as the Companies Act (as amended) of the Cayman Islands, or the "Companies Act" insofar as they relate to the material terms of our Ordinary Shares. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. It is subject to and qualified in its entirety by reference to our amended and restated Memorandum and Articles, which are incorporated by reference as an exhibit to the Annual Report on Form 20-F of which this Exhibit 2.1 is a part.

Description of Ordinary Shares

Type and Class of Securities (Item 9.A.5 of Form 20-F)

As of the date of the Annual Report on Form 20-F (the "Form 20-F") of which this Exhibit 2.1 is a part, Jyong Biotech Ltd. (the "Company", "we", "us" or "our") has only one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: the Company's ordinary shares.

Pursuant to our second amended and restated memorandum of association, our company's authorized share capital consists of 5,000,000,000 ordinary shares with a par value of US$0.00001 per share. As of May 14, 2026, there are 76,027,667 ordinary shares issued and outstanding.

Preemptive Rights (Item 9.A.3 of Form 20-F)

Our shareholders do not have preemptive rights.

Limitations or Qualifications (Item 9.A.6 of Form 20-F)

Not applicable.

Rights of Other Types of Securities (Item 9.A.7 of Form 20-F)

Not applicable.

Rights of Ordinary Shares (Item 10.B.3 of Form 20-F)

Class of Ordinary Shares

The Company has only one class of Ordinary Shares. Pursuant to our second amended and restated memorandum of association, our company's authorized share capital consists of 5,000,000,000 ordinary shares with a par value of US$0.00001 per share. Our ordinary shares are issued in registered form and are issued when registered in our register of members. We may not issue shares to bearer. Our shareholders who are non-residents of the Cayman Islands may freely hold and vote their shares. All of our shares to be issued will be issued as fully paid. As of the date of this report, the Company has no outstanding options, warrants and other convertible securities.

Dividends

The holders of our ordinary shares are entitled to such dividends as may be declared by our board of directors. Our amended and restated articles of association provide that dividends may be declared and paid out of the funds of our company lawfully available therefor. Under the laws of the Cayman Islands, our company may pay a dividend out of either profit or share premium account; provided that in no circumstances may a dividend be paid out of our share premium 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 meeting of shareholders is by show of hands unless a poll is demanded. A poll may be demanded by:

- the chairperson of such meeting;
- by at least three shareholders present in person or by proxy for the time being entitled to vote at the meeting;
- by shareholder(s) present in person or by proxy representing not less than one-tenth of the total voting rights of all shareholders having the right to vote at the meeting; and
- by shareholder(s) present in person or by proxy and holding shares in us conferring a right to vote at the meeting being shares on which an aggregate sum has been paid up equal to not less than one-tenth of the total sum paid up on all shares conferring that right.

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 cast attaching to the issued and outstanding ordinary shares at a meeting. A special resolution will be required for important matters such as a change of name, making changes to our memorandum and articles of association, a reduction of our share capital and the winding up of our company. Our shareholders may, among other things, sub-divide or consolidate their shares by ordinary resolution.

Cumulative Voting

Delaware law permits cumulative voting for the election of directors only if expressly authorized in the certificate of incorporation. 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.

Pre-emptive Rights

There are no pre-emptive rights applicable to the issue by us of new shares under either Cayman Islands law or our amended and restated articles of association.

General Meetings of Shareholders

As a Cayman Islands exempted company, we are not obliged by the Companies Act to call shareholders' annual general meetings. Our amended and restated articles of association provide that we shall, if required by the Companies Act or our amended and restated articles of association, in each year hold a general meeting as its annual general meeting, and shall specify the meeting as such in the notices calling it, and the annual general meeting shall be held at such time and place as may be determined by our directors. General meetings, including annual general meetings, may be held at such times and in any location in the world as may be determined by the Board. A general meeting or any class meeting may also be held by means of such telephone, electronic or other communication facilities as to permit all persons participating in the meeting to communicate with each other, and participation in such a meeting constitutes presence at such meeting.

Shareholders' general meetings may be convened by the chairperson of our board of directors or by a majority of our board of directors. Advance notice of at least ten clear days is required for the convening of our annual general shareholders' meeting (if any) and any other general meeting of our shareholders. A quorum required for any general meeting of shareholders consists of, at the time when the meeting proceeds to business, two shareholders holding shares which carry in aggregate (or representing by proxy) not less than one-third of all votes attaching to issued and outstanding shares in our company entitled to vote at such general meeting.

The Companies Act does not provide shareholders with any right to requisition a general meeting or 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 articles of association provide that only a majority of the Board or the Chairman of the Board may call extraordinary general meetings.

Transfer of Ordinary Shares

Subject to the restrictions in our amended and restated articles of association and applicable securities laws, 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 in a form prescribed by Nasdaq or any other form approved by our board of directors. Notwithstanding the foregoing, ordinary shares may also be transferred in accordance with the applicable rules and regulations of Nasdaq.

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 ordinary 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 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 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 in accordance with the rules of the Nasdaq, 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 may determine.

Liquidation

On the winding up of our company, if the assets available for distribution amongst our shareholders shall be more than sufficient to repay the whole of the share capital at the commencement of the winding up, the surplus shall be distributed amongst our shareholders in proportion to the par value of the shares held by them at the commencement of the winding up, subject to a deduction from those shares in respect of which there are monies due, of all monies payable to our company for unpaid calls or otherwise. If our assets available for distribution are insufficient to repay all of the paid-up capital, such assets will be distributed so that, as nearly as may be, the losses are borne by our shareholders in proportion to the par value of the shares held by them.

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 days prior to the specified time and place of payment. The shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption, Repurchase and Surrender of Shares

We may issue shares on terms that such shares are subject to redemption, at our option or at the option of the holders of these shares, on such terms and in such manner as may be determined by our board of directors. Our company may also repurchase any of our shares on such terms and in such manner as have been approved by our board of directors. Under the Companies Act, the redemption or repurchase of any share may be paid out of our company's profits, share premium or out of the proceeds of a new issue of shares made for the purpose of such redemption or repurchase, or out of capital if our 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.

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 list of shareholders or our corporate records. However, our amended and restated articles of association have provisions that provide our shareholders the right to inspect our register of members without charge, and to receive our annual audited financial statements. See "Where You Can Find Additional Information."

Issuance of additional Ordinary Shares

Our amended and restated articles of association authorizes 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 articles of association also authorizes our board of directors to establish from time to time one or more series of preference shares and to determine, with respect to any series of preference shares, the terms and rights of that series, including, among other things:

- the designation of the series;
- the number of shares of the series;
- the dividend rights, dividend rates, conversion rights and voting rights; and
- the rights and terms of redemption and liquidation preferences.

Our board of directors may issue preference shares without action by our shareholders to the extent of available authorized but unissued shares. Issuance of these shares may dilute the voting power of holders of ordinary shares.

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 shares with no par value;
- may obtain an undertaking against the imposition of any future taxation (such undertakings are usually given for 20 years in the first instance);
- may register by way of continuation in another jurisdiction and be deregistered in the Cayman Islands;
- may register as an exempted 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 that shareholder's 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).

Requirements to Change the Rights of Holders of Ordinary Shares (Item 10.B.4 of Form 20-F)

Variations of Rights of Shares

Whenever the capital of our company is divided into different classes the rights attached to any such class may, subject to any rights or restrictions for the time being attached to any class, only be varied with the sanction of a resolution passed by a majority of two-thirds of the votes cast at a separate meeting of the holders of the shares of that class. The rights conferred upon the holders of the shares of any class issued with preferred or other rights 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, allotment or issue of further shares ranking pari passu with such existing class of shares.

Limitations on the Rights to Own Ordinary Shares (Item 10.B.6 of Form 20-F)

Rights of Non-Resident or Foreign Shareholders

There are no limitations imposed by our amended and restated 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 articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

Provisions Affecting Change of Control (Item 10.B.5 of Form 20-F)

Anti-Takeover Provisions

Some provisions of our post-offering 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 preference shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preference 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 post-offering 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.

Ownership Threshold (Item 10.B.8 of Form 20-F)

There are no limitations imposed by our amended and restated 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 articles of association governing the ownership threshold above which shareholder ownership must be disclosed.

Differences Between the Law of Different Jurisdictions (Item 10.B.9 of Form 20-F)

The Companies Act is derived, to a large extent, from the older Companies Acts of England but does not follow recent English 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 U.S. corporations and their shareholders. Set forth below is a summary of certain significant differences between the provisions of the Companies Act applicable to us and the laws applicable to companies incorporated in the State of Delaware 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 consolidated 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 plan must be filed with the Registrar of Companies of the Cayman Islands together with a declaration as to the solvency of the consolidated or surviving company, a list of 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. Court approval is not required for a merger or consolidation which is effected in compliance with these statutory procedures.

A merger between a Cayman parent company and its Cayman subsidiary or subsidiaries does not require authorization by a resolution of shareholders of that Cayman subsidiary if a copy of the plan of merger is given to every member of that Cayman subsidiary to be merged unless that member agrees otherwise. For this purpose, a company is a "parent" of a subsidiary if it holds issued shares that together represent at least ninety percent (90%) of the votes at a general meeting of the subsidiary.

The consent of each holder of a fixed or floating security interest over a constituent company is required unless this requirement is waived by a court in the Cayman Islands.

Save in certain limited circumstances, a shareholder of a Cayman constituent company who dissents from the merger or consolidation is entitled to payment of the fair value of his shares (which, if not agreed between the parties, will be determined by the Cayman Islands court) upon dissenting to the merger or consolidation, provided the dissenting shareholder complies strictly with the procedures set out in the Companies Act. The exercise of dissenter rights will preclude the exercise by the dissenting shareholder of any other rights to which he or she might otherwise be entitled by virtue of holding shares, save for the right to seek relief on the grounds that the merger or consolidation is void or unlawful.

Separate from the statutory provisions relating to mergers and consolidations, the Companies Act also contains statutory provisions that facilitate the reconstruction and amalgamation of companies by way of schemes of arrangement, provided that the arrangement is approved by seventy-five per cent in value of the members or class of members, as the case may be, with whom the arrangement is to be made and a majority in number of each class of creditors with whom the arrangement is to be made, and who must in addition represent seventy-five per cent in value of each such class of 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 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.

The Companies Act also contains a statutory power of compulsory acquisition which may facilitate the "squeeze out" of a dissentient minority shareholder upon a tender offer. Where an offer is made by a company for the shares of another company and, upon the holders of not less than ninety per cent. (90%) of the shares which are the subject of the offer accepting the offer, the offeror may at any time within two (2) months after such acceptance, by notice in the prescribed manner require the dissenting shareholders to transfer their 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 by way of scheme of arrangement is thus approved and sanctioned, or if a tender offer is made and accepted, in accordance with the foregoing statutory procedures, a dissenting shareholder would have no rights comparable to appraisal rights, save that objectors to a takeover offer may apply to the Grand Court of the Cayman Islands for various orders that the Grand Court of the Cayman Islands has a broad discretion to make, 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.

The Companies Act also contains statutory provisions which provide that a company may present a petition to the Grand Court of the Cayman Islands for the appointment of a restructuring officer on the grounds that the company (a) is or is likely to become unable to pay its debts within the meaning of section 93 of the Companies Act; and (b) intends to present a compromise or arrangement to its creditors (or classes thereof) either, pursuant to the Companies Act, the law of a foreign country or by way of a consensual restructuring. The petition may be presented by a company acting by its directors, without a resolution of its members or an express power in its articles of association. On hearing such a petition, the Cayman Islands court may, among other things, make an order appointing a restructuring officer or make any other order as the court thinks fit.

Shareholders' Suits

In principle, we will normally be the proper plaintiff and as a general rule a derivative action may not be brought by a minority shareholder. However, based on English authorities, which would in all likelihood be of persuasive authority in the Cayman Islands, the Cayman Islands courts can be expected to follow and apply the common law principles (namely the rule in *Foss v. Harbottle* and the exceptions thereto) so that a non-controlling shareholder may be permitted to commence a class action against or derivative actions in the name of the company to challenge actions where:

- a company acts or proposes to act illegally or ultra vires;
- the act complained of, although not ultra vires, could only be effected duly if authorized by more than a simple majority vote that has not been obtained; and
- those who control the company are perpetrating a "fraud on the minority."

Our amended and restated articles of association contains a provision by which our shareholders waive any claim or right of action that they may have, both individually and on our behalf, against any director in relation to any action or failure to take action by such director in the performance of his or her duties with or for our Company, except in respect of any fraud, willful default or dishonesty of such director.

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 articles of association provide that that we shall indemnify our directors and officers, and their personal representatives, against all actions, proceedings, costs, charges, expenses, losses, damages or liabilities incurred or sustained by such persons, other than by reason of such person's 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 director or officer in defending (whether successfully or otherwise) any civil proceedings concerning our company or its 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 our directors and executive officers that provide such persons with additional indemnification beyond that provided in our amended and restated 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.

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 permits us to eliminate the right of shareholders to act by written consent and our amended and restated articles of association provide that any action required or permitted to be taken at any general meetings may be taken upon the vote of shareholders at a general meeting duly noticed and convened in accordance with our amended and restated articles of association and may not be taken by written consent of the shareholders without a meeting.

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.

The Companies Act 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 articles of association provide that only a majority of the Board or the chairperson of the Board may call extraordinary general meetings. 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, subject to certain restrictions as contained therein, directors may be removed with or without cause, by an ordinary resolution of our shareholders. An appointment of a director may be on terms that the director shall automatically retire from office (unless he has sooner vacated office) at the next or a subsequent annual general meeting or upon any specified event or after any specified period in a written agreement between the company and the director, if any; but no such term shall be implied in the absence of express provision. Under our amended and restated articles of association, a director's office shall be vacated if the director (i) becomes bankrupt or has a receiving order made against him or suspends payment or compounds with his creditors; (ii) is found to be or becomes of unsound mind or dies; (iii) resigns his office by notice in writing to the company; (iv) without special leave of absence from our board of directors, is absent from three consecutive meetings of the board and the board resolves that his office be vacated; (v) is prohibited by law from being a director or; (vi) is removed from office pursuant to the laws of the Cayman Islands or any other provisions of our amended and restated articles of association.

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 or a group who or 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 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, 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.

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 our amended and restated articles of association, if our share capital is divided into more than one class of shares, the rights attached to any such class may only be varied with the sanction of a resolution passed by a majority of two-thirds of the votes cast at a separate 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 memorandum and articles of association may only be amended with a special resolution of our shareholders.

Changes in Capital (Item 10.B.10 of Form 20-F)

We may from time to time by resolution of shareholders in the requisite majorities:

- to increase or decrease the authorized share capital of our Company;
- sub-divide our authorized and issued shares into a larger number of shares; and
- consolidate our authorized and issued shares into a smaller number of shares.

Debt Securities (Item 12.A of Form 20-F)

Not applicable.

Warrants and Rights (Item 12.B of Form 20-F)

Not applicable.

Other Securities (Item 12.C of Form 20-F)

Not applicable.

Description of American Depositary Shares (Items 12.D.1 and 12.D.2 of Form 20-F)

Not applicable.

Exhibit 4.9

Loan Agreement

This Loan Agreement is entered into by Jyong Biotech Ltd. (hereinafter referred to as "Party A") and Linkage Gladden Enterprise Ltd. (hereinafter referred to as "Party B"). The parties agree to the following terms regarding the loan:

1. Party A entered into this Loan Agreement with Party B on June 24, 2025, whereby Party A shall lend to Party B the sum of US$15,000,000.

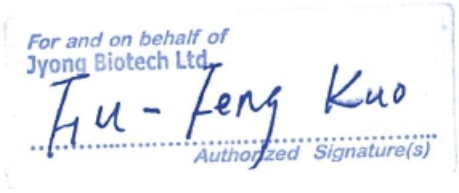
2. The loan period shall be from June 24, 2025 to June 23, 2027 (calculated from the actual date of remittance). Upon maturity, Party B shall repay the full principal plus accrued interest to Party A without delay.

3. Interest shall be calculated at an annual rate of 8%.

4. This Agreement is executed in two counterparts, with each party holding one copy.

Party A (Lender): Jyong Biotech Ltd.

Authorized Signature: Fu-Feng Kuo



Party B (Borrower): Linkage Gladden Enterprise Ltd.

Exhibit 8.1

Subsidiaries of the Registrant

Name	Place of Incorporation or Organization	Proportion of Ownership Interest
Top ShunXing Bio-Tech Co., Limited	Hong Kong	100%
Health Ever Bio-Tech Co., Ltd.	Taiwan	100%
Jyong Biotech International Pte. Ltd.	Singapore	100%
Innovative Biotech Co., Ltd.	PRC	100%
Genvace Biotechnology Co., Ltd.	Taiwan	100%

Exhibit 11.2

JYONG BIOTECH LTD.
POLICY ON INSIDER TRADING

This Insider Trading Policy describes the standards of Jyong Biotech Ltd. and its subsidiaries (the "**Company**") on trading, and causing the trading of, the Company's securities or securities of certain other publicly traded companies while in possession of confidential information. This Policy is divided into two parts: the first part prohibits trading in certain circumstances and applies to all directors, officers, employees and consultants of the Company and their respective immediate family members, and the second part imposes special additional trading restrictions and applies to all (i) directors of the Company, (ii) executive officers of the Company (together with the directors, "**Company Insiders**") and (iii) persons that the Company may designate from time to time as "Covered Persons" because of their position, responsibilities or their actual or potential access to material information ((i) through (iii), collectively, "**Covered Persons**").

One of the principal purposes of the federal securities laws is to prohibit so-called "insider trading." Simply stated, insider trading occurs when a person uses material nonpublic information obtained through involvement with the Company to make decisions to purchase, sell, give away or otherwise trade the Company's securities or the securities of certain other companies or to provide that information to others outside the Company. The prohibitions against insider trading apply to trades, tips and recommendations by virtually any person, including all persons associated with the Company, if the information involved is "material" and "nonpublic." These terms are defined in this Policy under Part I, Section 3 below. The prohibitions would apply to any director, officer, employee or consultant who buys or sells securities on the basis of material nonpublic information that he or she obtained about the Company, its customers, suppliers, partners, competitors or other companies with which the Company has contractual relationships or may be negotiating transactions.

PART I

1. Applicability

This Policy applies to all trading or other transactions in (i) the Company's securities, including common stock, options and any other securities that the Company may issue, such as preferred stock, notes, bonds and convertible securities, as well as to derivative securities relating to any of the Company's securities, whether or not issued by the Company and (ii) the securities of certain other companies, including common stock, options and other securities issued by those companies as well as derivative securities relating to any of those companies' securities, where the person trading used information obtained while working for the Company.

This Policy applies to all officers, employees and consultants of the Company and to all members of the Company's board of directors and their respective immediate family members.

2. General Policy: No Trading or Causing Trading While in Possession of Material Nonpublic Information

(a) No director, officer, employee, consultant or any of their immediate family members may purchase or sell, or offer to purchase or sell, any Company security, whether or not issued by the Company, while in possession of material nonpublic information about the Company. (The terms "material" and "nonpublic" are defined in Part I, Sections 3(a) and (b) below.)

(b) No director, officer, employee, consultant or any of their immediate family members who knows of any material nonpublic information about the Company may communicate that information to, or tip, any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

(c) No director, officer, employee, consultant or any of their immediate family members may purchase or sell any security of any other company while in possession of material nonpublic information that was obtained in the course of his or her involvement with the Company. No director, officer, employee, consultant or any of their immediate family members who know of any such material nonpublic information may communicate that information to, or tip, any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

(d) For compliance purposes, you should never trade, tip or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that you have reason to believe is material and nonpublic unless you first consult with, and obtain the advance approval of, the Compliance Officer (which is defined in Part I, Section 3(c) below).

3. Definitions

(a) Material. Insider trading restrictions come into play only if the information you possess is "material." Materiality, however, involves a relatively low threshold. Information is generally regarded as "material" if it has market significance, that is, if its public dissemination is likely to affect the market price of securities, or if it otherwise is information that a reasonable investor would want to know before making an investment decision.

Information dealing with the following subjects is reasonably likely to be found material in particular situations:

(i) significant changes in the Company's prospects;

(ii) significant write-downs in assets or increases in reserves;

(iii) developments regarding significant litigation or government agency investigations;

(iv) liquidity problems;

(v) changes in earnings estimates or unusual gains or losses in major operations;

(vi) major changes in the Company's management or the board of directors;

(vii) changes in dividends;

(viii) extraordinary borrowings;

(ix) major changes in accounting methods or policies;

(x) award or loss of a significant contract;

(xi) cybersecurity risks and incidents, including vulnerabilities and breaches;

(xii) changes in debt ratings;

(xiii) proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, or purchases or sales of substantial assets; and

(xiv) offerings of Company securities.

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction of a new product, the point at which negotiations or product development are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on a company's operations or stock price should it occur. Thus, information concerning an event that would have a large effect on stock price, such as a merger, may be material even if the possibility that the event will occur is relatively small. When in doubt about whether particular nonpublic information is material, you should presume it is material.

If you are unsure whether information is material, you should either consult the Compliance Officer before making any decision to disclose such information (other than to persons who need to know it) or to trade in or recommend securities to which that information relates or assume that the information is material.

(b) Nonpublic. Insider trading prohibitions come into play only when you possess information that is material and "nonpublic." The fact that information has been disclosed to a few members of the public does not make it public for insider trading purposes. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information. Even after public disclosure of information about the Company, you must wait until the close of business on the second trading day after the information was publicly disclosed before you can treat the information as public.

Nonpublic information may include:

(i) information available to a select group of analysts or brokers or institutional investors;

(ii) undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and

(iii) information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally two trading days).

As with questions of materiality, if you are not sure whether information is considered public, you should either consult with the Compliance Officer or assume that the information is nonpublic and treat it as confidential.

(c) Compliance Officer. The Company has appointed the Chief Financial Officer as the Compliance Officer for this Policy. The duties of the Compliance Officer include, but are not limited to, the following:

(i) assisting with implementation and enforcement of this Policy;

(ii) circulating this Policy to all directors, officers, employees and consultants of the Company and ensuring that this Policy is amended as necessary to remain up-to-date with insider trading laws;

(iii) pre-clearing all trading in securities of the Company by Covered Persons in accordance with the procedures set forth in Part II, Section 3 below;

(iv) providing approval of any Rule 10b5-1 plans under Part II, Section 1(c) below and any prohibited transactions under Part II, Section 4 below; and

(v) providing a reporting system with an effective whistleblower protection mechanism.

4. Exceptions

The trading restrictions of this Policy do not apply to the following:

(a) 401(k) Plan. Investing 401(k) plan contributions in a Company stock fund in accordance with the terms of the Company's 401(k) plan. However, any changes in your investment election regarding the Company's stock are subject to trading restrictions under this Policy.

(b) ESPP. Purchasing Company stock through periodic, automatic payroll contributions to the Company's employee stock purchase plan ("**ESPPs**") if the Company has any ESPPs. However, electing to enroll in an ESPP, making any changes in your elections under an ESPP and selling any Company stock acquired under an ESPP are subject to trading restrictions under this Policy.

(c) Options. Exercising stock options granted under the Company's incentive equity plans ("**Equity Plans**") for cash or the delivery of previously owned Company stock. However, the sale of any shares issued on the exercise of any stock options granted under any Equity Plans and any cashless exercise of any stock options granted under any Equity Plans are subject to trading restrictions under this Policy.

5. Violations of Insider Trading Laws

Penalties for trading on or communicating material nonpublic information can be severe, both for individuals involved in such unlawful conduct and their employers and supervisors, and may include jail terms, criminal fines, civil penalties and civil enforcement injunctions. Given the severity of the potential penalties, compliance with this Policy is absolutely mandatory.

(a) Legal Penalties. A person who violates insider trading laws by engaging in transactions in a company's securities when he or she has material nonpublic information can be sentenced to a substantial jail term and required to pay a criminal penalty of several times the amount of profits gained or losses avoided.

In addition, a person who tips others may also be liable for transactions by the tippees to whom he or she has disclosed material nonpublic information. Tippers can be subject to the same penalties and sanctions as the tippees, and the U.S. Securities and Exchange Commission (the "**SEC**") has imposed large penalties even when the tipper did not profit from the transaction.

The SEC can also seek substantial civil penalties from any person who, at the time of an insider trading violation, "directly or indirectly controlled the person who committed such violation," which would apply to the Company and/or management and supervisory personnel. These control persons may be held liable for up to three times the amount of the profits gained or losses avoided. Even for violations that result in a small or no profit, the SEC can seek penalties from a company and/or its management and supervisory personnel as control persons.

(b) Company-Imposed Penalties. Persons who violate this Policy may be subject to disciplinary action by the Company, including dismissal for cause. Any exceptions to the Policy, if permitted, may only be granted by the Compliance Officer and must be provided before any activity contrary to the above requirements takes place.

6. Inquiries

If you have any questions regarding any of the provisions of this Policy, please contact the Compliance Officer, Wei Zhang, by email at ir@jyongbio.com or by telephone at +886-2-2732-5205.

PART II

1. Blackout Periods

All Covered Persons are prohibited from trading in the Company's securities during blackout periods as defined below.

(a) Regular Blackout Periods. Trading in the Company's securities is prohibited during the period beginning at the close of the market on the date that is two weeks before the end of each fiscal period for which the Company publicly discloses its financial results and ending at the close of business on the second trading day following the date the Company's financial results are publicly disclosed and Form 6-K or Form 20-F is filed. During these periods, Covered Persons generally possess or are presumed to possess material nonpublic information about the Company's financial results.

(b) Other Blackout Periods. From time to time, other types of material nonpublic information regarding the Company (such as negotiation of mergers, acquisitions or dispositions, investigation and assessment of cybersecurity incidents or new product developments) may be pending and not be publicly disclosed. While such material nonpublic information is pending, the Company may impose special blackout periods during which Covered Persons are prohibited from trading in the Company's securities. If the Company imposes a special blackout period, it will notify the Covered Persons affected.

(c) Exception. These trading restrictions do not apply to transactions under a pre-existing written plan, contract, instruction, or arrangement under Rule 10b5-1 under the Securities Exchange Act of 1934 (an "**Approved 10b5-1 Plan**") that meet the following requirements:

(i) it has been reviewed and approved by the Compliance Officer at least five business days in advance of being entered into (or, if revised or amended, such proposed revisions or amendments have been reviewed and approved by the Compliance Officer at least five business days in advance of being entered into);

(ii) it provides that no trades may occur thereunder until expiration of the applicable cooling-off period specified in Rule 10b5-1(c)(ii)(B), and no trades occur until after that time. The appropriate cooling-off period will vary based on the status of the Covered Person. For directors and officers, the cooling-off period ends on the later of (x) 90 days after adoption or certain modifications of the 10b5-1 plan; or (y) two business days following disclosure of the Company's financial results in a Form 20-F or Form 6-K for the quarter in which the 10b5-1 plan was adopted. For all other Covered Persons, the cooling-off period ends 30 days after adoption or modification of the 10b5-1 plan. This required cooling-off period will apply to the entry into a new 10b5-1 plan and any revision or modification of a 10b5-1 plan;

(iii) it is entered into in good faith by the Covered Person, and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1, at a time when the Covered Person is not in possession of material nonpublic information about the Company; and, if the Covered Person is a director or officer, the 10b5-1 plan must include representations by the Covered Person certifying to that effect;

(iv) it gives a third party the discretionary authority to execute such purchases and sales, outside the control of the Covered Person, so long as such third party does not possess any material nonpublic information about the Company; or explicitly specifies the security or securities to be purchased or sold, the number of shares, the prices and/or dates of transactions, or other formula(s) describing such transactions; and

(v) it is the only outstanding Approved 10b5-1 Plan entered into by the Covered Person (subject to the exceptions set out in Rule 10b5-1(c)(ii)(D)).

No Approved 10b5-1 Plan may be adopted during a blackout period.

If you are considering entering into, modifying or terminating an Approved 10b5-1 Plan or have any questions regarding Approved Rule 10b5-1 Plans, please contact the Compliance Officer, Wei Zhang, by email at ir@jyongbio.com or by telephone at +886-2-2732-5205. You should consult your own legal and tax advisors before entering into, or modifying or terminating, an Approved 10b5-1 Plan. A trading plan, contract, instruction or arrangement will not qualify as an Approved 10b5-1 Plan without the prior review and approval of the Compliance Officer as described above.

2. Trading Window

Covered Persons are permitted to trade in the Company's securities when no blackout period is in effect. Generally, this means that Covered Persons can trade during the period beginning at the close of business on the second trading day following the date the Company's financial results are publicly disclosed and Form 6-K or Form 20-F is filed and ending at the close of the market on the date that is two weeks before the end of each fiscal period. However, even during this trading window, a Covered Person who is in possession of any material nonpublic information should not trade in the Company's securities until the information has been made publicly available or is no longer material. In addition, the Company may close this trading window if a special blackout period under Part II, Section 1(b) above is imposed and will re-open the trading window once the special blackout period has ended.

3. Pre-Clearance of Securities Transactions

(a) Because Company Insiders are likely to obtain material nonpublic information on a regular basis, the Company requires all such persons to refrain from trading, even during a trading window under Part II, Section 2 above, without first pre-clearing all transactions in the Company's securities.

(b) Subject to the exemption in subsection (d) below, no Company Insider may, directly or indirectly, purchase or sell (or otherwise make any transfer, gift, pledge or loan of) any Company security at any time without first obtaining prior approval from the Compliance Officer. These procedures also apply to transactions by such person's spouse, other persons living in such person's household and minor children and to transactions by entities over which such person exercises control.

(c) The Compliance Officer shall record the date each request is received and the date and time each request is approved or disapproved. Unless revoked, a grant of permission will normally remain valid until the close of trading two business days following the day on which it was granted. If the transaction does not occur during the two-day period, pre-clearance of the transaction must be re-requested.

(d) Pre-clearance is not required for purchases and sales of securities under an Approved 10b5-1 Plan once the applicable cooling-off period has expired. No trades may be made under an Approved 10b5-1 Plan until expiration of the applicable cooling-off period. With respect to any purchase or sale under an Approved 10b5-1 Plan, the third party effecting transactions on behalf of the Company Insider should be instructed to send duplicate confirmations of all such transactions to the Compliance Officer.

4. Prohibited Transactions

(a) Company Insiders are prohibited from trading in the Company's equity securities during a blackout period imposed under an "individual account" retirement or pension plan of the Company, during which at least 50% of the plan participants are unable to purchase, sell or otherwise acquire or transfer an interest in equity securities of the Company, due to a temporary suspension of trading by the Company or the plan fiduciary.

(b) Covered Persons, including any person's spouse, other persons living in such person's household and minor children and entities over which such person exercises control, are prohibited from engaging in the following transactions in the Company's securities unless advance approval is obtained from the Compliance Officer:

(i) ***Short-term trading*****.** Company Insiders who purchase Company securities may not sell any Company securities of the same class for at least six months after the purchase;

(ii) ***Short sales*****.** Covered Persons may not sell the Company's securities short;

(iii) ***Options trading*****.** Covered Persons may not buy or sell puts or calls or other derivative securities on the Company's securities;

(iv) ***Trading on margin or pledging***. Covered Persons may not hold Company securities in a margin account or pledge Company securities as collateral for a loan; and

(v) ***Hedging*****.** Covered Persons may not enter into hedging or monetization transactions or similar arrangements with respect to Company securities.

5. Acknowledgment and Certification

All Covered Persons are required to sign the attached acknowledgment and certification.

ACKNOWLEDGMENT AND CERTIFICATION

The undersigned does hereby acknowledge receipt of the Jyong Biotech Ltd. (the "**Company**") Insider Trading Policy (the "**Policy**"). The undersigned has read and understands (or has had explained) such Policy and agrees to be governed by such Policy at all times in connection with the purchase and sale of securities and the confidentiality of nonpublic information.

(Signature)

(Please print name)

Date:

Exhibit 12.1

Certification by the Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Fu-Feng Kuo, Chief Executive Officer of Jyong Biotech Ltd. (the "Company"), certify that:

1. I have reviewed this annual report on Form 20-F for the fiscal year ended December 31, 2025 of 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. The Company's other certifying officer and I are 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 Rule 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. The Company's other certifying officer and 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.

Dated May 14, 2026

By: */s/ Fu-Feng Kuo*
Name: Fu-Feng Kuo
Title: Chief Executive Officer and Chairwoman of the Board of Directors

Exhibit 12.2

Certification by the Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Wei Zhang, Chief Financial Officer of Jyong Biotech Ltd. (the "Company"), certify that:

1. I have reviewed this annual report on Form 20-F for the fiscal year ended December 31, 2025 of 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. The Company's other certifying officer and I are 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 Rule 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. The Company's other certifying officer and 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.

Dated May 14, 2026

By: */s/ Wei Zhang*
Name: Wei Zhang
Title: Chief Financial Officer

Exhibit 13.1

Certification by the Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Fu-Feng Kuo, Chief Executive Officer of Jyong Biotech Ltd. (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:

a. the Company's annual report on Form 20-F for the fiscal 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

b. 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.

Dated May 14, 2026

By: */s/ Fu-Feng Kuo*
Name: Fu-Feng Kuo
Title: Chief Executive Officer and
Chairwoman of the Board of Directors

Exhibit 13.2

Certification by the Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Wei Zhang, Chief Financial Officer of Jyong Biotech Ltd. (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:

a. the Company's annual report on Form 20-F for the fiscal 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

b. 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.

Dated May 14, 2026

By: */s/ Wei Zhang*
Name: Wei Zhang
Title: Chief Financial Officer

Exhibit 97.1

JYONG BIOTECH LTD.

POLICY FOR RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION

In accordance with the applicable rules of The Nasdaq Stock Market (the "Nasdaq Rules"), Section 10D and Rule 10D-1 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") ("Rule 10D-1"), the Board of Directors (the "Board") of Jyong Biotech Ltd. (the "Company") has adopted this Policy for Recovery of Erroneously Awarded Compensation (the "Policy"), which shall be effective on May 7, 2025 (the "Effective Date"). Capitalized terms used in this Policy but not otherwise defined herein are defined in Section 11.

1.0 Persons Subject to Policy

This Policy shall apply to current and former Executive Officers of the Company.

2.0 Compensation Subject to Policy

This Policy shall apply to Incentive-Based Compensation received on or after the Effective Date. For purposes of this Policy, the date on which Incentive-Based Compensation is "received" shall be determined under the Applicable Rules, which generally provide that Incentive-Based Compensation is "received" when the relevant Financial Reporting Measure is attained or satisfied, without regard to whether the grant, vesting or payment of the Incentive-Based Compensation occurs after the end of that period.

3.0 Recovery of Compensation

In the event that the Company is required to prepare a Restatement, the Company shall recover, reasonably promptly, the portion of any Incentive-Based Compensation that is Erroneously Awarded Compensation, unless the Committee has determined that recovery would be Impracticable. Recovery shall be required in accordance with the preceding sentence regardless of whether the applicable Executive Officer engaged in misconduct or otherwise caused or contributed to the requirement for the Restatement and regardless of whether or when restated financial statements are filed by the Company. For clarity, the recovery of Erroneously Awarded Compensation under this Policy will not give rise to any person's right to voluntarily terminate employment for "good reason," or due to a "constructive termination" (or any similar term of like effect) under any plan, program or policy of or agreement with the Company or any of its affiliates.

4.0 Manner of Recovery; Limitation on Duplicative Recovery

The Committee shall, in its sole discretion, determine the manner of recovery of any Erroneously Awarded Compensation, which may include, without limitation, reduction or cancellation by the Company or an affiliate of the Company of Incentive-Based Compensation or Erroneously Awarded Compensation, reimbursement or repayment by any person subject to this Policy of the Erroneously Awarded Compensation, and, to the extent permitted by law, an offset of the Erroneously Awarded Compensation against other compensation payable by the Company or an affiliate of the Company to such person. Notwithstanding the foregoing, unless otherwise prohibited by the Applicable Rules, to the extent this Policy provides for recovery of Erroneously Awarded Compensation already recovered by the Company pursuant to Sarbanes-Oxley Act Section 304 or Other Recovery Arrangements, the amount of Erroneously Awarded Compensation already recovered by the Company from the recipient of such Erroneously Awarded Compensation may be credited to the amount of Erroneously Awarded Compensation required to be recovered pursuant to this Policy from such person.

5.0 Administration

This Policy shall be administered, interpreted and construed by the Committee, which is authorized to make all determinations necessary, appropriate or advisable for such purpose. The Board may re-vest in itself the authority to administer, interpret and construe this Policy in accordance with applicable law, and in such event references herein to the "Committee" shall be deemed to be references to the Board. Subject to any permitted review by the applicable national securities exchange or association pursuant to the Applicable Rules, all determinations and decisions made by the Committee pursuant to the provisions of this Policy shall be final, conclusive and binding on all persons, including the Company and its affiliates, stockholders and employees. The Committee may delegate administrative duties with respect to this Policy to one or more directors or employees of the Company, as permitted under applicable law, including any Applicable Rules.

6.0 Interpretation

This Policy will be interpreted and applied in a manner that is consistent with the requirements of the Applicable Rules, and to the extent this Policy is inconsistent with such Applicable Rules, it shall be deemed amended to the minimum extent necessary to ensure compliance therewith.

7.0 No Indemnification; No Liability

The Company shall not indemnify or insure any person against the loss of any Erroneously Awarded Compensation pursuant to this Policy, nor shall the Company directly or indirectly pay or reimburse any person for any premiums for third-party insurance policies that such person may elect to purchase to fund such person's potential obligations under this Policy. None of the Company, an affiliate of the Company or any member of the Committee or the Board shall have any liability to any person as a result of actions taken under this Policy.

8.0 Application; Enforceability

Except as otherwise determined by the Committee or the Board, the adoption of this Policy does not limit, and is intended to apply in addition to, any other clawback, recoupment, forfeiture or similar policies or provisions of the Company or its affiliates, including any such policies or provisions of such effect contained in any employment agreement, bonus plan, incentive plan, equity-based plan or award agreement thereunder or similar plan, program or agreement of the Company or an affiliate or required under applicable law (the "Other Recovery Arrangements"). The remedy specified in this Policy shall not be exclusive and shall be in addition to every other right or remedy at law or in equity that may be available to the Company or an affiliate of the Company.

9.0 Severability

The provisions in this Policy are intended to be applied to the fullest extent of the law; provided, however, to the extent that any provision of this Policy is found to be unenforceable or invalid under any applicable law, such provision will be applied to the maximum extent permitted, and shall automatically be deemed amended in a manner consistent with its objectives to the extent necessary to conform to any limitations required under applicable law.

10.0 Amendment and Termination

The Board or the Committee may amend, modify or terminate this Policy in whole or in part at any time and from time to time in its sole discretion. This Policy will terminate automatically when the Company does not have a class of securities listed on a national securities exchange or association.

11.0 Definitions

"***Applicable Rules***" means Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder, the listing rules of the national securities exchange or association on which the Company's securities are listed, and any applicable rules, standards or other guidance adopted by the Securities and Exchange Commission or any national securities exchange or association on which the Company's securities are listed.

"***Committee***" means the committee of the Board responsible for executive compensation decisions comprised solely of independent directors (as determined under the Applicable Rules), or in the absence of such a committee, a majority of the independent directors serving on the Board.

"***Erroneously Awarded Compensation***" means the amount of Incentive-Based Compensation received by a current or former Executive Officer that exceeds the amount of Incentive-Based Compensation that would have been received by such current or former Executive Officer based on a restated Financial Reporting Measure, as determined on a pre-tax basis in accordance with the Applicable Rules.

"***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means each person who serves as an executive officer of the Company, as defined in Rule 10D-1(d) under the Exchange Act.

"***Financial Reporting Measure***" means any measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including GAAP, non-GAAP financial measures, as well as stock price and total stockholder return.

"***GAAP***" means United States generally accepted accounting principles.

"***Impracticable***" means (a) (i) the direct costs paid to third parties to assist in enforcing recovery would exceed the Erroneously Awarded Compensation; provided that the Company (i) has made reasonable attempts to recover the Erroneously Awarded Compensation, (ii) documented such attempt(s), and (iii) provided such documentation to the relevant listing exchange or association, (b) to the extent permitted by the Applicable Rules, the recovery would violate the Company's home country laws pursuant to an opinion of home country counsel; provided that the Company has (i) obtained an opinion of home country counsel, acceptable to the relevant listing exchange or association, that recovery would result in such violation, and (ii) provided such opinion to the relevant listing exchange or association, or (c) recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and the regulations thereunder.

"***Incentive-Based Compensation***" means, with respect to a Restatement, any compensation that is granted, earned, or vested based wholly or in part upon the attainment of one or more Financial Reporting Measures and received by a person: (a) after beginning service as an Executive Officer; (b) who served as an Executive Officer at any time during the performance period for that compensation; (c) while the Company has a class of its securities listed on a national securities exchange or association; and (d) during the applicable Three-Year Period.

"***Restatement***" means an accounting restatement to correct the Company's material noncompliance with any financial reporting requirement under securities laws, including restatements that correct an error in previously issued financial statements (a) that is material to the previously issued financial statements or (b) that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Restatement Date***" means the earlier to occur of (i) the date the Board, a committee of the Board or the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare a Restatement, or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare a Restatement.

"***Three-Year Period***" means the three completed fiscal years immediately preceding the date the Company is required to prepare a Restatement. The "Three Year Period" also includes any transition period (that results from a change in the Company's fiscal year) within or immediately following the three completed fiscal years identified in the preceding sentence. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months shall be deemed a completed fiscal year.