

## Risk Factors Comparison 2025-03-17 to 2024-03-27 Form: 10-K

**Legend:** **New Text** ~~Removed Text~~ Unchanged Text **Moved Text** Section

The following section includes the most significant factors that may adversely affect our business and operations. You should carefully consider the risks and uncertainties described below and all information contained in this Annual Report on Form 10-K before deciding to invest in our common stock. If any of the following risks actually occur, our business, financial condition, results of operations and growth prospects may be materially and adversely affected. In that event, the trading price of our common stock could decline, and you could lose all or part of your investment. **Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future.** Summary of Risk Factors Investing in our securities involves a high degree of risk. Below please find a summary of the principal risks we face. These risks are discussed more fully below.

- Our business is significantly dependent on the sales of ETUARY®, our marketed product in the PRC, amid a competitive landscape, and there is a possibility that we may not be able to sustain or boost the sales volume, pricing, and profitability of ETUARY.
- There is a risk that our marketed product in the PRC, ETUARY, along with any other products that **we may commercialize in the future, including nintedanib and avatrombopag, and** may receive approval in the future, may not attain sufficient market acceptance among physicians, healthcare facilities, pharmacies, patients, third-party payers, and the broader medical community, which is crucial for their commercial viability.
- The future of our business and financial outcomes is largely contingent on the progress and success of our product candidates in clinical and pre-clinical stages, such as ETUARY for future indications in the PRC, F573 in the PRC, and F351 in the PRC and in additional markets beyond the PRC. We face the risk of not being able to finalize their clinical development, secure necessary regulatory approvals, or accomplish their market launch successfully, or we may encounter substantial setbacks in these processes.
- To support the growth of our research and development activities and operations, we require further funding, which might not be obtainable on favorable terms or could be entirely unavailable. If we fail to secure the needed capital at the critical time, we might have to postpone, scale down, or halt some of our development projects, market introduction initiatives, or other operational aspects.
- The true market potential for our product and product candidates may be less than expected. Our expansion could be constrained by the current and emerging number of IPF patients in the PRC, pending the approval and profitable launch of expanded applications for ETUARY for future indications in the PRC, and our other product candidates.
- The approval procedures of the NMPA, FDA, and comparable foreign regulatory authorities are extensive, protracted, and inherently uncertain. Failure to secure necessary approvals, or encountering delays in the approval process, will prevent us from marketing our product candidates, such as ETUARY for future indications in the PRC, F573 in the PRC, and F351 in the PRC and in additional markets beyond the PRC, which may significantly affect our revenue generation.
- Should we or our licensors fail to secure, uphold, defend, or extend adequate patent and other intellectual property rights for our ~~product~~ **products**, ETUARY, **nintedanib and avatrombopag**, which ~~is~~ **are** approved in the PRC, and any product candidates globally, or if the breadth of these intellectual property rights is insufficient, our ability to effectively compete in our markets could be compromised.
- We have established, and may continue to establish, collaborative agreements and strategic partnerships. However, there is no guarantee we will fully achieve the anticipated benefits from these collaborations, alliances, or licensing agreements, and conflicts could emerge with our present or prospective partners.
- Clinical drug development involves a lengthy and expensive process and outcomes are uncertain, and we may not successfully complete clinical trials for drugs under development, including ETUARY for future indications in the PRC, F573 in the PRC, and F351 in the PRC and in additional markets beyond the PRC, or demonstrate the safety and efficacy of our product candidates to the satisfaction of regulatory authorities.
- ~~We are developing F351 for the treatment of liver fibrosis associated with NASH. The requirements for approval of F351 by the NMPA, FDA and comparable foreign regulatory authorities are unknown, may be difficult to predict, and may change over time, which makes it difficult to predict the timing and costs of clinical development and the likelihood of marketing approval.~~
- Our ongoing success is reliant on our capacity to retain key executives and to recruit, maintain, and inspire skilled professionals.
- If our intangible assets are impaired, our results of operations and financial condition may be adversely affected.
- Modifications to laws, regulations, and rules by the PRC government could lead to alterations in our operational processes and business approaches.
- There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.
- The market price of our common stock ~~is expected~~ **has been, and may continue** to be **volatile**. ~~We may be unable to integrate successfully and realize the anticipated benefits of the Contributions.~~
- We will continue to incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with regulations related to operating as a public company.

**Risks Related to Our Financial Condition and Capital Requirements** Our business is significantly dependent on the sales of ETUARY, our marketed product in the PRC, amid a competitive landscape, and there is a possibility that we may not be able to sustain or boost the sales volume, pricing, and profitability of ETUARY. We are a biotechnology company and have only generated revenues from the commercial sale of ETUARY, which is approved in the PRC, and certain generic drugs. We only have one product and certain generic drugs for commercial sale and are still in the early stages of development of our other product candidates. We are largely dependent on sales of ETUARY, but we may not be able to maintain ETUARY's sales volumes, pricing levels or profit margins. Sales of ETUARY accounted for **99.3% and 98.9%** and ~~96.9%~~ of our total revenue in **2024 and 2023** and ~~2022~~, respectively, and we expect that sales of ETUARY will continue to comprise a substantial portion of our total revenue in the near future. As a result, any reduction in sales or profit

margins of ETUARY will have a material negative impact on our business and results of operations. In addition, the pharmaceutical industries are characterized by rapid changes in technology, constant enhancement of industrial know-how and frequent emergence of new products, which renders our targeted markets highly competitive. Notably, the IPF drug market in the PRC is characterized by increasingly fierce competition, with **one-several** pifrenidone product and **one-nintedanib product products** approved and commercialized, in addition to our **product products ETUARY and nintedanib, which Gyre Pharmaceuticals acquired the commercial rights to in May 2024**. There are also several drug candidates that have entered into Phase 2 or more advanced clinical trial stage. With the increase in the penetration rate of IPF drugs and the expansion of the overall market, including past new market participants, we expect that more market players will join the IPF market, and, consequently, the sales of our product ETUARY, ~~which accounted for 55.3% of the total market in 2022, has decreased from 78.8% of the total market share in 2021, and may continue to decrease.~~ For details, see “ — Business — Our Products and Product Pipeline — ETUARY: National Category 1. 1 New Drug for IPF Approved in 2011 — Market Opportunities and Competition ” in this Annual Report. New entrants to the IPF market in the PRC may exert downward pressure on our average selling price of ETUARY, which may negatively impact sales and / or profit of ETUARY. Many of our competitors, including foreign pharmaceutical companies, may have substantially greater clinical, research, regulatory, manufacturing, marketing, financial and human resources compared to us. Certain of our competitors may be actively engaged in research and development in areas where we have products or where we are developing product candidates or new indications for our existing products. Other companies may discover, develop, acquire or commercialize products more quickly or more successfully than we do. Moreover, there may also be significant consolidation in the pharmaceutical industry among our competitors or ventures among competitors that may increase their market share. Furthermore, our competitors may apply for and obtain marketing approvals in the PRC, United States or other countries for products with the same intended use as our generic products, ETUARY and product candidates more rapidly than we do. The capacity of the relevant authorities, such as the NMPA, FDA or other comparable foreign regulatory authorities, to concurrently review multiple marketing applications for the same type of innovative drug may be limited. Therefore, such authorities’ review of our product candidates may be delayed when there is concurrent review of our product candidates with our competitors’ products, and the registration process of our products may be prolonged. In addition to market competition from generic drugs and other products or therapies indicated for the same disease, many of the factors discussed in this Risk Factors section could adversely affect sales of ETUARY, including but not limited to, pricing pressures caused by government policies and inclusion or removal from the governmental medical insurance coverage, market acceptance among the medical community, disruptions in manufacturing or distribution, issues with product quality or side effects and disputes over intellectual property. Moreover, despite our efforts, we may be unable to develop or acquire new products that would diversify our business and reduce our dependence on ETUARY. We have devoted most of our financial resources to research and development, including our preclinical and clinical development activities. Our ability to generate revenue and realize profitability depends on the successful completion of the development of our product candidates, obtaining necessary regulatory approvals, and manufacturing and commercializing our product candidates, which is contingent upon various factors, including: • the clinical development of ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC; • enhancing our commercial manufacturing capabilities; • our ability to attract, hire and retain skilled personnel ; • the successful enrollment in, and completion of, clinical trials, as well as completion of pre-clinical studies and favorable safety and efficacy data therefrom ; • receipt of regulatory approvals; • the performance by contract research organizations (“ CROs ”), or other third parties, of their duties to us in a manner that complies with our trial protocols and applicable laws and protects the integrity of the resulting data; • our ability to acquire or in-license other product candidates and technologies; • obtaining, maintaining, protecting and enforcing patent, trade secret and other intellectual property and proprietary protection and regulatory exclusivity, and ensuring we do not infringe, misappropriate or otherwise violate the patent, trade secret or other intellectual property and proprietary rights of third parties ; • successfully launching commercial sales, **including our plan to commercially launch nintedanib and avatrombopag**; • obtaining and / or maintaining favorable governmental and private medical reimbursement; • efficiently and cost-effectively enhancing our marketing platform and distribution capabilities; • competition with other products and product candidates; • continued acceptable safety profile following regulatory approval, including of ETUARY; • creating additional infrastructure to support operations as a public company and our product development and planned future commercialization efforts ; and • delays or other issues with any of the above. We may not be able to achieve one or more of the foregoing factors in a timely manner or at all. As a result, we could experience significant delays in or obtaining or not be able to obtain approval for and / or successful commercialization of our product, ETUARY, and product candidates, which would render us unable to achieve our planned milestones and materially harm our drug development prospects. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to sustain or increase profitability on a quarterly or annual basis. Failure to sustain or increase profitability would depress the value of our common stock and could impair our ability to raise capital, expand our business, maintain research and development efforts, diversify product offerings or even continue operations. A decline in the value of our common stock could also cause you to lose all or part of your investment. The development, commercialization, manufacturing, marketing, sales and distribution of biopharmaceutical products and product candidates is capital-intensive. We have only generated revenues from the commercial sale of ETUARY and certain generic drugs in the PRC and will not be able to generate any product revenues in addition to those generated by ETUARY and certain generic drugs until we receive approval to sell our other product candidates from the NMPA, FDA or other regulatory authorities. As we have only generated revenue from commercial sales of ETUARY and certain generic drugs to date and do not expect to generate any revenue from our other product candidates until they obtain regulatory approval, if ever, we will need to raise substantial additional capital in order to fund our future research and development, including any new clinical trials, product development, partnerships with third parties

and strategic collaborations. ~~If we continue with preclinical and clinical development activities, we will continue to incur expenses related to the preclinical and clinical development of our product candidates.~~ However, we expect to need to raise substantial additional capital to continue the clinical development of ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC, and depending on the availability of capital, may need to delay or cease development of some or all of our product candidates. Even if we raise additional capital, we may elect to focus our efforts on one or more development programs and delay or cease other development programs. While we expect that the implementation of our strategies and business plans will require us to rely in part on external financing sources, **including our ATM Program with Jefferies LLC**, our ability to obtain additional capital on commercially reasonable terms is subject to a variety of factors, many of which are outside of our control, including our future financial condition, results of operations and cash flows, the global economic conditions, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government policies on lending. Additional funds may not be available when we need them on terms that are acceptable, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate some or all of our research or development programs, and we may not be able to execute our strategies and business plans as currently contemplated, which could have a material adverse effect on our business, financial condition and results of operations. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: • the costs and results of preclinical studies or clinical trials of ETUARY, F351, F573, F528 and F230 or other product candidates, and expenses related to potential clinical development of such candidates; • the expenses associated with promoting academic marketing and expanding our sales and distribution network; • the number and characteristics of product candidates that we pursue; • ~~the costs we incur related to the sale of our legacy assets or claims; • the~~ terms and timing of any future collaboration, licensing or other arrangements that we may establish; • our need and ability to retain key management and hire scientific, technical, business and medical personnel; • the outcome, timing and cost of regulatory approvals; • our efforts to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights; • the effect of competing technological and market developments; • the costs and timing associated with manufacturing our products, including ETUARY and generic products and product candidates for which we may receive regulatory approval, and establishing commercial supplies and sales, marketing and distribution capabilities; • market acceptance of any product candidates for which we may receive regulatory approval; • the capital expenditure required to increase our production capacity and to expand and upgrade our facilities; • the costs of continuing to operate our business, including costs associated with being a public company; and • the extent to which we acquire, license or invest in businesses, products or technologies. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the ~~recent~~ disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from public health crises, the conflict between Russia and Ukraine, ~~the Hamas-Israel war~~ **conflicts in attacks on marine vessels traversing the Red Sea Middle East**. For details regarding the risks related to the relations between the PRC and the United States, see “ — Risks Related to Our Business Operations in the PRC — Changes in the political and economic policies of the PRC government or relations between the PRC and the United States may affect our business, financial condition and results of operations. ” If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our strategy. ~~If our board of directors elects to seek product candidates for development, we will face the risks related to discovery, development and commercialization of our product candidates set forth in this section, in addition to other risks described in this Risk Factors section.~~ Raising additional funds by issuing securities or through licensing arrangements may cause dilution to stockholders, restrict our operations or require us to relinquish proprietary rights. To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of common stockholders. We currently have in place an **Equity Distribution Open Market Sale Agreement AgreementSM** with **Jefferies LLC Piper Sandler & Co.** that permits us, subject to applicable SEC regulations, to issue up to \$ 50. 0 million of shares of our common stock in “ at the market ” transactions at prevailing market prices. Debt financing, if available at all, 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 licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us. We may also seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. There can be no assurance that we will be able to obtain additional funding if, and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, curtail or eliminate one or more, or all, of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may grow our business in part through acquisitions, which may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and have material adverse effect on our ability to manage our business, and we may fail to successfully complete such acquisitions or enhance post- acquisition performances in the future. To enhance our growth and benefit our product development, technology advancement and distribution network, we have in the past and may continue to acquire businesses, products, technologies or know- how or enter into strategic partnerships. Any completed, in- process or potential acquisition or strategic partnership may entail numerous risks, including: • inability to identify suitable acquisition targets and reach agreement on acceptable terms; • lack of access to financing for acquisitions on acceptable terms or at all, or otherwise on assumption of additional indebtedness

or contingents and issuance of our equity securities; • failure to obtain or secure the governmental approvals and third- party consents necessary to consummate any proposed acquisition; • increased operating expenses, including research and development expenses due to an increased number of product candidates, administrative expenses and selling expenses; • assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel; • diversion of our management’ s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition; • difficulty in retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products and product candidates; • inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs; and / or • deficiencies in internal controls, data adequacy and integrity, product quality and regulatory compliance and product liabilities in the acquired business we discover after such acquisition. Our plan to grow our business through such acquisitions may not materialize as expected. Our high gross margin during the years ended December 31, **2024 and 2023** and ~~2022~~ may not be sustainable. During the years ended December 31, **2024 and 2023** and ~~2022~~, we maintained a high level of gross margin. Our profit margins were **96.3 % and 95.9 %** and ~~95.3 %~~ for the years ended December 31, **2024 and 2023** and ~~2022~~, respectively, due to our mature technology and significant cost reduction due to the scale effect. However, there can be no assurance that we will sustain a similarly high gross margin in the future. Various factors may affect our gross margin, many of which are beyond our control. For example, changes in the competitive landscape of the relevant markets may decrease the average selling prices of ETUARY, which may have a negative effect on our gross margin. Moreover, our gross margin will be influenced by various components of our costs, such as the cost of raw materials. For details, see “ — Risks Relating to Manufacture and Supply of Our Product — Fluctuations in prices of our raw materials and energy supply, as well as other costs associated with our production processes, may have a material adverse effect on us if we are not able to pass the cost increases on to our customers ” in this Risk Factors section. Our five largest customers accounted for a substantial amount of our revenue during the years ended December 31, **2024 and 2023** and ~~2022~~, which subjects us to concentration risks. Our five largest customers accounted for a substantial amount of our revenue for the years ended December 31, **2024 and 2023** and ~~2022~~. As such, we may be exposed to credit risks, and there can be no assurance that we can properly assess and respond in a timely manner to changes in our customers’ credit profile. As of each of December 31, **2024 and 2023** and ~~2022~~, we had certain concentrations of credit risk of 10 %. In addition, as of December 31, **2024, 54.3 % and 84.9 %**, and as of December 31, 2023, 50.5 % and 85.5 %, and as of December 31, 2022, 45.1 % and 78.3 %, of our trade receivables were due from our largest customer and our five largest customers, respectively. If such customers’ cash flows, working capital, financial condition or results of operations decrease, they may be unable, or they may otherwise be unwilling, to pay trade receivables owed to us promptly or at all. Any substantial defaults or delays could materially and adversely affect our cash flows, and if we terminate our relationships with our customers as a result of such customers’ default or payment delay, then that may adversely and materially affect our cash flows and operations. If any of our major customers stop purchasing ETUARY or substantially reduce order size in the future, whether due to the termination or amendment of our contractual relationship with such customer, or due to any other reason unrelated to us, we may not be able to identify and sell ETUARY to an alternative customer in a timely manner, or at all. As a result, our business and financial performance may be materially and adversely affected. We may face risk regarding the obsolescence of our inventories. Our inventories consist of raw materials, works in progress, semi- finished goods and finished goods. As of December 31, **2024 and 2023** and ~~2022~~, our inventories were valued at \$ **46.3** million and \$ **64.13** million, respectively. During the years ended December 31, **2024 and 2023** and ~~2022~~, we did not identify material inventory items requiring impairment provisioning, and we believe that maintaining appropriate levels of inventory helps us meet market demands in a timely manner. We generally purchase supplies based on our estimated demand and manufacturing capacity, and our management system covers each stage of the warehousing process. The storage and distribution of our inventories are closely monitored in order to keep our inventories and logbook consistent. However, as our business expands, our inventory levels may increase and the risk of obsolescence may increase accordingly. Furthermore, any unexpected material fluctuations in the supplies or changes in customers’ preferences may lead to decreased demand and overstocking of supplies and increase the risk of obsolescence. We have intangible assets primarily consisting of product development in progress, patents, technological know- how, and computer software, which accounted for a considerable portion of our total assets as of December 31, **2024 and 2023** and ~~2022~~. The value of our intangible assets is based on a number of assumptions made by our management. If any of these assumptions do not materialize, or if the performance of our business is not consistent with such assumptions, we may have to write off a significant portion of our intangible assets and record a significant impairment loss. In addition, our determination on whether intangible assets are impaired requires an estimation of the carrying amount and recoverable amount of an intangible asset. If the carrying amount exceeds its recoverable amount, our intangible assets may be impaired, which could have a material adverse effect on our business, financial condition and results of operations. We may be subject to credit risk in collecting trade receivables due from our customers. As of December 31, **2024 and 2023** and ~~2022~~, our trade receivables amounted to \$ **15.19.26** million and \$ 15. **62** million, respectively, which primarily represented the balances due from our distributors. Our liquidity and cash flow are directly affected by our customers’ ability to pay us in a timely manner, but there can be no assurance that our customers will not default on us in the future, despite our efforts to conduct credit assessments. During the years ended December 31, **2024 and 2023** and ~~2022~~, our trade receivables turnover days were **60 days and 50 days** and ~~46~~ days, respectively. If any of our customers’ business, cash flow, conditions or results of operations decrease, such customers may be unable or unwilling to pay trade receivables owed to us promptly or at all. Bankruptcy or deterioration of the credit condition of our major customers could also materially and adversely affect our collection of trade receivables. For details of the risk associated with concentrations of credit risk that we are exposed to, see “ — Our five largest customers accounted for a substantial amount of our revenue during the years ended December 31, **2024 and**

2023 and 2022, which subjects us to concentration risks.” in this Risk Factors section. If significant amounts due to us is not settled in a timely manner, we may incur significant write-offs and our liquidity and cash flow may be adversely affected. We have historically received government grants and have been entitled to preferential tax treatment, but we may not continue to receive government financial incentives in the future. We have historically received government grants in connection with certain of our research and development and manufacturing activities, and recognized government grants under other income and gains of \$ 0.1 million and \$ 1.0 million and \$ 0.9 million for the years ended December 31, 2024 and 2023 and 2022, respectively. For details of the amounts of our other recognized income, see Note 4 to the Audited Financial Statements of Gyre Therapeutics, Inc. in this Annual Report. We were also entitled to a preferential corporate income tax rate of 15 % for each of the years ended December 31, 2024 and 2023 and 2022 as a High and New Technology Enterprise. In addition, our product ETUARY, which is approved in the PRC, has been entitled to a preferential VAT treatment at the tax rate of 3 %. However, there can be no assurance of the continued availability of such preferential treatment. Our eligibility for government grants and preferential tax rates depends on a variety of factors, including, but not limited to, the assessment of our improvement on existing technologies, relevant government policies and the availability of funding at different granting authorities. In addition, the timing, amount and criteria of government financial incentives are determined within the sole discretion of the PRC government authorities. Government financial incentives are non-recurring in nature, and there can be no guarantee that we will continue to receive government incentives. In addition, some government financial incentives may be subject to the satisfaction of certain conditions, including compliance with the applicable financial incentive agreements and completion of the specific projects therein, which we may not satisfy. Any reduction or elimination of the government financial incentives we currently receive could have an adverse effect on our financial condition.

**Risks Related to Our Business Operations and Product Candidates**

The commercial success of our existing **marketed product, ETUARY, future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025,** and future approved products, if any, depends upon the degree of market acceptance such products can achieve, particularly among physicians, hospitals, pharmacies and other medical institutions, which is contingent upon a number of factors. Such factors affecting the market acceptance of a current or future approved product, if any, may include:

- the clinical indications for which the product is approved;
- the safety and efficacy of the product;
- the potential and perceived advantages and disadvantages of the product, relative to competing or alternative products or treatments;
- the affordability of the product;
- the cost of treatment in relation to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our relationships with patient communities;
- the availability of third-party coverage and adequate reimbursement;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- the strength of marketing and distribution support;
- the prevalence and severity of any side effects;
- the current diagnostic conditions of the disease for which the product is indicated, which may be influenced by the number of physicians from the relevant department and their respective experiences, available diagnostic methods and equipment therefor; and
- the effectiveness of our sales and marketing efforts.

If our existing and future approved products, if any, fail to achieve or maintain widespread market acceptance, or if new products introduced by our competitors are perceived more favorably by healthcare practitioners and patients, are more cost-effective or otherwise render our products obsolete, the demand for our products may decline and our business and profitability may be materially and adversely affected.

**If any of our product candidates receives marketing approval for the treatment of pneumoconiosis has been approved approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others** in the PRC, **and medical community.** ~~doctors~~ **Doctors** may not accept or use ETUARY as a treatment for pneumoconiosis even if ETUARY receives marketing approval for such indication. ~~Similarly, to date, no specific therapeutic drugs treating HBV-associated liver fibrosis have been approved worldwide, and doctors~~ **Doctors** may not accept or use F351 as a treatment for liver fibrosis even if F351 receives marketing approval. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues from or receive any return on our investment in any such product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate their safety and efficacy, but there can be no assurance that such trials will be completed in a timely or cost-effective manner, due to the inherently unpredictable nature of clinical drug development. We have only obtained regulatory approval for one product **that we developed**, ETUARY for the treatment of IPF in the PRC, ~~that we have developed~~, and it is possible that none of our existing product candidates **in development** or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Events that may prevent successful or timely completion of clinical development may include:

- regulators, institutional review boards or ethics committees not authorizing us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- our inability to reach agreements on acceptable terms with prospective CROs, SMOs and hospitals as trial centers;
- manufacturing issues, including problems with manufacturing, supply quality, compliance with GMP, or obtaining sufficient quantities of a product candidate for use in a clinical trial in a timely manner;
- clinical trials producing negative or inconclusive results, resulting in additional clinical trials or abandoning drug development programs;
- changes to the clinical trial protocol;
- our third-party contractors’ failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- our suspending or terminating clinical trials for various reasons, including negative or inconclusive clinical response or a finding that participants are being exposed to unacceptable health risks or experiencing adverse effects;
- the cost of clinical trials being greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials being insufficient or inadequate;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- participants choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- occurrence of adverse effects or serious adverse effects associated with the product candidate that are viewed to outweigh its potential benefits;
- the occurrence of serious adverse events in clinical trials of competing products or

conducted by competitors; • third- party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol or other regulatory requirements or committing fraud; and • the results of pre- clinical studies or early clinical trials not being predictive of the results of later- stage clinical trials, and initial or interim results of a trial not being predicative of final results. If we are required to conduct additional preclinical studies or clinical trials of our product candidates, including of ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC or other testing, or if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • be delayed in obtaining regulatory approval from the NMPA, FDA, EMA or other regulatory authorities for our product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC; • not obtain regulatory approval at all and lose our ability to further develop and commercialize our product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC; • be required to conduct additional clinical trials or other testing beyond those that we currently contemplate; • obtain regulatory approval for indications or patient populations that are not as broad as intended or desired; • continue to be subject to post- marketing testing requirements from the NMPA, FDA, EMA or other regulatory authorities; • be unable to be listed in the NRDL in the PRC; or • experience having the product removed from the market after obtaining regulatory approval. Consequentially, any delays in completing our clinical trials may increase our costs, delay our product candidate development and approval process, and jeopardize our ability to commercialize our approved products and generate revenues. Liver fibrosis is an area of our focus, and our key product candidate in this area is F351. Our future clinical trials for F351 may not be successful. We expect to invest a substantial amount of our efforts and financial resources into the research and development of F351. F351 is currently in its Phase 3 clinical trial in the PRC and has the potential to be the world’ s first approved drug to treat liver fibrosis associated with CHB. F351 was granted a Breakthrough Therapy designation by the NMPA’ s CDE in March 2021 and the patient enrollment for our Phase 3 clinical trial was commenced in January 2022. As of October 2023, the 248 patient Phase 3 clinical trial in the PRC was fully enrolled. However, F351’ s Breakthrough Therapy designation does not increase the likelihood that F351 will ultimately receive approval from the NMPA or other comparable regulatory authorities. **We expect to have In October 2024, the last patient out in 2024 and submit completed the 52- week pivotal Phase 3 trial, an and NMPA application for F351 in we expect to report top- line data by the second PRC in the first- quarter of 2025. In addition, we are actively preparing an IND application in the United States that we expect to file by the end- first half of 2024-2025 for a Phase 2 clinical trial to evaluate F351 for the treatment of advanced liver fibrosis associated with noncirrhotic NASH- MASH . Following IND clearance, we plan to initiate a Phase 2a- 2, PoC clinical trial in 2025 in the United States , subject to positive trends in the Phase 3 trial of F351 in the PRC, to evaluate the safety, tolerability, PK, and PD of F351 for patients with advanced liver fibrosis associated with noncirrhotic NASH- MASH . The FDA has provided pre- IND advice on the design of the planned Phase 2a- 2 trial of F351 and provided guidance on the contents of the IND filing. Our clinical If we observe positive trends in the Phase 2a trial trials may be adversely affected by offF351, we expect to initiate a Phase 2 trial of F351 in the United States- March 2024 marketing approval for Rezdiffra or the potential regulatory approvals for one or more investigational MASH products .** F351 will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote F351, or any other product candidates, before we receive marketing approval from the NMPA, FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals. The success of F351 will depend on a variety of factors. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of F351, even if approved. If we are not successful in commercializing F351, or are significantly delayed in doing so, our business will be materially harmed. If we experience delays or difficulties in the commencement of clinical trials or patient enrollment in clinical trials, our regulatory approvals could be delayed or prevented. We or our collaborators may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate, enroll and maintain enrollment of a sufficient number of eligible patients to participate in these trials as required by the NMPA, FDA or similar regulatory authorities outside the PRC or the United States. Furthermore, there are inherent difficulties in enrolling NASH- MASH patients, which can currently only be definitively diagnosed through a liver biopsy. Specifically, identifying patients most likely to meet NASH- MASH enrollment criteria on biopsy is an on- going challenge, with existing clinical indicators lacking both sensitivity and specificity. As a result, NASH- MASH trials often suffer from high levels of screen failure following central review of the baseline liver biopsy, which can lead to lower enrollment. As a result of such difficulties and the significant competition for recruiting NASH- MASH patients in clinical trials, we or our future collaborators may be unable to enroll the patients we need to complete clinical trials on a timely basis, or at all. In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical trials for the same indications and seek to enroll patients in their studies that may otherwise be eligible for our clinical studies or trials. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites. The availability of other approved products and other products in clinical trials have and may limit the number of patients willing to participate in our clinical trials. Patient enrollment is affected by other factors including: • the severity of the disease under investigation; • the eligibility criteria for the study in question; • the perceived risks and benefits of the product

candidate under study; • the efforts to facilitate timely enrollment in clinical trials; • clinical trials of other product candidates in the same indication; • laboratory testing and turnaround time for samples needed for eligibility assessments; • the patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; and • the proximity and availability of clinical trial sites for prospective patients. Our inability to enroll a sufficient number of patients for our clinical trials will result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in clinical trials conducted by us may also result in increased development costs for our product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing. Our ~~substantial investment in research and development in order to develop our product, ETUARY, and other product candidates, and to enhance our technologies may ultimately fail to materialize.~~ The global pharmaceutical market is constantly evolving, and we must keep pace with new technologies and methodologies to maintain our competitive position. Our future success partially depends on our ability to launch new products that meet evolving market demands, in particular, new drugs, that are effective in treating new diseases and illnesses. However, there can be no assurance that we will be able to respond to emerging or evolving trends by improving our product portfolio in a timely manner, or at all. For the years ended December 31, 2023 and 2022, we incurred substantial expenditure related to the research and development of our product, ETUARY, and other product candidates, and we expect to continue to invest significant amounts of human and capital resources to develop our product and product candidates while enhancing our technologies that will allow us to advance our pipeline products. We also intend to continue to strengthen our technical capabilities in drug discovery, development, and manufacturing, which are capital and time intensive. However, there can be no assurance that we will be able to develop, improve or adapt to new technologies and methodologies, successfully identify new technological opportunities, or develop and bring new or enhanced products to market. Our commercialized product, ETUARY, which is approved in the PRC, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025** and any other future product, if approved, may be excluded or removed from national, provincial or other government- sponsored medical insurance programs. Under medical insurance programs in the PRC, patients are entitled to reimbursement of all or a portion of the cost of pharmaceutical products listed in the NRDL, the relevant provincial reimbursement drug lists, or other medical insurance reimbursement lists. However, such inclusion is based on a variety of factors, including clinical needs, use frequency, efficacy, safety and price, which may be outside of our control. Moreover, the relevant PRC government authorities may, from time to time, review and revise, or change the scope of reimbursement for, the products that are included in the medical insurance reimbursement lists. While our product ETUARY, which is approved in the PRC, has been included in the NRDL as a Category B drug for its IPF indication since 2017, there can be no assurance that it will remain so listed, or unimpacted negatively by changes in the scope of reimbursement. To the extent that our future approved product candidates are not included in any medical insurance reimbursement list, or if any such insurance schemes are changed or canceled, which results in the removal of such product candidates from the relevant medical insurance reimbursement lists, patients may choose, and hospitals, pharmacies and other medical institutions may recommend, alternative treatment methods, which may reduce demand for our product, ETUARY, and future products, if approved, and adversely impact our sales. We may face pressure to lower the prices of our commercialized product, ETUARY, which is approved in the PRC, and any other future product, if approved, in order for such products to qualify for medical insurance reimbursement or due to market competition. We may face pressure to lower the prices of our commercialized product, ETUARY, which is approved in the PRC, and any other future product, if approved, in order to have such product candidates included in the medical insurance reimbursement lists, while such low price and reimbursement may not necessarily lead to increased sales. It is difficult to estimate the net effect of decreased prices and the potential of increased sales on our profitability, and our profits from the sales of our future products may decrease if we significantly lower prices without a greater increase in sales. In addition, it is typical that the prices of pharmaceutical products will decline over the life of the product as a result of, among other things, increased competition from substitute products, the tender process by the hospitals or the government authorities, pricing policies of the relevant government authorities, or voluntary price adjustments by pharmaceutical companies. Any strategic downward price adjustments of our existing or future approved products due to market competition could have a materially adverse effect on our business and results of operations. Moreover, our marketed **product** ETUARY is subject to the risk of being included in the PRC’s centralized volume- based procurement scheme. For details, see “ — In the future, the policies of centralized volume- based procurement set by the PRC government may cover our commercialized product, ETUARY, and any other future products, if approved, and the prices of such product may decrease, which in turn may have a material adverse impact on our revenue, financial condition and results of operation ” in this Risk Factors section. We may fail to win bids to sell our commercialized product, ETUARY, and any other future products, if approved, to PRC public hospitals through the centralized tender process. Because a considerable portion of pharmaceutical products we sell to our distributors are sold to public hospitals and other medical institutions in the PRC, we must submit bids in a centralized tender process to supply our commercialized product, ETUARY, and any other future products, if approved, to these institutions at specified prices. Each public medical institution in the PRC must generally procure drugs through a provincial centralized drug purchase platform and make substantially all of its purchases of pharmaceutical products through a centralized tender process. Our bids submitted in the centralized tender process are generally considered on the basis of price relative to substitute products and the clinical effectiveness of such substitute products, as well as the quality of our product and services, among other things. As a result, our sales volumes and profitability of ETUARY depend on our ability to successfully differentiate our product and price our bids in a manner that enables us to succeed in the centralized tender process at profitable levels. However, we may fail to win bids in a centralized tender process due to various factors, including reduced demand for the relevant product, noncompetitive bidding price, failure to meet certain quality requirements, or the relevant products being perceived to be less clinically effective than competing products. If our commercialized product, ETUARY, and any other future products, if approved, are not selected in the centralized tender process in one or more regions, our sales of the relevant product

to the public hospitals in those regions may encounter difficulties, and our market share, revenues and profitability could be adversely affected. In the future, the policies of centralized volume- based procurement set by the PRC government may cover our commercialized product, ETUARY, and any other future products, if approved, and the prices of such product may decrease, which in turn may have a material adverse impact on our revenue, financial condition and results of operation. PRC government authorities have implemented policies that aim to further increase the affordability of pharmaceutical products, including the centralized volume- based drug procurement system. For further details, see “ Business — Product Pricing — Centralized Tender Process and Centralized Volume- based Procurement System ” and “ Business — Regulatory Requirements in the PRC — Other PRC Regulations in Relation to the Pharmaceutical Industry — Centralized Drug Procurement and Use ” in this Annual Report. Future procurement by the PRC government is expected to include drugs listed in the NRDL that have great market demand and high purchase price, and such future procurement is expected to gradually cover all types of domestically marketed drugs in the PRC necessary for clinical use and of reliable quality to the extent possible. As a result, all appropriate drugs may be procured thereunder in the PRC. Appropriate procurement methods for “ orphan drugs ” and drugs in shortage may be actively explored to ensure stable supply. Our marketed product, ETUARY, is currently not subject to the centralized volume- based procurement process. However, it is uncertain whether the centralized volume- based procurement scope would be expanded in the future and result in the inclusion of our product ETUARY, which is approved in the PRC, or other product candidates if commercialized, which may cause their retail prices to decrease. Moreover, if any products comparable or similar to our product, generic drugs or product candidates if commercialized are included in the centralized volume- based procurement, patients’ willingness to use such products may be materially and adversely affected and we may need to change our pricing strategy. If any or all of the foregoing were to occur, our sales revenue may decrease, which in turn would have a material adverse impact on our financial condition, profitability and results of operation. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products, since the market opportunities for our product candidates may be smaller than we anticipate. Similarly, the actual market size of our product ETUARY, which is approved in the PRC, may not be as large as we anticipate. The total addressable market opportunity will depend on, among other things, acceptance of the product by the medical community and patient access, product pricing and reimbursement. Moreover, the number of patients in the addressable markets may be lower than expected, patients may not be amenable to treatment with our product, or new patients may become increasingly difficult to identify or access. Further, new studies may change the estimated incidence or prevalence of the diseases that our product candidates target. Any of the above unfavorable developments could have a material adverse effect on our business, financial condition and results of operations. In particular, if the existing and newly identified cases of IPF patients in the PRC are fewer than we expect, our growth and financial position may be negatively impacted until and if the expanded indications of ETUARY and our other product candidates such as F351 are approved and become profitable. According to Frost & Sullivan, the prevalence of IPF in the PRC has increased from 83-89, 002 patients in 2017-2018 to 131-145, 654-776 patients in 2022-2023, and is expected to increase to 214-238, 664-000 patients by 2027-2028 and 320-322, 677-000 patients by 2031. Notwithstanding the short term increase in the prevalence of IPF, with strengthening of the public health system as well as medical and technological advancement in the PRC, the potential risks that cause IPF may be lowered or eliminated in the future which in turn may lead to corresponding decrease in the prevalence of IPF in the PRC. The shrinking prevalence of IPF in the PRC, as a result, may have a negative impact on the market size of ETUARY. We may be unable to conduct effective academic marketing. Effective marketing and successful sales are crucial for us to increase the market penetration of ETUARY in the PRC, expand our coverage of hospitals, pharmacies and other medical institutions and promote new products, if any, in the future. In particular, we place a strong emphasis on academic marketing, through which we promote ETUARY to medical professionals, hospitals, pharmacies and other medical institutions. While our sales and marketing force actively works with medical professionals, hospitals, pharmacies and other medical institutions and we endeavor to inform them of the distinctive characteristics, advantages, safety and efficacy of ETUARY as compared to our competitors’ products, we may not be able to successfully enhance our product awareness. We may fail to maintain a qualified sales and marketing force. In order to successfully market and sell our commercialized product, ETUARY, which is approved in the PRC, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved, our sales and marketing teams are expected to possess a relatively high level of technical knowledge, up-to- date understanding of industry trends, necessary expertise in the relevant therapeutic areas and products, as well as sufficient promotion and communication abilities. However, there can be no assurance that there will be a sufficient amount of competent sales professionals with the relevant rare disease knowledge and / or academic KOLs or doctor networks available for hire. As a result, if we are unable to effectively train our in- house sales representatives or monitor and evaluate their academic marketing performances, our sales and marketing may be less successful than desired. Moreover, our ability to attract, motivate and retain a sufficient number of qualified sales professionals is especially important because we primarily rely on our in- house sales force to market our product. As competition for experienced marketing, promotion and sales personnel is intense, we may be unable to attract, motivate and retain a sufficient number of marketing, promotion and sales professionals. If we fail to maintain a qualified sales and marketing force, sales volume of our commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved, may be adversely affected and we may be unable to expand our coverage of hospitals, pharmacies and other medical institutions or increase our market penetration. We may fail to maintain or expand an effective distribution network for our commercialized product, ETUARY, which is approved in the PRC, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved, or further expand our distribution channel. As we primarily rely on our network of distributors to distribute commercialized product, ETUARY, in the PRC, and intend to continue engaging distributors to sell our commercialized

product, ETUARY, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved, in the foreseeable future, our ability to maintain and grow our business depends on our ability to maintain and manage a sufficient number of distributors with an extensive sales network, which we could fail to achieve for several reasons. Our distributors may be unable to maintain or expand their sales network, or may encounter difficulties in selling our commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag**, and any other future products, if approved. Our distributors might elect not to renew their agreements with us or otherwise terminate their business relationships with us for various reasons, such as price controls or other factors that substantially reduce the margins they can obtain through the resale of our commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag**, and any other future products, if approved. Further, we may fail to find an appropriate group of distributors suitable for our commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag**, and any other future products, if approved, or the costs of doing so may become prohibitively high. Any disruption to our distribution network, including our failure to maintain relationships, form new relationships or renew our existing distribution agreements, could negatively affect our ability to sell our commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag**, and any other future products, if approved, and may materially and adversely affect our business, results of operations, financial condition and prospects. We may fail to sufficiently and promptly respond to clinical demand and market changes in the pharmaceutical industry. Clinical demand and market conditions for pharmaceutical products may change rapidly and significantly, and our success in part depends on our ability to anticipate product offering lead- times and demand, identify customer preferences and adapt our products to these preferences. We may need to adjust our research and development plan, production scale and schedule, product portfolio and inventory levels based on customer demand, sales trends and other market conditions. However, there can be no assurance that we will be able to sufficiently and promptly respond to changes in clinical demand and purchasing patterns in a timely manner or at all. Geopolitical events and global economic conditions, such as public health crises, the ~~conflict~~ **conflicts** between Russia and Ukraine and ~~in the Middle East Israel-Hamas war~~ **in the Middle East Israel-Hamas war** may impact our third- party supply of the raw materials and components needed for our product, ETUARY, and product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC, which increases the risk that we will not have sufficient quantities of such product, generic drugs or product candidates or will not have such quantities at an acceptable cost, which will delay, prevent or impair our commercialization, marketing or development efforts, as applicable. If supplies of the raw materials for our product, ETUARY, or product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC, are significantly delayed, or if the third parties that we engage to supply any materials or to manufacture any products for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the effects of global economic conditions, including **new or increased tariffs and other barriers to trade, trade and other international disputes**, inflation and **rising fluctuating interest rates**, **slower growth or recession, tighter credit, volatility in financial markets, high unemployment, labor availability constraints**, public health crises, **significant natural disasters, including as a result of climate change, changes to fiscal and monetary policy or government budget dynamics, particularly in the pharmaceutical and biotech areas, political and military conflict**, **including the conflicts** between Russia and Ukraine and ~~in the Middle East Hamas-Israel war~~ **in the Middle East Hamas-Israel war**, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. **For example, trade policies and geopolitical disputes (including as a result of China- Taiwan relations) and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures occur in regions where we source our components or raw materials. In addition, tensions between the United States and the PRC have led to a series of tariffs being imposed by the United States on imports from China mainland, as well as other business restrictions. Tariffs increase the costs of the components and raw materials we source. Countries may also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact the Company's operations and supply chain**. In addition, if we are not able to obtain adequate supplies of our product, generic drugs or product candidates or the substances used to manufacture them, it will be more difficult for us to commercialize, market or develop our product, generic drugs or product candidates, as applicable, and compete effectively. Our current and anticipated dependence upon third- party suppliers may adversely affect our ability to develop our product, generic drugs, and product candidates and could delay our clinical trials and development programs as well as marketing and commercialization efforts, and otherwise harm our operations and financial condition and increase our costs and expenses. See “— Risks Related to Our Reliance on Third Parties — Because we rely on a limited number of suppliers for certain of our raw materials, we may experience supply interruptions that could harm our ability to manufacture products .” ~~For details regarding the risks related to the relations between the PRC and the United States, see “— Risks Related to Our Business Operations in the PRC — Changes in the political and economic policies of the PRC government or relations between the PRC and the United States may affect our business, financial condition and results of operations .”~~ Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our distributors, suppliers, research institution collaborators and other business partners, could be subject to natural or man- made disasters, health epidemics or business interruptions, for which we are predominantly self- insured. Damage or extended periods of interruption to our and our partners' administration, development, research, manufacturing or storage facilities due to fire, natural disaster, health epidemic, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development or commercialization of some or all of ETUARY, our generic products or product candidates, seriously harm our and our partners' operations and financial condition and increase our and our partners' costs and expenses. We have

limited insurance coverage, and any claims beyond our insurance coverage may result in substantial costs and a diversion of resources. We operate in the pharmaceutical industry, which involves numerous operating risks and occupational hazards. The insurance policies we maintain are required under the applicable laws and regulations as well as based on our assessment of our operational needs and industry practice. However, there can be no assurance that the existing insurance coverage is sufficient to compensate for actual losses suffered or incurred. In addition, there are certain types of losses, such as losses from war, acts of terrorism, health or public security hazards, earthquakes, typhoons, flooding and other natural disasters, for which we cannot obtain insurance at a reasonable cost or at all. If an uninsured loss or a loss in excess of insured limits were to occur, our business, results of operations and financial condition may be materially and adversely affected. For details of the specific risks of inadequate insurance coverage in the event of product liability claims and environmental liabilities, see “ — We may be subject to product liability claims that could expose us to costs and liabilities ” and “ — If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business, ” respectively, in this section. Risks Related to the Discovery, Development and Commercialization of Our Product Candidates We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for these product candidates that later prove to have greater commercial potential. 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 development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We may be unable to identify, discover, or develop new product candidates, or to identify additional therapeutic opportunities for our product candidates, in order to expand or maintain our product pipeline. We may not be able to continue to identify and develop new product candidates to enrich our current pipeline. Research programs to pursue the development of our product candidates for additional indications and to identify new product candidates and product targets require substantial technical, financial and human resources. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be successfully developed, much less receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will materially and adversely affect our future growth and prospects, which likely would result in significant harm to our financial position and adversely affect our stock price. Results from preclinical or early stage clinical trials, including the results of our preclinical testing and early clinical trials of ETUARY, F351 and F573, may not be confirmed in later trials or be predictive of the success of later clinical trials. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later- stage clinical trials. Trials of our product candidates in larger numbers of patients may not have similar efficacy results and could result in adverse effects that were not observed in the earlier trials with smaller numbers of patients. We will be required to demonstrate substantial evidence through well- controlled clinical trials that our product candidates are safe and effective before we can seek marketing approvals for their commercial sale. Demonstrations of efficacy or an acceptable safety profile in our prior preclinical studies does not mean that future clinical trials will yield the same results. For instance, while ETUARY is approved in the PRC for the treatment of IPF, it may not be approved for the treatment of other indications, such as ~~PD SSe-ILD, DM-ILD, pneumoconiosis~~ or DKD, or in other markets. In addition, we do not know whether F351 will perform in future clinical trials as F351 has performed in preclinical studies and early clinical trials conducted by us in the PRC, and, despite F351’ s Phase 1 trial in the United States showing promising evidence of tolerability and PK and our Phase 2 clinical trial in the PRC demonstrating results in the reversal of CHB- associated fibrosis ~~to~~. **To date, there is are no approved effective clinical therapy therapies for CHB- associated liver fibrosis , and no specific therapeutic products have been approved worldwide.** We also do not know whether F573 will perform in its Phase 2 clinical trial for ALF / ACLF as it has performed in its Phase 1 clinical observation of tolerability and PK. Product candidates, including ETUARY, F351 and F573, may fail to demonstrate in later- stage clinical trials sufficient safety and efficacy to the satisfaction of the NMPA, FDA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and earlier stage clinical trials. Regulatory authorities may also limit the scope of later- stage trials until we have demonstrated satisfactory safety or efficacy results in earlier- stage trials. In particular, although ETUARY is approved in the PRC for the treatment of IPF, it may not perform in the Phase 3 clinical ~~trials for the treatment of SSe-ILD and DM-ILD, Phase 3 clinical~~ trial for the treatment of pneumoconiosis ~~or Phase 1 clinical trial of ETUARY for the DKD Program~~. In addition, we are actively preparing an IND application that we expect to file ~~by in~~ **by in the end first half of 2024-2025** for a Phase 2 clinical trial to evaluate F351 for the treatment of advanced liver fibrosis associated with noncirrhotic ~~NASH-MASH~~. Following IND clearance, we plan to initiate a Phase ~~2a-2~~, **PoC clinical trial in 2025 in the United States , subject to positive trends in the Phase 3 trial of F351 in the PRC,** to evaluate the safety, tolerability, PK, and PD of F351 for patients with advanced liver fibrosis associated with noncirrhotic ~~NASH-MASH~~. The FDA has reviewed the planned Phase ~~2a-2~~ **trial of F351 in the United States and provided comments on the design, trial assessment, and the contents of the IND filing .** ~~If we observe positive trends in the Phase 2a trial of F351, we expect to initiate a larger Phase 2 trial in F351.~~ Although data from liver fibrosis associated with CHB patients in our Phase 2 clinical trial in the PRC demonstrated F351 has the potential to improve liver fibrosis, the efficacy of F351 in prior preclinical studies in a ~~NASH-MASH~~ **NASH-MASH** model does not mean that future clinical trials will yield the same results. In addition to the pre- IND guidance provided, at the time of review of the IND application, the NMPA, FDA or other comparable foreign regulatory

authorities may require additional investigations (nonclinical) and analyses (both nonclinical and clinical, including the analysis of the supportive clinical trials conducted in the PRC) before it accepts the IND file to ensure that there is sufficient and adequate information on the risks to human subjects. Such additional requests may delay the timelines for the IND filing and initiation of the planned Phase 2a-2 trial in NASH-MASH - associated liver fibrosis. Furthermore, if the NMPA or FDA believes that additional data is necessary to supplement our clinical study data and Phase 2a-2 clinical trial data, then the NMPA or the FDA may require us to conduct additional trials before expanding into a broader Phase 2 clinical trial. There is no guarantee that the NMPA, FDA and other comparable foreign regulatory authorities will consider the data that is expected to be obtained in the planned Phase 2a-2 trial in the United States sufficient to allow us to expand the development of F351 in a larger Phase 2 or confirmatory Phase 3 clinical trial. There is no guarantee that we will be able to complete such trials on the timelines we anticipate or that such trials will produce positive results. Any limitation on our ability to conduct clinical trials could delay or prevent regulatory approval or limit the size of the patient population to which we may market our product candidates, if approved. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage NASH-MASH clinical trials after achieving positive results in earlier development, and we may face similar setbacks. Many companies that believed their product candidates performed satisfactorily in preclinical studies and early clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of clinical trials for our product candidates warrant marketing approval, the NMPA, FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Any Phase 2, Phase 3 or other clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. Preliminary, “top-line” or interim 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. We have publicly disclosed and may in the future publicly disclose preliminary or top-line data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures. Any preliminary or top-line data should be viewed with caution until the final data are available. From time to time, we have also disclosed and may in the future disclose interim data from our preclinical studies and clinical trials. Interim 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 or as patients from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the likelihood of approval or commercialization of the particular product candidate and our company in general. In addition, from time to time we may disclose top line or summary information regarding a particular preclinical study or clinical trial. Such summary information is necessarily based on more fulsome and extensive information, and investors or regulators may not agree with what we determine is material or otherwise determine is appropriate information to include in our disclosure. If the preliminary, top-line or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

~~A variety of risks associated with marketing our product candidates internationally may materially adversely affect our business. We may also seek regulatory approval of our product candidates, including ETUARY for future indications in the PRC, F573 in the PRC, and F351 in the PRC and in additional markets beyond the PRC, outside of the PRC and United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including differing regulatory requirements in foreign countries. Risks associated with international operations may materially adversely affect our business, financial condition and results of operations.~~ Our product, ETUARY, which is approved in the PRC, and product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC, may cause or be perceived to cause significant adverse events, toxicities or other undesirable side effects that may result in a safety profile that could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, marketing approval or market acceptance, limit their commercial potential and profile of an approved label, adversely affect our reputation and results of operations or result in significant negative consequences following any regulatory approval. If our product candidates, including ETUARY, F351, F573, F528 and F230, are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or INDs, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Many times, side effects are only detectable after investigational product candidates are tested in large-scale, Phase 3 trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that any of our current product candidates and any future product candidates has serious or life-threatening side effects or other side effects that outweigh the potential therapeutic benefit, the development of the product candidate may fail or be delayed, or,

if the product candidate has received marketing approval, such approval may be revoked, which would harm our business, prospects, operating results and financial condition. Any adverse events or serious adverse events reported in our clinical trials caused by our product candidates could give rise to significant negative consequences. Such consequences may include:

- regulatory authorities may order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications;
- regulatory authorities may seek an injunction against our product candidates manufacture or distribution;
- regulatory authorities may withdraw approvals or revoke licenses of an approved product candidate, or we may determine to do so even if not required;
- regulatory authorities may require additional warnings on the label, including “boxed” warnings, of an approved product candidate or impose other limitations on an approved product candidate;
- regulatory authorities may issue safety alerts, require press releases or other communications containing warnings or other safety information about the product;
- regulatory authorities may require us to change the way such product is administered;
- we may be required to develop a REMS for the product candidate, which could include a medication guide outlining the risks of such side effects for distribution to patients, or to incorporate additional requirements under REMS;
- we may be required to conduct additional clinical trials or post-market studies;
- we could be subject to litigation proceedings and held liable for harm caused to patients;
- we could be found in breach of contract with our major customers;
- patient 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 anticipated;
- our commercialized products could be removed from medical insurance reimbursement lists or be rendered unable to participate in the centralized tender process in the PRC;
- regulatory authorities may impose fines, injunctions or criminal penalties;
- we may fail to achieve or maintain market acceptance of a particular product candidate, if approved, which may cause serious harm to our business; and
- our reputation may suffer.

Undesirable or unintended side effects may be a result of a number of factors that are outside of our control, including potential side effects not revealed in clinical testing, unusual but severe side effects in isolated cases, defective products not detected by our quality management system, and misuse of our products by end-users. Further, our product, generic drugs and future products, if approved, may be perceived to cause severe side effects if other pharmaceutical companies’ products containing the same or similar active pharmaceutical ingredients, raw materials or delivery technologies as our product, generic drugs and future products, if approved, cause or are perceived to have caused severe side effects, or if regulators or international institutions determine that products containing the same or similar pharmaceutical ingredients as our product, generic drugs and future products, if approved, cause severe side effects. Our product, generic drugs and future products, if approved, may also be perceived to cause severe side effects when a conclusive determination as to the cause of the severe side effects is not obtained or is unobtainable. In general, the anticipated clinical trials of F351 will include patients with advanced liver fibrosis who are at risk of further progression to cirrhosis and deterioration, but are not critically ill. A certain percentage of patients with HBV-induced liver fibrosis treated with F351 have experienced adverse events, including gastrointestinal diseases, ear and labyrinth diseases, systemic diseases, metabolic and nutritional diseases, skin and subcutaneous tissue diseases, heart organ diseases, and hepatobiliary system diseases. However, the risk / benefit of F351 in **NASH-MASH** may differ from that shown in HBV liver fibrosis patients and there is always a risk that the severity and frequency of the adverse events may worsen. See the section entitled “ — Business — **Our Product Candidate For Liver Fibrosis: F351 Overview (Hydronidone)**.”

In addition, the patient populations treated with our product candidates in our various Phase 3 clinical trials have serious diseases that make them susceptible to significant health risks. Therefore, these patients may experience adverse events, including serious adverse events. In conducting drug research and development, we face potential liabilities; in particular, product liability claims or lawsuits that could cause us to incur substantial liabilities. We face an inherent risk of product liability as a result of clinical trials if our product candidates cause, or are perceived to cause, injury, or are found to be otherwise unsuitable during clinical testing. Regardless of the merits or eventual outcome, such liability claims may, among others, result in:

- decreased demand for our product candidates after commercialization;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources; and
- substantial monetary awards to trial participants or patients.

To cover such liability claims arising from clinical trials, we have clinical trial insurance for all of our trials, which are necessary for the approval of commercialization of our pipeline products. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may also not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. Adverse drug reactions and negative results from off-label use of our commercialized product, ETUARY, which is approved in the PRC, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved, could materially harm our business reputation, product brand name, and financial condition and expose us to liability. Products distributed or sold in the pharmaceutical market may be subject to off-label drug use, and may be prescribed for an indication, dosage or in a dosage form that is not in accordance with regulatory approved usage and labeling. As such, our product, ETUARY, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and future products, if approved, may be subject to off-label drug use and may be prescribed to a patient population, or in a dosage or dosage form that has not been approved by competent authorities, which may render our product, generic drugs and future products, if approved, less effective or entirely ineffective and cause adverse drug reactions. Any of these occurrences can create negative publicity and significantly harm our business reputation, product brand name, commercial operations and financial condition, including our share price. These occurrences may also expose us to liability and cause, or lead to, a delay in the progress of our clinical trials and may ultimately result in failure to obtain regulatory approval for our product candidates. Breakthrough Therapy designation by the FDA for any product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval. F351 was granted a Breakthrough Therapy designation by the PRC’s NMPA’s CDE in March 2021 and the patient enrollment

for its Phase 3 clinical trial was commenced in January 2022. However, F351's Breakthrough Therapy designation does not increase the likelihood that F351 will ultimately receive approval from the NMPA or other comparable regulatory authority. We may, in the future, apply for Breakthrough Therapy designation in the United States, or the equivalent thereof in other foreign jurisdictions (where available), for our product candidates, depending on robustness of the clinical benefit in clinical trials. In the United States, Breakthrough Therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the NDA. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

**Risks Relating to Manufacture and Supply of Our Product and Product Candidates**

Manufacturing pharmaceutical products on a large commercial scale is highly exacting and complex, and we and our third-party manufacturers may encounter problems during the process. The manufacturing of pharmaceutical products is highly complex, and problems may arise during manufacturing for a variety of reasons, including, but not limited to: • equipment malfunction; • failure to follow specific protocols and procedures; • changes in product specification; • low quality or insufficient supply of raw materials; • delays in the construction of new facilities or the expansion of our existing manufacturing facilities and limits to manufacturing capacity due to regulatory requirements; • changes in the types of products produced; • advances in manufacturing techniques; • physical limitations that may inhibit continuous supply; • man-made or natural damages, other disasters and environmental factors; and • shortage of qualified personnel or key contractors. Despite our quality control and assurance system and procedures, we may not be able to eliminate such risks, which may delay or suspend our manufacturing activities, and we may not be able to secure temporary, alternative manufacturers for our product, generic drugs or product candidates with the terms, quality and costs acceptable to us, or at all. If we encounter any manufacturing problems, including those listed above, our clinical trials and / or the availability of our product, ETUARY, which is approved in the PRC, generic drugs and future products, if approved, for commercial sale may be delayed, and we may spend significant time and costs in order to rectify such problems and maintain production at our manufacturing facilities. Moreover, products with quality issues may have to be discarded, resulting in product shortages or additional expenses. Furthermore, manufacturing methods and formulation are sometimes altered through the development of product candidates from clinical trials to approval, and further to commercialization, in an effort to optimize manufacturing processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause the product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay the commercialization of product candidates and require bridging studies or the repetition of one or more clinical trials, which may result in increases in clinical trial costs, delays in product approvals and jeopardize our ability to commence product sales and generate revenue. We plan to use F351 capsules manufactured by Wuxi Biologics, and may continue to use foreign CROs and CMOs in the future. Wuxi Biologics has completed manufacturing one lot of the F351 capsules for our planned Phase 2a-2 clinical trial in the U. S.

**WuXi Biologics is identified in the U. S. legislation known as the BIOSECURE Act, which was proposed in the 118th Congress, as a "biotechnology company of concern." The version of the BIOSECURE Act introduced in the U. S. House of Representatives during the 118th Congress would prohibit federal agencies from entering into procurement contracts with, as well as providing grants and loans to, an entity that uses biotechnology equipment or services from a biotechnology company of concern, and includes a grandfathering provision allowing biotechnology equipment and services provided or produced by named "biotechnology companies of concern" under a contract or agreement entered into before the effective date until January 1, 2032. The pathway and timing for the BIOSECURE Act or its provisions to become law are uncertain.**

Foreign CMOs may be subject to U. S. legislation, including the proposed BIOSECURE Act, sanctions, and trade restrictions and other requirements by foreign regulatory regulators requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies. For example, the biopharmaceutical industry in the PRC is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our collaborators in the PRC which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in the PRC's public health, economic, political, and social conditions and the uncertainty around the PRC's relationship with other governments, such as the United States and the U. K., could also negatively impact our ability to manufacture our product candidates for our planned clinical trials or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay our clinical development programs. For more details, see "— Risks Related to Our Business Operations in the PRC — Changes in the political and economic policies of the PRC government or relations between the PRC and the United States may affect our business, financial condition and results of operations." In addition, we plan to enter into various development,

manufacturing and clinical supply services agreements with third- party manufacturers for drug substance and drug product manufacturing of our other product candidates. If our third- party manufacturers are not able to provide sufficient quantities or quality of our product candidates on a timely basis, or at all, whether due to production shortages or other supply delays or interruptions resulting from public health crises or otherwise, our preclinical trials, clinical trials or regulatory approvals, as applicable, may be delayed. Significant portions of our research and development resources are focused on manufacturing. If any of our third- party manufacturers experiences difficulties in scaling production or experiences product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error or improper storage conditions, the potential trials of the affected product candidate would be delayed, perhaps substantially, which could materially and adversely affect our business. We and our contract manufacturers will be subject to significant regulation with respect to manufacturing our product, ETUARY, which is approved in the PRC, and our product candidates. Delays in completing and receiving regulatory approvals for our and our third- party manufacturing facilities could delay our development plans or commercialization efforts. All entities involved in the preparation of therapeutics for clinical studies or commercial sale, including us and any contract manufacturers for ETUARY and our other product candidates, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical studies must be manufactured in accordance with GMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product, generic drugs or product candidates that may not be detectable in final product testing. Our existing and planned manufacturing facilities, as well as our manufacturing process, and our third- party manufacturing facilities and process, will be subject to ongoing, periodic inspection by the NMPA, the FDA or other comparable regulatory agencies to ensure compliance with GMP, which is usually the prerequisite to obtain marketing approval. Moreover, we and our third- party manufacturers must obtain various permits, certificates and other approvals for our manufacturing facilities and other premises from the relevant administrative authorities at various stages of property development, including, planning permits, construction permits, land use rights certificates, environmental assessments, fire control assessments, construction completion inspections and ownership certificates. Failure to comply with applicable regulations could lead to: • increased expense and result in sanctions being imposed on us (including fines, injunctions, civil penalties, requirements to suspend or pause one or more of our clinical trials); • failure to obtain marketing approval of our product candidates; • delays, suspension or withdrawal of approvals; supply disruptions; • license revocation; seizures or recalls of product, generic drugs or product candidates; and • operating restrictions and criminal prosecutions, any of which could materially and adversely harm our business. We may experience substantial disruption to our production sites and problems in manufacturing our product, ETUARY, which is approved in the PRC, and future products, if approved. We are dependent on our manufacturing facilities in Beijing, PRC and Cangzhou, PRC. The continued operation of our manufacturing facilities and our production safety may be substantially interrupted due to a number of factors, many of which are outside of our control. These factors may include fire, flood, earthquakes, power outages, fuel shortages, mechanical breakdowns, terrorist attacks and wars, or other natural disasters, as well as loss of licenses, certifications and permits, changes in governmental planning for the land underlying these facilities or their vicinity and regulatory changes. Moreover, the production activities on our manufacturing facilities may be suspended on a temporary basis due to governmental policies or regulations, including that on environmental protection or organizing public events. If the operation of any of our manufacturing facilities is substantially disrupted, we may not be able to replace the equipment or inventories at such facilities, or use different sites or a third- party contractor to continue our production in a legal, timely and cost- effective manner or at all. Although we maintain property insurance for certain properties, machinery and equipment and other assets owned, operated or deemed important for us, in line with industry practice in the PRC, we do not have certain types of insurance, such as business interruption insurance. The amount and nature of our insurance coverage may not be sufficient to cover any substantial losses in the event of a significant disruption to any of our manufacturing facilities. Since September 2021, as a result of the shortage of coal supply combined with high electricity demand from manufacturers, the PRC has experienced widespread power outages. The PRC government has imposed power curbs, including imposing power restrictions on factories in a number of provinces in the PRC to deal with an imbalance in energy supply and demand. As of December 31, 2023-2024, we have not received any notice from relevant government authorities ordering us to temporarily suspend or limit production, and our Beijing and Cangzhou production centers were not subject to any power restrictions. The PRC government imposed power restrictions did not have a material adverse impact on our business operations or financial performance during the years ended December 31, 2024 and 2023 and 2022. We may not be able to meet the increasing demand for our commercialized product, ETUARY, which is approved in the PRC, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved, maintain adequate manufacturing capacity or successfully manage our anticipated growth. To produce ETUARY, **nintedanib, avatrombopag** and our increasing number of product candidates, if approved, in the quantities that we believe will be required to meet anticipated market demand, we may need to increase our production capacity over the initial level of production by constructing new manufacturing facilities and production lines. However, our ability to successfully implement our expansion plan for increasing production capacities is subject to a number of risks and uncertainties, including, but not limited to, the risk of construction delays and delays in equipment procurement, and our ability to timely recruit sufficient qualified staff to support the increase in our production capacity. If we are unable to do so, are delayed, face costs that are not economically feasible or cannot find a third- party manufacturer, we may not be able to produce ETUARY and our future approved product candidates, if any, in sufficient quantities to meet future demand. Moreover, our plans to increase our production capacities require significant capital investment and the actual costs of our expansion plan may exceed our original estimates, which could adversely affect the return on our expenditure. Furthermore, given the size of our

existing and planned manufacturing facilities, we may not be able to fully utilize within a reasonable period of time after we commence operation. During the construction and ramp-up period, there may be significant changes in the macroeconomics of the pharmaceutical industry, including, among other things, market demand, product and supply pricing trends and customer preferences. Any adverse trends in this area could result in operational inefficiency and unused capacity in our facilities. Fluctuations in prices of our raw materials and energy supply, as well as other costs associated with our production processes, may have a material adverse effect on us if we are not able to pass the cost increases on to our customers. In order to manufacture our commercialized product, ETUARY, which is approved in the PRC, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved, we must obtain sufficient quantities of high-quality raw materials and stable supply of energy and power at commercially acceptable prices and in a timely manner, which exposes us to risks associated with fluctuations in prices of raw materials. The prices of such materials may be affected by a number of factors, including market supply and demand, the PRC, the United States or international environmental and regulatory requirements, natural disasters and the global and local economic conditions. In addition, we may be subject to fluctuations in other costs associated with our production processes, such as costs of waste disposal, which are beyond our control. We may have limited capability to increase our revenue in a timely manner, and a significant increase in such costs may increase our cost of sales and negatively affect our profit margins. Failure to maintain optimal inventory levels could increase our operating costs or lead to unfulfilled customer orders. We are required to maintain optimal inventory levels in order to satisfy demand coming from our distribution network and successfully meet our customers' demand. However, we may not be able to maintain proper inventory levels of our commercialized product, ETUARY, which is approved in the PRC, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, generic drugs and any other future products, if approved, as a result of rapid changes in product life cycles, changing clinical demands and uncertainty of product developments and launches, as well as the volatile economic environment in the PRC. There can be no assurance that we can accurately predict these trends and events and avoid over-stocking or under-stocking our commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag**, generic drugs and any other future products, if approved. Further, demand for our commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag**, generic drugs and any other future products, if approved, could change significantly between the time when the products are ordered and the time they are ready for delivery. Inventory levels in excess of demand may result in inventory write-downs, expiration of our product or an increase in inventory holding costs and a potential negative effect on our liquidity. On the other hand, if we underestimate demand, we may experience inventory shortages which may, in turn, result in unfulfilled customer orders, leading to a negative impact on our customer relationships. We have in the past formed, and may in the future seek and form, strategic alliances, joint ventures or other collaborations, including entering into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our existing commercialized ~~product~~ **products**, ETUARY, **nintedanib and avatrombopag**, which ~~is~~ **are** approved in the PRC, generic drugs and product candidates, including ETUARY, F351, F573, F528, F230, and any future product candidates that we may develop. Our strategic collaboration with partners involves numerous risks. We may not achieve the revenue and cost synergies expected from the transactions, as such synergies are inherently uncertain and subject to significant business, economic and competitive uncertainties and contingencies, many of which are difficult to predict and are beyond our control. In addition, the synergies from our collaboration with our partners may be offset by other costs incurred during the collaboration, including increases in other expenses, operating losses or problems in the business unrelated to our collaboration. Moreover, disputes may arise between us and our current or future collaboration partners. Such disputes or our partners' failure to fully perform their obligations may cause delay or termination of the research, development or commercialization of our product, generic drugs or product candidates, or result in costly litigation or arbitration that may divert management attention and resources. In particular, international business relationships subject us to additional risks that may materially and adversely affect our ability to attain or sustain profitable operations, including, difficulty of effective enforcement of contractual provisions in local jurisdictions, and third-party collaborators may not properly obtain, maintain, protect or enforce our patent, trade secret and other intellectual property rights and regulatory exclusivity for our product, generic drugs or product candidates or may use our intellectual property that exposes us to potential litigation or other intellectual property-related proceedings that could jeopardize or invalidate our intellectual property. We face significant competition in seeking appropriate collaborators. Whether we can reach a definitive agreement with a collaborator will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of preclinical trials, the likelihood of approval by the NMPA, FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator may also consider alternative products, product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us. There can also be no assurance that we will enter into any collaboration agreements, or that any such agreements will be on favorable terms. Collaborations are complex and time consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future 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 product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, and increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development

or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. Our rights to develop and commercialize some of our product candidates, are subject, in part, to the terms and conditions of licenses granted to us by others. The success of our collaborations with our partners depends on each party's performing its respective obligations under the relevant collaboration agreement. Such agreements may impose on us diligence obligations in product development or commercialization, payment obligations when certain development or regulatory milestones and sales are achieved and other obligations. If we fail to comply with our obligations under our current or future agreements, our counterparties may have the right to terminate these agreements, in which event we may not be able to develop, manufacture or market the product candidate that is covered under the agreements. Termination of the licenses or assignments provided for under these agreements or reduction or elimination of our rights under these agreements may result in us having to negotiate new or amended agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. In addition, we may not have the exclusive right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the product or product candidates that we are licensed or assigned from third parties. In the event that these patents and patent applications are not prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business, our rights to the relevant intellectual property may be reduced or eliminated, and our right to develop and commercialize the product, generic drugs or product candidates covered under the agreement could be adversely affected. Moreover, the third parties on whom we rely with respect to licenses to certain patent rights and other intellectual property rights that are important or necessary to the development, manufacture or commercialization of our product, generic drugs or product candidates may themselves rely on upstream licenses from other third parties. Such sub-licenses may not provide exclusive rights to use the covered intellectual property in all relevant fields of use or in all territories in which we may wish to develop or commercialize our product candidates, and add further uncertainties and complications as to the scope of our rights under the relevant agreement. Further, the license or assignment agreements we have entered into, or will enter into in the future, are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our advancement through our collaboration relationship with its partners. We rely on third parties to conduct certain aspects of our preclinical studies and any clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such tasks or trials. We rely on third parties such as CROs, medical institutions and clinical investigators to conduct certain aspects of preclinical development, including assay development and testing, and to enroll qualified patients and conduct, supervise and monitor clinical trials. For more details, see " — Business — Our Research and Development " in this Annual Report. Our reliance on these third parties for preclinical and clinical development activities reduces our control over these activities. Our reliance on these third parties, however, will not relieve us of our regulatory responsibilities, including ensuring that our clinical studies are conducted in accordance with good clinical practices, and the investigational plan and protocols contained in the relevant regulatory application, such as an IND. In addition, the CROs with whom we contracts may not complete activities on schedule or may not conduct our preclinical studies or clinical studies in accordance with regulatory requirements or our clinical study design. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, compromise the quality or accuracy of the clinical data obtained by CROs or our investigators due to failure to adhere to our clinical protocols or regulatory requirements, or the quality of the products manufactured fails to comply with GMP, our efforts to complete development and obtain regulatory approvals for, and to commercialize, our product, generic drugs and product candidates may be delayed or prevented. In addition, we, our CROs for clinical programs and our investigators are required to comply with GCP for all of our product candidates in clinical development. If we or any of our CROs or investigators fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the NMPA, FDA or comparable regulatory authorities may require us to perform additional clinical trials before considering whether to approve our marketing applications, which would delay the regulatory approval process. If our distributors act in violation of the relevant agreements, or if sub- distributors with whom we have not entered into distribution agreements do not comply with policies and measures that our distributors agree to comply with, our business, prospects and reputation could be materially and adversely affected. While we rely on the distribution agreements and the policies and measures we have in place to manage our distributors, we cannot guarantee that these agreements, policies and measures will be able to effectively manage our distributors, or that our distributors will comply with our agreements and policies. If our distributors take one or more of the following actions, our business, results of operations, prospects and reputation may be adversely affected: • failing to distribute our product, generic drugs and future products, if approved, in the manner we contemplate, impairing the effectiveness of our distribution network; • breaching the distribution agreements or our policies and measures; • failing to maintain the requisite licenses, permits or approvals or failure to comply with applicable regulatory requirements; and • violating any applicable anti-corruption, anti- bribery, competition or other laws and regulations. Any such actual or alleged violation or non- compliance by our distributors of the distribution agreements, our policies or any applicable laws and regulations could result in the erosion of our goodwill, expose us to liabilities, disrupt our distribution network and create an unfavorable public perception about the quality of our product, ETUARY, generic drugs and future products, if approved. Moreover, some of our distributors engage sub- distributors to distribute our product, and we do not engage these sub- distributors directly or maintain contractual relationships with them. Instead, we mainly rely on our distributors to manage and control their sub- distributors in accordance with regulatory requirements, the terms of the distribution agreements between us and our distributors and our policies for our distributors. Since our control is limited over these sub- distributors, there is no assurance that the sub- distributors will comply

with the geographical restrictions agreed to with our distributors or other distribution requirements under our distribution agreements and policies. As a result, there can be no assurance that we will be able to identify or remediate any practices by any sub- distributors' that may be detrimental to our business in a timely manner or at all, which may adversely affect our results of operations and reputation. During the years ended December 31, 2024 and 2023 and 2022, we had a small number of suppliers, with whom we believe we have stable relationships. However, the stability of operations and business strategies of our suppliers are beyond our control, and there can be no assurance that we will be able to maintain a stable relationship and high- quality outsourced raw materials or services with our large suppliers.

Risks Related to Employee Matters, Managing Growth and Our Business Operations Our ongoing success is reliant on our capacity to retain key executives and to recruit, maintain, and inspire skilled professionals. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our executive management and scientific personnel. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. In addition, we will need to add personnel to achieve our business objectives. The loss of the services of any of our executive officers, other key employees, and our inability to find suitable replacements, or our inability to hire new clinical development and manufacturing personnel, could result in delays in product development and harm our business. We conduct our U. S. operations at our facility in San Diego, California. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. In the PRC, we compete for qualified personnel with other pharmaceutical and biotechnology companies, universities and research institutions. The pool of suitable candidates is limited, and we may not be able to hire and retain enough skilled and experienced scientists or other technical personnel at the current level of wages, and may need to offer higher compensation and other benefits, which could materially and adversely affect our financial condition and results of operations. To induce valuable employees to remain with us, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of management and scientific and development teams have terminated and may terminate their employment with us on short notice. Our employees are under at- will employment arrangements, which means that any of our employees can leave employment with us at any time, with or without notice. Failure to retain, replace or recruit personnel could harm our business. Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management. Our failure to integrate these individuals and create effective working relationships among them and other members of management could result in inefficiencies in the development and commercialization of our product, generic drugs and product candidates, harming future marketing approvals, sales of our product, generic drugs and product candidates and our results of operations. Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and collaborators. Misconduct by these parties could include intentional failures to comply with the regulations of the NMPA, FDA, SEC and non- PRC and non- U. S. regulators, to provide accurate information to the NMPA, FDA and non- PRC and non- U. S. regulators, to comply with healthcare fraud and abuse laws and regulations in the PRC, United States and abroad, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained during clinical studies that could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee 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 comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. As a public company, we have and will continue to incur significant legal, accounting and other expenses, including costs associated with public company reporting and corporate governance requirements, in order to comply with the rules and regulations imposed by the Sarbanes- Oxley Act and the Dodd- Frank Wall Street Reform and Consumer Protection, as well as rules implemented by the SEC and Nasdaq. Stockholder activism, the political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways that are not currently anticipated. Our management and other personnel need to devote a substantial amount of time to compliance with regulations related to operating as a public company. In addition, these rules and regulations make it difficult and expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain our current levels of such coverage. We expect that we will annually incur significant expenses to comply with the requirements imposed on us as a public company. Our management team has not previously managed and operated a U. S. public company. These executive officers and other personnel will need to devote substantial time to gaining expertise related to public company reporting requirements and compliance with applicable laws and regulations to ensure that we comply with all of these requirements. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on the board of directors or on

board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms. Increased labor costs negatively affect our operations and have an adverse impact on our profitability. Our strategies and business growth may require us to hire additional employees, and we may also hire additional employees as a result of acquisitions. The average cost of labor in the PRC has been steadily increasing in recent years as a result of inflation, government- mandated wage increases and other changes in PRC labor laws, as well as competition for talent and qualified employees among pharmaceutical companies. As a result, increased labor costs could have negative effects on our growth and decrease our profitability. Risks Related to Our Intellectual Property ~~Should we or our licensors fail to secure, uphold, defend, or extend adequate patent and other intellectual property rights for our product, ETUARY, which is approved in the PRC, and any product candidates globally, or if the breadth of these intellectual property rights is insufficient, our ability to effectively compete in our markets could be compromised.~~ We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our ~~product~~ **products**, ETUARY, **nintedanib and avatrombopag, which are approved in the PRC**, and product candidates. In order to protect the technologies, products and product candidates that we consider commercially important, we have filed and continue to file patent applications in the PRC, United States and other countries. However, applying for patent protection is an expensive and time- consuming process, and we may not be able to successfully file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. For example, there can be no assurance that we were the first to make the inventions claimed in our patents or pending patent applications because of the delay between publications of discoveries in scientific or patent literature and actual discoveries and patent applications. Under the " first- to- file " system adopted by the PRC, and ~~recently~~, the United States, even after reasonable investigation, we may be unable to determine with certainty whether our product, product candidates, processes, technologies, improvement and other related matters are or may become unpatentable because a third party filed or may file a patent application earlier than we have or do for inventions thereunder that are the same or substantially similar to our inventions **. Additionally, the USPTO and patent offices in other jurisdictions have often required that patent applications directed to pharmaceutical and / or biotechnology- related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Accordingly, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated. Thus, there is no assurance as to the degree and range of protections any of our patents, if issued, may afford us or whether patents will be issues**. Third parties may challenge the validity, enforceability or scope of our patents, which may result in those patents being narrowed or invalidated. The patent applications that we own may fail to result in issued patents with claims that cover our product and product candidates in the PRC, United States or in other foreign countries. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product or product candidates or prevent others from designing around our claims. Certain of our patents also cover processes, for which enforcement can be difficult. Any of these outcomes could impair our ability to prevent competition from third parties that may have an adverse impact on our business. If the patents or patent applications we hold or have in- licensed for ETUARY, our programs or product candidates are invalidated or fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product or product candidates, it could threaten our ability to commercialize future products. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. In the PRC, the amendment to the PRC Patent Law (the " Amended PRC Patent Law ") provides for patent term extension and patent linkage. The Amended PRC Patent Law and relevant implementing regulations provide a cause of action to allow a patent holder to initiate a declarative action during the regulatory review process of a drug to determine whether the drug **in review** falls within the **relevant scope of the patent scope of such patent holder**, which may be comparable to the patent linkage system in the United States. The system requires that the NMPA continue to review the potentially infringing follow- on application during any lawsuit by the innovator. However, the NMPA may not approve the follow- on application pending resolution of the patent litigation in favor of the follow- on application or for a specified period of time, whichever is shorter. The Amended PRC Patent Law and relevant implementing regulations also provide patent term extension, similar to the United States, for the patent term lost during the regulatory review process of a new drug upon the patent holder' s request. The extended term shall not exceed five years, and the total patent term ~~after market entry~~ of the new drug **from the date of its market approval** shall not exceed 14 years. However, **subject to the decision of relevant authorities**, the patents we have in- licensed or own in the PRC may not be eligible to be extended for any patent term lost during the regulatory review process. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Once the patent life has expired for a product, we may be subject to competition from generic medications. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent and other elements of our product candidate discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises and physical and electronic security of our information technology systems **. Enforcing a claim that a party illegally obtained and is using our trade secrets is challenging and the outcome is unpredictable. In addition, courts outside of the United States may be less willing to protect trade secrets**. While we have confidence in these individuals, organizations and systems,

agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Although we expect all of our employees and consultants to assign their applicable inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide guarantee that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. Moreover, some of our employees, including senior management, may have been employed at other pharmaceutical companies, including our competitors or potential competitors. Such employees may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. In the event that litigation is necessary to defend against such claims, we may be subject to monetary damages and lose valuable intellectual property rights or personnel. Further, filing, prosecuting and defending patents on our product, ETUARY, and product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the PRC and United States are less extensive than those in the PRC and United States. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the PRC or United States. As a result, we may encounter significant problems in protecting and defending our intellectual property in the PRC, United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition. In addition, we may be involved in claims and disputes of intellectual property infringement in other jurisdictions, and the defense of these claims or disputes, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements. The China National Intellectual Property Administration (the "CNIPA") and other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. For example, in several stages over the lifetime of a patent, periodic maintenance fees are due to be paid to the CNIPA and other patent agencies. Although an inadvertent lapse can, in many cases, be cured by payment of a late fee or by other means in accordance with the applicable rules, non-compliance could result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Such non-compliance events may include failure to respond to official actions in a timely manner, non-payment of fees, and failure to properly submit formal documents. In addition, under PRC patent law, any applicant that applies for a patent in a foreign country for an invention or utility model accomplished in the PRC must report to the CNIPA for confidentiality examination. If the applicant fails to report to the CNIPA for confidentiality examination, the patent right may not be granted if an application is later filed in the PRC. The scope of our patent protection may be uncertain, and third-party claims of intellectual property infringement or challenging the inventorship or ownership of our patents may prevent or delay our development and commercialization efforts. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future are to be issued as patents, they may not be issued in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, the patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the PRC and United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, third-party submissions of prior art to the CNIPA, USPTO or other related intellectual property offices, oppositions, inter partes reexamination proceedings before the CNIPA, USPTO, and corresponding foreign patent offices and post-grant proceedings such as opposition, derivation, revocation, invalidation, re-examination or inter partes review, or interference proceedings or similar proceedings in foreign jurisdictions challenging the priority of our invention or other features of patentability of our patents and patent applications. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product, ETUARY, and product candidates may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that the manufacture, use or sale of our product, ETUARY, and our product candidates infringes patents held by such third parties, or that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product, generic drugs and product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates or current product may infringe. Parties making

claims against us may obtain injunctive or other equitable relief that could effectively block our ability to further develop and commercialize one or more of our product, ETUARY, and our product candidates unless we redesigned infringing products (which may be impossible) or obtained a license under the applicable patents (which may not be available on commercially reasonable terms or at all), or until such patents expire. We may be involved in lawsuits to protect or enforce our patents. Competitors may infringe our patents. To counter infringement or unauthorized use, we or our collaborators may be required to file infringement claims that can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one of our patents is not valid, is unenforceable and / or is not infringed, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse determination or outcome of a third-party submission, proceeding or litigation may result in loss of patent rights or exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to prevent competitors from using or commercializing similar or identical technologies and products, or limit the duration of the patent protection of our technologies, product, ETUARY, and product candidates. Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the PRC or United States. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims, regardless of their merit, would cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, in addition to paying royalties, redesign infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. 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. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Changes in patent law could diminish the value of patents generally, which may impair our ability to protect ETUARY and our product candidate pipeline. Decisions made by the National People's Congress of the PRC and the CNIPA could change the laws and regulations governing patents in unpredictable ways that may affect our ability to obtain new patents or to enforce our existing patents and / or future patents. The United States has enacted and is currently implementing wide-ranging patent reform legislation. In addition, recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Similar changes in the laws of other jurisdictions may impact the value of our patent rights or our other intellectual property rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, there is uncertainty with respect to the value of patents once obtained, if any. As the laws and regulations governing patents evolve in the PRC and other jurisdictions, such changes may have a negative impact on our intellectual property protection. We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third-party may hold intellectual property, including patent rights, that is important to or necessary for the development of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. We may fail to protect our trademarks and trade names, which may negatively affect our ability to build brand recognition in our markets of interest. We currently own issued trademark registrations and have trademark applications pending in order to build name recognition among potential partners and customers in our markets of interest. However, such trademark registrations and applications subject us to risks of trademark invalidity, dilution and infringement. Our trademark registrations and applications may be subject to a governmental or third-party objection, and may be challenged, infringed, circumvented or declared generic. If an issued trademark registration or trademark application is successfully challenged, then we may not be able to register or maintain such trademark registration or application. Moreover, as our product, ETUARY, continues to be marketed, such product's reliance on our trademarks to differentiate us from our competitors may increase. We may not be able to prevent third parties from adopting, registering or using trademarks and trade dress that infringe, dilute or otherwise violate our trademark rights, or from engaging in conduct that constitutes unfair competition, defamation or other violations of our trademark rights. In addition, owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names may pursue trade name or trademark infringement claims against us. If we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively in our markets of interest, and our business may be adversely affected. Intellectual property rights may not address all potential threats to our

business or competitive advantage. The degree of 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. The limitations of currently available intellectual property protection regimes include that: • others may be able to make products that are similar to ETUARY or our product candidates or utilize similar technologies that are not covered by our owned and licensed patents; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights; • the proprietary technologies on which we rely may not be patentable; and • we may choose not to file a patent for certain trade secrets or know-how, yet a third party may 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 Regulatory Approval of Our Product Candidates and Other Compliance Matters** All material aspects of research, development, manufacturing and commercialization of our product, ETUARY, which is approved in the PRC, and product candidates are heavily regulated. Obtaining regulatory approvals and maintaining compliance with applicable laws and regulations is a lengthy, expensive and uncertain process which requires the expenditure of substantial time and financial resources. Failure to comply with the applicable requirements at any time during the drug development process or approval process, or after approval, may subject us to administrative or judicial sanctions. These sanctions could include, but are not limited to, a regulator's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, warning or untitled letters, voluntary or mandatory product recalls, product seizures, total or partial suspension of production or distribution, import alerts, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process of obtaining regulatory approvals, in the PRC, United States and abroad, is unpredictable, expensive and typically takes many years following commencement of clinical trials, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Other than certain generic drugs, we have only ~~one three~~ **successfully commercialized approved product products**; **(i) ETUARY, which is approved in the PRC for the treatment of IPF; (ii) nintedanib, which is approved in the PRC for the treatment of IPF; and (iii) avatrombopag maleate tablets for the treatment of thrombocytopenia ("TP") associated with chronic liver disease ("CLD") in adult patients undergoing elective diagnostics procedures or therapy. We also received approval to expand the indication for avatrombopag maleate tables to include chronic idiopathic thrombocytopenia ("ITP") in January 2025. However, only ETUARY is currently commercialized. We expect to commercially launch nintedanib and avatrombopag in 2025. ETUARY is currently** in its ~~Phase 3 clinical trials in the PRC for the treatment of SSe-ILD and DM-ILD,~~ Phase 3 clinical trial for the treatment of pneumoconiosis and Phase 1 clinical trial of ETUARY for the DKD Program. Although ETUARY is approved in the PRC for the treatment of one indication, we may be unable to successfully commercialize ETUARY in the PRC for the treatment of other indications. In addition, F351 is currently in its Phase 3 clinical trial in the PRC for liver fibrosis associated with CHB. In addition, F351 currently has one active IND application with the FDA in the United States for the treatment of liver fibrosis associated with a broad spectrum of chronic liver diseases. In the future, it is expected that an additional IND will be filed for F351 specifically for liver fibrosis associated with ~~NASH~~ **MASH**, and we may file additional IND applications for future indications or future product candidates. If any such future IND is not timely cleared by the FDA, our clinical development timeline may be negatively impacted and any future clinical programs may be delayed or terminated. As a result, we may be unable to obtain regulatory approvals or successfully commercialize our product candidates. We also have an early clinical-stage product pipeline that includes F573 for ALF / ACLF treatment. F573 has entered into Phase 2 clinical trials in the PRC. We completed our Phase 1 clinical observations of tolerability and PK in July 2022 and initiated our Phase 2 clinical study of F573 in March 2023. We have also established a tiered preclinical product pipeline. For instance, we are researching and developing F528 for the treatment of COPD. In addition, our product candidate F230 is currently in its preclinical phase and has demonstrated the potential to significantly alleviate PAH in animal studies. ~~In~~ **and, on March 13, 2024, we submitted an IND application for F230 in the PRC, and in May 2024, the NMPA approved such IND.** We cannot guarantee that any preclinical studies and clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our product candidates is susceptible to the risk of failure at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a suitable population of patients, the occurrence of severe or medically or commercially unacceptable adverse events, failure to comply with protocols or applicable regulatory requirements and determination by the NMPA, FDA or any comparable foreign regulatory authority that a drug product is not approvable. It is possible that even if one or more of our product candidates has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. We cannot commercialize product candidates in the PRC or United States without first obtaining regulatory approval from the NMPA or the FDA, respectively. Similarly, we cannot commercialize product candidates outside of the PRC or United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of our product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our product candidates are both safe and effective for each targeted indication. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Further, our product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC, may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval. The NMPA, FDA and

comparable foreign regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including:

- the NMPA, FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- We may be unable to demonstrate to the satisfaction of the NMPA, FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the NMPA, FDA or comparable foreign regulatory authorities for approval;
- serious and unexpected drug-related side effects may be experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- We may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the NMPA, FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the PRC, United States or elsewhere, and we may be required to conduct additional clinical trials;
- the NMPA, FDA or the applicable foreign regulatory authority may disagree regarding the formulation, labeling and / or the specifications of our product candidates;
- the NMPA, FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the NMPA, FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

The approval requirements for our product candidates are likely to vary by jurisdiction such that success in one jurisdiction is not necessarily predicative of success elsewhere. We may experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an IRB;
- recruiting suitable patients to participate in trials;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; and
- manufacturing sufficient quantities of qualified materials under Current Good Manufacturing Practice ("cGMPs") regulations and applying them on a subject-by-subject basis for use in clinical trials.

We could also experience delays in obtaining approval if physicians encounter unresolved ethical issues, including but not limited to those associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles given the serious nature of the diseases for the core indications for our product candidates. Additionally, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which the trials are being conducted, the Data Monitoring Committee for the trial, or by the NMPA, FDA or other regulatory authorities for a number of reasons, including failure to conduct the clinical trial in accordance with regulatory requirements or its clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues, or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, the FDA review and approval process could be delayed by any future shutdown of the U. S. government, and our development activities could be harmed or delayed as a result. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, our ability to commercialize our product candidates will be harmed and our ability to generate revenue will be materially impaired. Additionally, delays in completing trials will increase costs, delay our product development and approval process, and impair our ability to commence product sales and generate revenue. Many of the factors that could create or lead to a delay in the commencement or completion of clinical trials may lead to the denial of regulatory approval for our product candidates. Of the large number of drugs in development, only a small percentage successfully complete the NMPA, FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC, which would significantly harm our business, results of operations and prospects. If we were to obtain approval, regulatory authorities may approve any of our product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC, for fewer or more limited indications than we request, including failing to approve the most commercially promising indications, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, including ETUARY for future indications, F573, F528, and F230 in the PRC, and F351 in the PRC and potentially additional markets beyond the PRC, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be materially impaired. We are developing F351 for the treatment of liver fibrosis associated with ~~NASH~~-MASH. **The requirements for approval of F351 by the NMPA, FDA and comparable foreign regulatory authorities are unknown, may be difficult to predict, and may change over time, which makes it difficult to predict the timing and costs of clinical development and the likelihood of marketing approval. We are developing F351 for the treatment of liver fibrosis associated with MASH.** Although there are guidelines issued by the FDA for the development of drugs for the treatment of ~~NASH~~-MASH, the development of a novel product candidate such as F351 may be more expensive and take longer in the United States than for other, better known or extensively studied product candidates. As other companies are in later stages of clinical trials for their potential ~~NASH~~-MASH therapies, we expect that the path for regulatory approval for ~~NASH~~-MASH

therapies may continue to evolve in the near term as these other companies refine their regulatory approval strategies and interact with regulatory authorities. Such evolution may impact our future clinical trial designs, including trial size and endpoints, in ways that we cannot predict today. In particular, regulatory authority expectations about liver biopsy data may evolve especially as more information is published about the inherent variability in liver biopsy data. Certain of our competitors have experienced regulatory setbacks for **NASH-MASH** therapies following communications from the FDA. We currently do not know the impact, if any, that these setbacks could have on the path for regulatory approval for **NASH-MASH** therapies generally or for F351. Our anticipated development costs would likely increase if development of F351 or any future product candidate is delayed because we are required by the NMPA, FDA or other comparable regulatory authorities to perform studies or trials in addition to, or different from, those that we currently anticipate, or make changes to ongoing or future clinical trial designs. In addition, if we are unable to leverage our safety database for **NASH-MASH** indications, we may be required to perform additional trials, which would result in increased costs and may affect the timing or outcome of our clinical trials. In addition, F351 may not be developed as a monotherapy, but as a part of a combination therapy, which will add to the complexity of clinical development and may cause further delays in F351's development and affect our costs and divert management's resources. Our failure to obtain or renew certain approvals, licenses, permits and certificates required for our business may materially and adversely affect our business, financial condition and results of operations. Pursuant to relevant laws and regulations, we are required to obtain and maintain various approvals, licenses, permits and certificates from relevant authorities to operate our business. Some of these approvals, permits, licenses and certificates are subject to periodic renewal and / or reassessment by the relevant authorities, and the standards of such renewal and / or reassessment may change from time to time. Any failure to obtain or renew any approvals, licenses, permits and certificates necessary for our operations may result in enforcement actions thereunder, including orders issued by the relevant regulatory authorities ceasing our operations, and may include corrective measures requiring capital expenditure or remedial actions. If the interpretation or implementation of existing laws and regulations changes, or new regulations come into effect requiring us to obtain any additional approvals, permits, licenses or certificates that were previously not required to operate our existing businesses, there can be no assurance that it will successfully obtain such approvals, permits, licenses or certificates. Our relationships with customers and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third- party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our product, ETUARY, and future products, if approved. As a pharmaceutical company, even though we do not and may not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. These regulations include: • the Federal Healthcare Anti- Kickback Statute that prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid, and which will constrain our marketing practices and the marketing practices of our licensees, educational programs, pricing policies, and relationships with healthcare providers or other entities; • the federal physician self- referral prohibition, commonly known as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients to providers of " designated health services " with whom the physician or a member of the physician's immediate family has an ownership interest or compensation arrangement, unless a statutory or regulatory exception applies; • federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent, and which may expose entities that provide coding and billing advice to customers to potential criminal and civil penalties, including through civil whistleblower or qui tam actions, and including as a result of claims presented in violation of the Federal Healthcare Anti- Kickback Statute, the Stark Law or other healthcare-related laws, including laws enforced by the FDA; • HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services that, as amended by HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • federal physician sunshine requirements under the ACA, which requires manufacturers of approved drugs, devices, biologics and medical supplies to report annually to the U. S. Department of Health and Human Services, information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; • the Federal Food, Drug, and Cosmetic Act, which, among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off- label use and regulates the distribution of drug samples; and • state and foreign law equivalents of each of the above federal laws, such as 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 requiring pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and which may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state and foreign laws governing the privacy and

security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws such as HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Our operations are subject to various fraud and abuse laws, including, but not limited to, the PRC Anti- Unfair Competition Law, the PRC Criminal Law and the physician payment sunshine laws and regulations. There are ambiguities as to what is required to comply with any of these requirements, and violations of such fraud and abuse laws may be punishable by criminal and / or civil sanctions, including penalties, fines and / or exclusion or suspension from governmental healthcare programs and debarment from contracting with the relevant jurisdiction. As law enforcement authorities increase their focus on enforcing these laws, efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations may involve substantial costs. 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 the PRC 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 certain 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 the PRC 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 clinical trials outside of the PRC and United States, to sell our commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved, abroad 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, be required to disgorge profits, and incur 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 commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved, 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 product, ETUARY, and future products, if approved, or our failure to obtain any required import or export authorization for such 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 product, ETUARY, and future products, if approved, may create delays in the introduction of such products in international markets or, in some cases, prevent the export of such 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 product, ETUARY, and future products, if approved, or in our decreased ability to export such products to, existing or potential customers with international operations. Any decreased use of our product, ETUARY, and future products, if approved, or limitation on our ability to export or sell such products would likely adversely affect our business. Our results of operations may be adversely affected by current and potential future healthcare legislative and regulatory actions. All jurisdictions in which we conduct our research, development, manufacturing and commercialization activities regulate these activities in great depth and detail. Obtaining regulatory approvals is a lengthy, expensive and uncertain process. We intend to focus our activities in the major markets of the PRC and the United States. These geopolitical areas all have strict regulation on medical devices, and, in doing so, they employ broadly similar regulatory strategies, including regulation of product development, approval, manufacturing, sales and marketing and distribution of medical devices. However, regulatory regimes vary in different regions, which makes regulatory compliance more complex and costly for companies like us that plan to operate in each of these regions. **The price** Legislative and regulatory actions affecting government prescription drug procurement and reimbursement programs occur relatively frequently. In the United States, the ACA was enacted in 2010 to expand healthcare coverage. Since then, numerous efforts have been made to repeal, amend or administratively limit the ACA in whole or in part. For example, the Tax Cuts and Jobs Act, signed into law by President Trump in 2017, repealed the individual health insurance mandate, which is considered a key component of **pharmaceuticals** the ACA. In December 2018, a Texas federal district court struck down the ACA on the grounds that the individual health insurance mandate is unconstitutional, although this ruling has been stayed pending appeal. The ongoing challenges **a topic of considerable public**

discussion that could lead to price controls or the other ACA and new legislative proposals price-limiting strategies by payors that have resulted in uncertainty regarding the effect ACA's future viability and destabilization of lowering payment and reimbursement rates for drugs the health insurance market. The resulting impact on our or business is uncertain and could be material otherwise making the commercialization of pharmaceuticals less profitable. Efforts Many federal and state legislatures have considered, and adopted, healthcare policies intended to control curb rising healthcare costs, such as the Inflation Reduction Act of 2022. These cost-containment measures may include, among other measures: requirements for pharmaceutical companies to negotiate prescription drug prices with government healthcare programs; controls could also have a material adverse effect on government-funded reimbursement for drugs; new our or business. For example, in 2018, President Trump and the Secretary of the U. S. Department of Health and Human Services released the "American Patients First Blueprint" and have begun implementing certain portions. The initiative includes proposals to increase increased generic requirements to pay prescription drug rebates to government healthcare and biosimilar competition; enable the Medicare program programs to negotiate, including if drug prices increase at a higher rate than inflation; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more directly expensive branded product; and public funding for improve transparency regarding drug prices and ways to lower our consumers' out-of-pocket costs cost effectiveness research, which may. The Trump administration also proposed to establish an "international pricing index" that would be used by government as a benchmark to determine the costs and private third potentially limit the reimbursement of drugs under Medicare Part B. Among other pharmaceutical manufacturer industry party payors related proposals, Congress has proposed bills to make alter the benefit structure to increase manufacturer contributions in the catastrophic phase. The volume of drug pricing-related bills dramatically increased under the previous Congress, and the resulting impact on our business is uncertain and could be material. The extent to which the 118th Congress will continue this approach is uncertain. The IRA provides CMS with the ability to directly negotiate prescription drug and biologic prices with manufacturers and to cap out-of-pocket spending for Medicare Part D enrollees. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics covered coverage under Medicare Parts B and payment decisions D that lack generic or biosimilar competition. Political Price negotiations for Part D begin in 2023. Taking effect in 2023, economic the IRA provides a new "inflation rebate" that requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Parts B or D increases faster than the rate of inflation. The IRA contains a number of other provisions intended to reduce drug spending and regulatory developments the federal deficit, and the IRA's impact on competition and commercialization is uncertain but could be material. In addition, many may further complicate developments in healthcare systems and states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing. These developments could, such for example, impact our potential licensing agreements as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information commercial and collaborative partners may also consider the impact of these pressures on their licensing strategies. Any new laws or to place a maximum price ceiling regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our products product candidates purchased by state agencies. For example The implementation of any price controls caps on in 2017, California's governor signed a prescription drug drugs or price transparency requirements state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Both Congress and state legislatures are considering various bills that would reform drug purchasing and price negotiations, allow greater use of utilization management tools to limit Medicare Part D coverage, facilitate the import of low priced drugs from outside the United States and encourage the use of generic drugs. Such initiatives and legislation may cause added pricing pressures on our future products, if approved in the United States. Changes to the Medicaid program at the federal or state level could also have a material adverse adversely effect affect on our business. Proposals that could impact coverage and reimbursement of our future products, operating if approved in the United States, including giving states more flexibility to manage drugs covered under the Medicaid program and permitting the re-importation of prescription medications from Canada or other countries, could have a material adverse effect by limiting our future products', if approved in the United States, use and coverage. Furthermore, state Medicaid programs could request additional supplemental rebates on our products as a result of an increase in the federal base Medicaid rebate. To the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, they could use the enactment of these increased rebates to exert pricing pressure on our future products, if approved in the United States, and the adverse effects may be magnified by their adoption of lower payment schedules. Other proposed regulatory actions affecting manufacturers could have a material adverse effect on our business. It is difficult to predict the impact, if any, of any such proposed legislative and regulatory actions or resulting state actions on the use and reimbursement of our future products, if approved, in the United States, but our results and financial condition of operations may be adversely affected. The policies of the NMPA may change, or additional government regulations may be enacted, that could prevent, limit or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our profitability. We cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions in the PRC, where the regulatory environment is constantly evolving. For example, if changes to regulatory requirements and guidance require us to substantially amend clinical trial protocols, we may experience increased costs or inability to complete clinical trials in a timely manner or at all. Changes in government regulations relating to pharmaceutical product registrations and approvals, such as a relaxation in regulatory requirements, or the introduction of simplified approval procedures, could lower the barriers to entry for potential competitors, or increased regulatory requirements could increase the difficulty to satisfy such requirements. In recent years in the PRC, there have been,

and will likely continue to be, efforts to enact administrative or legislative measures that include more rigorous coverage criteria and may result in downward pressure on prices on our product, ETUARY, and future products, if approved. For details of the risks associated with such downward pricing pressure, see “ — Risks Related to Our Business Operations and Product Candidates — We may face pressure to lower the prices of our commercialized product, ETUARY, which is approved in the PRC, and any other future product, if approved, in order for such products to qualify for medical insurance reimbursement or due to market competition ” in this Risk Factors section. Furthermore, any changes in laws and regulations on collection and transfer of personal data in the PRC, including the Personal Information Protection Law of the PRC and the Administrative Regulations on Human Genetic Resources of the PRC, could affect our ability to use medical data and subject us to liability for the use of such data for previously permitted purposes. The PRC government or other government authorities in countries where we plan to sell our commercialized product, ETUARY, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any other future products, if approved in the PRC, could adopt new or different regulations with respect to sales of pharmaceutical products to address bribery, corruption or other concerns. New or different regulations could result in increased costs incurred by us, our employees or distributors in selling our product, ETUARY, and future products, if approved, or impose restrictions on sales and marketing activities, which could, in turn, increase our costs. We are subject to evolving privacy and data protection laws, including HIPAA and the EU General Data Protection Regulation (EU) 2016 / 679 (“ GDPR ”). If we fail to protect personal information or comply with existing or future data protection regulations, our business, financial condition, results of operations and prospects may be materially adversely affected. Numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity, and other processing of personal information. HIPAA establishes a set of national privacy and security standards for the protection of protected health information (as defined in HIPAA) (“ PHI ”) by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. HIPAA requires covered entities and business associates, such as us, to develop and maintain policies with respect to the protection of, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a data breach. The collection and use of personal health data and other personal data in the EU is governed by the provisions of the GDPR, which came into force in May 2018, related data protection laws in individual EU Member States as well as implementations of the GDPR in the European Economic Area. The GDPR establishes a number of strict requirements and restrictions applicable to the processing (processing includes collecting, analyzing and transferring) of personal data (i. e., data which identifies an individual or from which an individual is identifiable) in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the ~~notification obligations~~ **personal data breaches which may have to be notified** to the national data protection authorities and ~~or data subjects~~, **the measures to be taken when engaging processors (in particular in case of a data breach)**, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation. Furthermore, it affords various rights to individuals (e. g., the right to access or erasure of personal data), and imposes potential penalties for breaches of up to 4 % of the annual worldwide turnover or € 20 million, whichever is greater. In case of a breach of the GDPR, individuals (e. g., study subjects) may also have a right to compensation for financial or non- financial losses (e. g., distress). There may be circumstances under which a failure to comply with the GDPR, or the exercise of individual rights under the GDPR, would limit our ability to utilize clinical trial data collected on study subjects. Furthermore, there is a growing trend towards the required public disclosure of clinical trial data in the EU, which adds to the complexity of obligations relating to processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation (EU CTR), EMA disclosure initiatives and voluntary commitments by industry. Failing to comply with these obligations could lead to government enforcement actions and significant penalties, harm to reputation, and adversely impact the business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the CTR and the GDPR, further adds to the complexity. In addition, we are subject to various U. S. state laws which may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. Because our operations involve the use of hazardous chemical materials and may produce hazardous waste, we are subject to numerous environmental, health and safety laws and regulations, including those governing air emissions, discharge of water and the handling, use, storage, treatment and disposal of hazardous materials and wastes. While we have entered into hazardous waste disposal agreements 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 the use or disposal of our 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 for failure to comply with such laws and regulations. Further, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage, use or disposal of hazardous materials and waste. We maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. We are subject to extensive ongoing regulatory obligations and continued regulatory review related to our commercialized product, ETUARY, which is approved in the PRC, and we may be subject to such obligations and review related to our future product candidates, if approved, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience

unanticipated problems with our product candidates. Our product, ETUARY, which is approved in the PRC, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and any product candidates that are approved in the future remain subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, distribution, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including requirements in the PRC, federal and state requirements in the United States and requirements of comparable foreign regulatory authorities, as described in “Business — Government Regulation” of this Annual Report. In addition, regulatory approvals may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, our commercialized product, ETUARY, which is approved in the PRC, **future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025**, and our product candidates, if approved, and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export will be subject to comprehensive regulation by the NMPA, FDA and other regulatory agencies in the PRC, United States and by comparable foreign regulatory authorities, respectively. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCPs for any clinical trials that we conduct following approval. Manufacturers of drug products and their facilities are also subject to continual review and periodic, unannounced inspections by the NMPA, FDA and other regulatory authorities for compliance with cGMPs. In addition, following an approval for commercial sale of any product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, may be subject to additional review and approval by the NMPA, the FDA, and / or comparable regulatory authorities. If we fail to comply with applicable regulatory requirements, or there are safety or efficacy problems with a product, a regulatory agency or enforcement authority may, among other things: • issue warning or notice of violation letters; • impose civil or criminal penalties; • suspend or withdraw regulatory approval; • suspend any of our ongoing clinical studies; • refuse to approve pending applications or supplements to approved applications submitted by us; • impose restrictions on our operations, including closing our contract manufacturers’ facilities; • seize or detain products, or require a product recall; or • require entry into a consent decree. Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. The PRC government **may intervene in, influence or exert control over Gyre Pharmaceuticals’ operations, which could result in an adverse change in our operations. The PRC government** has some oversight and discretion over the conduct of our business in the PRC and may intervene ~~or in,~~ influence ~~or exert control over~~ our operations ~~as the government deems appropriate to further regulatory, political and societal goals~~. The PRC 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 do the same regarding our industry, including~~ policies regarding our industry that could require us to seek permission from the PRC authorities to continue to operate our business in the PRC. **The central or local governments may impose new, stricter regulations or interpretations of existing regulations that could potentially affect our business, financial condition and results of operations. Furthermore, regulations introduced by the NMPA concerning drug inspection, investigation, evidence collection and disposal are relatively new, and because of the limited volume of published judicial and administrative decisions, which are non-binding in nature, the interpretation and enforcement of these laws and regulations are uncertain. In addition, the implementation of laws and regulations may be in part based on government policies and internal rules that are subject to the interpretation and discretion of different government agencies (some of which are not published on a timely basis or at all) that may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until sometime after the violation. The imposition of new regulations or interpretations of existing regulations can occur quickly with little advance notice. We may incur penalties for any failure to comply with PRC laws and regulations. In addition, any litigation in the PRC, regardless of outcome, may be protracted and result in substantial costs and diversion of resources and management attention. Since PRC administrative and court authorities have discretion in interpreting and implementing statutory and contractual terms, it may be difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we enjoy. If we were to become subject to the direct intervention or influence of the PRC government due to changes in laws or other unforeseeable reasons, including it may require a material and potentially adverse change in our operations in the PRC. Furthermore, the PRC government has indicated an intent to increase oversight and control over offerings of companies with significant operations in the PRC that are to be conducted in foreign markets. For example, in July 2021, the relevant PRC government authorities made public the Opinions on Strictly Scrutinizing Cracking Down Illegal Securities Activities in Accordance with the Law 7. These opinions emphasized the need to strengthen the administration over illegal securities activities and new rules published for comments the supervision of overseas listings by the PRC government China-based companies and proposed to take effective measures, including such as promoting the construction of relevant regulatory systems to deal with the risks and incidents faced by China-based overseas-listed companies. In February 2023, the China Securities Regulatory Commission (the “CSRC”) released** the Trial

Administrative Measures of Overseas Securities Offering and Listing by Domestic Enterprises to become (the “ Trial Measures ”), which came into effect on March 31, 2023, establish. The Trial Measures comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies’ securities and regulate both direct and indirect overseas offering and listing of PRC domestic companies’ securities by adopting a new filing-based regulatory regime. In February 2023, the CSRC and other PRC governmental authorities jointly issued the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (the “ Confidentiality Provisions ”), which came into effect on March 31, 2023. According to regulate the Confidentiality Provisions, PRC domestic companies that directly or indirectly conduct overseas offerings and listings shall strictly abide by the laws and regulations on confidentiality when providing or publicly disclosing, whether directly or through their overseas listed entities, materials to securities services providers. In the event such materials contain state secrets or working secrets of government agencies, PRC domestic companies shall first obtain approval from authorities, and file with the secrecy administrative department at the same level with the approving authority; in the event that such materials, if divulged, will jeopardize national security or public interest, PRC domestic companies shall comply with procedures stipulated by national regulations. Given the recent nature of the introduction of the Trial Measures and the Confidentiality Provisions, there remains uncertainty as to the interpretation and implementation of regulatory requirements related to overseas securities offerings and other capital markets activities. If (i) we were mistakenly conclude that certain regulatory filings, permissions and approvals are not required, (ii) applicable laws, regulations, or interpretations change, or (iii) we are required to become subject obtain such filings, permissions or approvals in the future, we may be unable to obtain them direct intervention in a timely manner, or at all, and such filings, permissions or approvals may be denied or rescinded even if obtained. We may face adverse actions or sanctions by the CSRC or other PRC regulatory agencies if we are unable to comply with such requirements, which may result in fines and penalties, restrictions on or our influence operations, having to delist from a stock exchange outside of China, the halting of securities offerings to foreign investors and other actions that could materially and adversely affect our operations and the interest of our investors. In addition, the risks that the PRC government at any time due to changes in laws or other unforeseeable reasons, it may intervene or influence require a material change in our operations in the PRC. In addition, the risks that the PRC government may intervene or influence our operations in the PRC at any time could significantly limit or completely hinder our ability to offer or continue to offer securities to investors and cause the value of such securities to significantly decline or be worthless. The pharmaceutical industry in the PRC is highly regulated and such regulations are subject to change, which may affect approval and commercialization of our product, ETUARY, and product candidates. The pharmaceutical industry in the PRC is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. For details of a discussion of regulatory requirements that are applicable to our current and planned business in the PRC, see “ — Business — Regulatory Requirements in the PRC ” in this Annual Report. We believe our strategy and approach are consistent with the PRC government’ s policies, but we cannot ensure that our strategy and approach will continue to be consistent. In recent years, the regulatory framework for the pharmaceutical industry in the PRC has undergone significant changes, and we expect that it will continue to undergo significant changes. Any such changes or amendments may result in: • increased compliance costs on our business; • delays in or prevention of successful development or commercialization of our product candidates; or • reduction of the current benefits we experience and believe are available to us from developing and manufacturing drugs in the PRC. The PRC authorities have also become increasingly vigilant in enforcing laws in the pharmaceutical industry, and any failure by us to maintain compliance with applicable laws and regulations may result in the suspension or termination of our business activities in the PRC. Adverse changes in political, economic and other policies of the PRC government could have a material adverse effect on the overall economic growth of the PRC, which could reduce the demand for our commercialized product, ETUARY, future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025, and any other future products, if approved, or otherwise materially and adversely affect our business, operations or competitive position. Our business, results of operations, financial condition and prospects may be influenced to a significant degree by economic, political, legal and social conditions in the PRC. The PRC’ s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange, allocation of resources and an evolving regulatory system. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources, but some of these measures may have a negative effect on us. For example, our financial condition and results of operations may be adversely affected by government control over capital investments or changes in tax regulations that are currently applicable to us. Growth of the PRC economy has been uneven across different regions and among various economic sectors of the PRC, and there can be no assurance that future growth will be sustained at similar rates or at all. If the business environment or economic conditions in the PRC deteriorates from the perspective of domestic or international investment, our business may also be adversely affected. The PRC legal system is a civil law system based on written codes and statutes. Unlike the common law system, prior court decisions may be cited as persuasive authority, but have limited precedential value. Since the late 1970s, the PRC government has promulgated a comprehensive system of laws, rules and regulations governing economic matters in general. However, as these laws and regulations are relatively recent and the number of published decisions is limited, their interpretation and enforcement involve significant and certainties, and can be inconsistent and unpredictable. Since PRC administrative and court authorities have significant discretion in interpreting and implementing statutory and contractual terms, it may be more difficult to evaluate the outcome of administrative and court proceedings and the level of legal protection we may experience compared to developed legal systems. These uncertainties may impede our ability to enforce the contracts we have entered into and could materially and adversely affect our business, financial condition and results of operation. Furthermore, PRC laws and regulations

afford significant protection to state- owned assets. Contributions that may lead to losses of state- owned assets are subject to heightened scrutiny by the competent authorities, and the competent authorities have significant discretion in interpreting and implementing the relevant laws and regulations. In the event we or our affiliates conduct transactions with state- owned enterprises or their affiliates, we are exposed to risks and uncertainties involving the potential of loss of state- owned assets, which may subject us to liabilities and could materially and adversely affect our business, financial condition and results of operation. The PRC legal system is based in part on government policies and internal rules, some of which are not published on a timely basis or at all, and which may have a retroactive effect. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation. Implementation of the labor laws and regulations in the PRC may adversely affect our business and results of operations, and failure to fully comply with PRC labor- related laws may expose us to potential liabilities and penalties. Pursuant to the PRC Labor Contract Law, employers are subject to stricter requirements in terms of signing labor contracts, minimum wages, paying remuneration, determining the term of employees' probation and unilaterally terminating labor contracts. Due to lack of detailed interpretative rules and broad discretion of the local competent authorities, it is uncertain as to how the labor contract law and its implementation rules will affect our current employment policies and practices. Our employment policies and practices may violate the labor contract law or its implementation rules, and we may thus be subject to related penalties, fines or legal fees. Compliance with the labor contract law and its implementation rules may increase our operating expenses, in particular, our personnel expenses. In the event that we decide to terminate some of our employees or otherwise change our employment or labor practices, the labor contract law and its implementation rules may also limit our ability to effect those changes in a desirable or cost- effective manner, which could adversely affect our business and results of operations. According to the Social Insurance Law, employees must participate in pension insurance, work- related injury insurance, medical insurance, unemployment insurance and maternity insurance, and the employers must, together with their employees or separately, pay the social insurance premiums for such employees. Recently, the PRC government enhanced its measures relating to social insurance collection, which may lead to stricter enforcement. We expect our labor costs to increase due to the implementation of these laws and regulations. Compliance with the Social Insurance Law and its implementation rules may increase our operating expenses, in particular, our personnel expenses. As the interpretation and implementation of these laws and regulations are still evolving, there can be no assurance that our employment practice policy will at all times be deemed to be in full compliance with labor- related laws and regulations in the PRC, which may subject us to labor disputes or government investigations. If we are deemed to have violated relevant labor laws and regulations, we could be required to provide additional compensation to our employees and our business, financial condition and results of operations could be materially and adversely affected. Fluctuations in exchange rates may result in foreign currency exchange losses. The change in the value of the Renminbi against other currencies may fluctuate and is affected by, among other things, changes in the PRC' s political and economic conditions and the PRC' s foreign exchange policies, as well as supply and demand in the local market. We are exposed to the risks of market forces or government policies and their impact on the exchange rate between Renminbi or other currencies in the future. Substantially all of our revenue and costs are denominated in Renminbi and most of our financial assets are also denominated in Renminbi. Any significant fluctuations in the value of the Renminbi may materially and adversely affect our liquidity and cash flows and the value of our financial assets. Our operations are subject to and may be affected by changes in PRC tax laws and regulations. The PRC government from time to time adjusts or changes its tax laws and regulations, and future adjustments or changes to PRC tax laws and regulations, together with any uncertainty resulting therefrom, could have an adverse effect on our results of operations. Our product ETUARY, which is approved in the PRC, has been subject to a preferential VAT treatment at the tax rate of 3 %, applicable to a number of drugs for rare diseases, since March 2019. However, there can be no assurance that our applicable VAT rate will stay the same or decrease, and any future changes to the VAT policies may negatively impact the selling price of ETUARY and future approved product candidates. Furthermore, under the amended Individual Income Tax Law, foreign nationals who have no domicile in the PRC, but have resided in the PRC for a total of 183 days or more in a tax year, are subject to PRC individual income tax on their income gained within or outside the PRC. The amended Individual Income Tax Law may materially affect our ability to attract and retain highly skilled foreign scientists and research technicians to work in the PRC. We are also subject to periodic examinations on fulfillment of our tax obligation under the PRC tax laws and regulations by PRC tax authorities, and there can be no assurance that any such examinations by PRC tax authorities would not result in fines, other penalties or actions that could adversely affect our business, financial condition and results of operations, as well as our reputation. We may be restricted from transferring our scientific data abroad or using human genetic resources collected in the PRC. On March 17, 2018, the General Office of the State Council promulgated the Measures for the Management of Scientific Data (the " Scientific Data Measures "), which provides a broad definition of scientific data and relevant rules for the management of scientific data. According to the Scientific Data Measures, enterprises in the PRC must seek governmental approval before any scientific data involving a state secret may be transferred abroad or to foreign parties. Upon approval by the competent authorities, the enterprise shall undergo the required procedures, and enter into the confidentiality agreements with the users of the scientific data. Further, any researcher conducting research funded at least in part by the PRC government is required to submit relevant scientific data for management by the entity to which such researcher is affiliated before such data may be published in any foreign academic journal. Given that the term " state secret " is not clearly defined, if and to the extent any data collected or generated in connection with our R & D of medical drug candidates are subject to the Scientific Data Measures and any subsequent laws as required by the relevant government authorities, there can be no assurance that we can always obtain relevant approvals for sending scientific data (such as the results of our pre- clinical studies or clinical trials conducted within the PRC) abroad or to our foreign partners in the PRC. As a result, we may be subject to fines and other administrative penalties imposed by those government authorities. In addition, pursuant to the Service Guide, the sampling, collection or research activities of human genetic resources through clinical trials is required to be filed online with the China

Human Genetic Resources Management Office. Furthermore, the Administrative Regulations on Human Genetic Resources of the PRC (~~the “Human Genetic Resources Regulation”~~) stipulates that collecting human genetic resources of the PRC’s important genetic families and specific regions, or collecting those human genetic resources in such categories and quantities as prescribed by the administrative department for science and technology under the State Council, preserving the PRC’s human genetic resources and providing the basic platform for scientific research, utilization of the PRC’s human genetic resources for international cooperation in scientific research, as well as transporting the PRC’s materials of human genetic resources abroad shall be subject to the approval of the administrative department for science and technology under the State Council. If we are unable to obtain necessary approvals or comply with the regulatory requirements in a timely manner, or at all, our R & D of drug candidates may be hindered. If the relevant government authorities consider the transmission of our scientific data or collection and usage of human genetic resources to be in violation of the requirements under applicable PRC laws and regulations, we may be subject to fines and other administrative penalties imposed by those government authorities. Furthermore, it is possible that the regulation may be interpreted and applied in a manner that is inconsistent with our clinical trial practices, potentially resulting in the confiscation of human genetic resources samples and associated data and administrative fines. Due to our operations in the PRC, our business, results of operations and financial condition may be influenced to a certain degree by economic, political, legal and social conditions in the PRC or changes in government relations between the PRC and the United States or other governments. There is significant uncertainty about the future relationship between the United States and the PRC with respect to trade policies, treaties, government regulations and tariffs. ~~the~~ **The** PRC’s economy differs from the economies of developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate, control of foreign exchange and allocation of resources. While the PRC’s economy has experienced significant growth over the past four decades, growth has been uneven across different regions and among various economic sectors. The PRC government has implemented various measures to encourage economic development and guide the allocation of resources. Some of these measures may benefit the overall PRC economy, but may have a negative effect on us. In addition, in the past, the PRC government implemented certain measures, including interest rate increases, to control the pace of economic growth. These measures may cause a decrease in economic activity in the PRC, which may affect our business and results of operations. During the years ended December 31, **2024 and 2023** ~~and 2022~~, we directly and indirectly relied on certain overseas suppliers to obtain raw materials, and we have directly and indirectly relied on collaboration with entities in foreign countries and regions in connection with our business operations. We may also pursue partnerships with entities in foreign countries and regions in the future. our business is therefore subject to changing international economic, regulatory, social and political conditions, and local conditions in foreign countries and regions. As a result, the PRC’s political relationships with those foreign countries and regions may affect development and commercialization of our product, ETUARY, and product candidates. Additionally, the PRC’s political relationships with those foreign countries and regions may also affect our current and future relationships with third parties. There can be no assurance that our existing or potential collaborators will not alter their perception of us or their preferences as a result of adverse changes to the state of political relationships between the PRC and the relevant foreign countries or regions, and such alteration may cause a decline in the demand for our product, ETUARY, and future products, if approved, and adversely affect our business, financial condition, results of operations, cash flows and prospects. In July 2021, the PRC government provided new guidance on the PRC- based companies raising capital outside of the PRC, including through arrangements called variable interest entities (“VIEs”). In light of such developments, the SEC has imposed enhanced disclosure requirements on the PRC- based companies seeking to register securities with the SEC. Although we do not have a VIE structure, due to our operations in the PRC, any future PRC, U. S. or other rules and regulations that place restrictions on capital raising or other activities by companies with operations in the PRC could affect our business and results of operations. If the business environment in the PRC deteriorates from the perspective of domestic or international investment, or if relations between the PRC and the United States or other governments deteriorate, the PRC government may intervene with our operations and our business in the PRC and United States. Changes in U. S. and PRC regulations may impact our business, our operating results and our ability to raise capital. The U. S. government, including the SEC, has made statements and taken certain actions that led to changes to United States and international relations, and will impact companies with connections to the United States or the PRC, including imposing several rounds of tariffs affecting certain products manufactured in the PRC, imposing certain sanctions and restrictions in relation to the PRC and issuing statements indicating enhanced review of companies with certain operations based in the PRC. It is unknown whether and to what extent new legislation, executive orders, tariffs, laws or regulations will be adopted, or the effect that any such actions would have on companies with significant connections to the United States or to the PRC, our industry or on us. We conduct research activities and has business operations both in the United States and the PRC. Any unfavorable government policies on cross- border relations and / or international trade, including increased scrutiny on companies with certain operations based in the PRC, capital controls or tariffs, may affect the competitive position of our drug product, generic drugs and product candidates, the hiring of scientists and other research and development personnel, the demand for our drug product, the import or export of raw materials in relation to drug development or our ability to raise capital, or prevent us from selling our drug product in certain countries. Furthermore, the SEC has issued statements primarily focused on companies with certain operations based in the PRC, such as us. For example, on July 30, 2021, Gary Gensler, Chairman of the SEC, issued a Statement on Investor Protection Related to Recent Developments in the PRC, pursuant to which Chairman Gensler stated that he has asked the SEC staff to engage in targeted additional reviews of filings for companies with certain operations based in the PRC. The statement also addressed risks inherent in companies with VIE structures. We do not have a VIE structure and are not in an industry that is subject to foreign ownership limitations by the PRC. However, it is possible that our periodic reports and other filings with the SEC may be subject to enhanced review by the SEC and this additional scrutiny could affect our ability to effectively raise capital in the United States. In response to the SEC’s July 30, 2021 statement, the China Securities Regulatory Commission (“CSRC”) announced on

August 1, 2021 that “[i]t is our belief that Chinese and U. S. regulators shall continue to enhance communication with the principle of mutual respect and cooperation, and properly address the issues related to the supervision of the PRC- based companies listed in the U. S. so as to form stable policy expectations and create benign rules framework for the market.” While the CSRC will continue to collaborate “closely with different stakeholders including investors, companies, and relevant authorities to further promote transparency and certainty of policies and implementing measures,” it emphasized that it “has always been open to companies’ choices to list their securities on international or domestic markets in compliance with relevant laws and regulations.” If any new legislation, executive orders, tariffs, laws and / or regulations are implemented, if existing trade agreements are renegotiated, if the U. S. or the PRC governments take retaliatory actions due to the recent U. S.- PRC tension or if the PRC government exerts more oversight and control over securities offerings that are conducted in the United States, such changes could have an adverse effect on our business, financial condition and results of operations, and our ability to raise capital. Compliance with the PRC’ s new Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, regulations and guidelines relating to the multi- level protection scheme on cyber security and any other future laws and regulations may entail significant expenses and could affect our business. The PRC has implemented or will implement rules and is considering a number of additional proposals relating to data protection. The Data Security Law provides that the data processing activities must be conducted based on “data classification and hierarchical protection system” for the purpose of data protection and prohibits entities in the PRC from transferring data stored in the PRC to foreign law enforcement agencies or judicial authorities without prior approval by the PRC government. Additionally, the PRC’ s Cyber Security Law and the Administrative Measures for the Hierarchical Protection of Information Security requires companies to take certain organizational, technical and administrative measures and other necessary measures to ensure the security of their networks and data stored on their networks. Under the multi- level protection scheme (“MLPS”), entities operating information systems must have a thorough assessment of the risks and the conditions of their information and network systems to determine the level of the entity’ s information and network systems. These levels range from the lowest Level 1 to the highest Level 5 pursuant to a series of national standards on the grading and implementation of the classified protection of cyber security. The grading result will determine the set of security protection obligations that entities must comply with. Entities classified as Level 2 or above should report the grade to the relevant government authority for examination and approval. Recently, the Cybersecurity Administration of China (“CAC”) has taken action against several PRC internet companies in connection with their initial public offerings on U. S. securities exchanges for alleged national security risks and improper collection and use of the personal information of PRC data subjects. According to the official announcement, the action was initiated based on the National Security Law, the Cyber Security Law and the Cybersecurity Review Measures, which are aimed at “preventing national data security risks, maintaining national security and safeguarding public interests.” Pursuant to the Revised CAC Measures, critical information infrastructure operators procuring network products and services, and online platform operators (as opposed to “data processors” in the Revised Draft CAC Measures) carrying out data processing activities which affect or may affect national security, shall conduct a cybersecurity review pursuant to the provisions therein. In addition, online platform operators possessing personal information of more than one million users seeking to be listed on foreign stock markets must apply for a cybersecurity review. On November 14, 2021, the CAC further published the Regulations on Network Data Security Management (Draft for Comment), or the Draft Management Regulations, under which data processors refer to individuals and organizations who determine the data processing activities in terms of the purpose and methods at their discretion. The Draft Management Regulations reiterate that data processors shall be subject to cybersecurity review if (i) they process personal information of more than one million persons and they are aiming to list on foreign stock markets or (ii) their data processing activities affect or may affect PRC national security. The Draft Management Regulations also request data processors seeking to list on foreign stock markets to annually assess their data security by themselves or through data security service organizations, and submit the assessment reports to relevant competent authorities. As the Draft Management Regulations are released only for public comment, the final version and the effective date thereof is subject to change. As of the date of this Annual Report, we have not received any notice from any PRC regulatory authority identifying us as a “critical information infrastructure operator,” “online platform operator” or “data processor,” or requiring us to go through the cybersecurity review procedures pursuant to the Revised CAC Measures and the Draft Management Regulations. Based on our understanding of the Revised CAC Measures, and the Draft Management Regulations if enacted as currently proposed, we do not expect to become subject to cybersecurity review by the CAC for issuing securities to foreign investors because: (i) the clinical and preclinical data we handle in our business operations, either by its nature or in scale, do not normally trigger significant concerns over PRC national security and (ii) we have not processed, and does not anticipate to process in the foreseeable future, personal information for more than one million users or persons. However, there remains uncertainty as to how the Revised CAC Measures, and the Draft Management Regulations, if enacted as currently proposed, will be interpreted or implemented. Furthermore, there remains uncertainty as to whether the PRC regulatory authorities may adopt new laws, regulations, rules, or detailed implementation and interpretation in relation, or in addition, to the Revised CAC Measures and the Draft Management Regulations. While we intend to closely monitor the evolving laws and regulations in this area and take all reasonable measures to mitigate compliance risks, we cannot guarantee that our business and operations will not be adversely affected by the potential impact of the Revised CAC Measures, the Draft Management Regulations or other laws and regulations related to privacy, data protection and information security. Furthermore, the Personal Information Protection Law provides a comprehensive set of data privacy and protection requirements that apply to the processing of personal information and expands data protection compliance obligations to cover the processing of personal information of persons by organizations and individuals in the PRC, and the processing of personal information of persons in the PRC outside of the PRC if such processing is for purposes of providing products and services to, or analyzing and evaluating the behavior of, persons in the PRC. The Personal Information Protection Law also provides that critical information infrastructure operators and

personal information processing entities who process personal information meeting a volume threshold to be set by PRC cyberspace regulators are also required to store in the PRC personal information generated or collected in the PRC, and to pass a security assessment administered by PRC cyberspace regulators for any export of such personal information. Lastly, the Personal Information Protection Law contains proposals for significant fines for serious violations of up to approximately \$ 7. 2 million or 5 % of annual revenues from the prior year and may also be ordered to suspend any related activity by competent authorities. We do not maintain, nor do we intend to maintain in the future, personally identifiable health information of patients in the PRC. Interpretation, application and enforcement of these laws, rules and regulations evolve from time to time and their scope may continually change, through new legislation, amendments to existing legislation or changes in enforcement. Compliance with the PRC' s new Cyber Security Law and Data Security Law could significantly increase the cost to us of providing our service offerings, require significant changes to our operations or even prevent us from providing certain service offerings in jurisdictions in which we currently operate or in which we may operate in the future. Despite our efforts to comply with applicable laws, regulations and other obligations relating to privacy, data protection and information security, it is possible that our practices, offerings or platform could fail to meet all of the requirements imposed on us by the Cyber Security Law, the Data Security Law and / or related implementing regulations. Any failure on our part to comply with such law or regulations or any other obligations relating to privacy, data protection or information security, or any compromise of security that results in unauthorized access, use or release of personally identifiable information or other data, or the perception or allegation that any of the foregoing types of failure or compromise has occurred, could damage our reputation, discourage new and existing counterparties from contracting with us or result in investigations, fines, suspension or other penalties by PRC government authorities and private claims or litigation, any of which could adversely affect our business, financial condition and results of operations. Even if our practices are not subject to legal challenge, the perception of privacy concerns, whether or not valid, may harm our reputation and brand and adversely affect our business, financial condition and results of operations. Moreover, the legal uncertainty created by the Data Security Law, the Revised CAC Measures and the recent PRC government actions could adversely affect our ability, on favorable terms, to raise capital. Restrictions on currency exchange, including the risks of transferring cash outside of the PRC, may limit Gyre Pharmaceuticals' ability to receive and use effectively financing in foreign currencies or Gyre Therapeutics' ability to transfer cash from Gyre Pharmaceuticals or other potential investors in the PRC. Gyre Pharmaceuticals' ability to obtain currency exchange is subject to significant foreign exchange controls and, in the case of transactions under the capital account, requires the approval of and / or registration with PRC government authorities, including the State Administration of Foreign Exchange, or SAFE. In particular, if Gyre Pharmaceuticals finances by means of foreign debt from ~~BJC~~ **BJCContinent Pharmaceuticals** Limited or other foreign lenders, the amount is not allowed to, among other things, exceed the statutory limits and such loans must be registered with the local branch of SAFE. If Gyre Pharmaceuticals finances by means of additional 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 MOFCOM, or its local branch or registration with other governmental authorities in the PRC. In light of the various requirements imposed by PRC regulations on loans to, and direct investment in, PRC- based entities by offshore holding companies, there can be no assurance that Gyre Pharmaceuticals will be able to complete the necessary government requirements or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by Gyre Pharmaceuticals. If Gyre Pharmaceuticals fails to adhere to such requirements or obtain such approval, Gyre Pharmaceuticals' ability to capitalize or otherwise fund Gyre Pharmaceuticals' PRC operations, including Gyre Pharmaceuticals' technology development may be negatively affected, which could materially and adversely affect Gyre Pharmaceuticals' ability to fund and expand Gyre Pharmaceuticals' business. Gyre Therapeutics may not be able to transfer funds out of Gyre Pharmaceuticals, or Gyre Therapeutics might face difficulties in transferring funds from investors in the PRC should Gyre Therapeutics decide to solicit investments from investors in the PRC, in a timely manner due to restrictions imposed by the PRC authorities. PRC regulations relating to the establishment of offshore special purpose companies by residents in the PRC may subject our PRC resident beneficial owners in the PRC to liability or penalties, or may otherwise adversely affect us. The Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles, or SAFE Circular 37 requires residents of the PRC to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with such residents' legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a " special purpose vehicle. " The term " control " under SAFE Circular 37 is broadly defined as the operation rights, beneficiary rights or decision- making rights acquired by residents of the PRC in the offshore special purpose vehicles or PRC companies by such means as acquisition, trust, proxy, voting rights, repurchase, convertible bonds or other arrangements. SAFE Circular 37 further requires amendment to the registration in the event of any changes with respect to the basic information of or any significant changes with respect to the special purpose vehicle, such as an increase or decrease of capital contributed by PRC residents, share transfer or exchange, merger, division or other material events. If the shareholders of the offshore holding company who are residents of the PRC do not complete their registration with the local SAFE branches, the PRC subsidiaries may be prohibited from making distributions of profits and proceeds from any reduction in capital, share transfer or liquidation to the offshore parent company and from carrying out subsequent cross- border foreign exchange activities, and the offshore parent company may be restricted in its ability to contribute additional capital into its PRC subsidiaries. Moreover, failure to comply with the SAFE registration and amendment requirements described above could result in liability under PRC law for evasion of applicable foreign exchange restrictions. Certain residents of the PRC may hold direct or indirect interests in our company, and we will request residents of the PRC who we know hold direct or indirect interests in our company, if any, to make the necessary applications, filings and amendments as required under SAFE Circular 37 and other related rules. However, we may not at all times be fully aware or informed of the identities of our stockholders or beneficial

owners that are required to make such registrations, and we cannot provide any assurance that these residents will comply with our requests to make or obtain any applicable registrations or comply with other requirements under SAFE Circular 37 or other related rules. The failure or inability of our PRC resident stockholders to comply with the registration procedures set forth in these regulations may subject us to fines or legal sanctions, restrictions on our cross-border investment activities. Moreover, failure to comply with the various foreign exchange registration requirements described above could result in liability under PRC law for circumventing applicable foreign exchange restrictions. As a result, our business operations and our ability to make distributions to you could be materially and adversely affected. Any failure to comply with PRC regulations regarding the registration requirements for our employee equity incentive plans may subject us to fines and other legal or administrative sanctions, which could adversely affect our business, financial condition and results of operations. Pursuant to the Notices on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Publicly Listed Companies, or the Stock Option Rules and other relevant rules and regulations, PRC citizens or non-PRC citizens residing in the PRC for a continuous period of not less than one year who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. Our employees who are PRC citizens or who reside in the PRC for a continuous period of not less than one year and who participate in our stock incentive plans will be subject to such regulation. We plan to assist our employees to register their equity awards. However, any failure of PRC individual beneficial owners and holders of equity awards under our stock incentive plans to comply with the SAFE registration requirements may subject them to fines and legal sanctions. Since Gyre Pharmaceuticals is a legal entity registered in Beijing, PRC, it is classified as a PRC tax resident for PRC income tax purposes by default, and such classification results in unfavorable tax consequences to Gyre Pharmaceuticals and its non-PRC shareholders. Under Article 2 of the PRC Enterprise Income Tax Law, a resident enterprise is an enterprise that is established within the territory of the PRC or an enterprise established with a “de facto management body” within the PRC. Gyre Pharmaceuticals is a PRC tax resident for PRC tax purposes by default because it is a legal entity registered in Beijing, PRC. Because Gyre Pharmaceuticals is a PRC tax resident for PRC enterprise income tax purposes, Gyre Pharmaceuticals is subject to PRC tax at a rate of 25% on its worldwide income, which materially reduces Gyre Pharmaceuticals’ net income. In addition, Gyre Pharmaceuticals is also subject to PRC tax resident income tax reporting obligations. Furthermore, because Gyre Pharmaceuticals is a PRC tax resident for enterprise income tax purposes, gains realized on the Contributions may be subject to PRC tax, at a rate of 10% in the case of non-PRC enterprises or 20% in the case of non-PRC individuals (in each case, subject to the provisions of any applicable tax treaty), if such gains are deemed to be from PRC sources. Gyre Pharmaceuticals and its shareholders face uncertainties with respect to indirect transfers of equity interests in PRC resident enterprises or other assets attributed to a PRC establishment of a non-PRC company, or other assets attributable to a PRC establishment of a non-PRC company. Enhanced scrutiny over acquisition transactions by the PRC tax authorities may have a negative impact on potential offshore restructuring transactions or sales of the shares of Gyre Pharmaceuticals’ offshore holding companies or investments where PRC taxable assets are involved. The PRC tax authorities have enhanced their scrutiny over the direct or indirect transfer of certain taxable assets, including, in particular, equity interests in a PRC resident enterprise, by a non-resident enterprise by promulgating and implementing Notice of Ministry of Finance and State Administration of Taxation (“SAT”) on Several Issues relating to Treatment of Corporate Income Tax Pertaining to Restructured Business Operations of Enterprises (“Circular 59”) and the Notice on Strengthening Administration of Enterprise Income Tax for Share Transfers by Non-PRC Resident Enterprises (“Circular 698”). Pursuant to the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises (“Bulletin 7”) an “indirect transfer” of assets, including equity interests in a PRC resident enterprise, by non-PRC resident enterprises may be recharacterized and treated as a direct transfer of PRC taxable assets, if such arrangement does not have a reasonable commercial purpose and was established for the purpose of avoiding payment of PRC enterprise income tax. As a result, gains derived from such indirect transfer may be subject to PRC enterprise income tax. According to Bulletin 7, “PRC taxable assets” include assets attributed to an establishment in the PRC, immovable properties located in the PRC, and equity investments in PRC resident enterprises, in respect of which gains from their transfer by a direct holder, being a non-PRC resident enterprise, would be subject to PRC enterprise income taxes. When determining whether there is a “reasonable commercial purpose” of the transaction arrangement, factors to be taken into consideration include: whether the main value of the equity interest of the relevant offshore enterprise derives from PRC taxable assets; whether the assets of the relevant offshore enterprise mainly consists of direct or indirect investment in the PRC or if its income mainly derives from the PRC; whether the offshore enterprise and its subsidiaries directly or indirectly holding PRC taxable assets have real commercial nature which is evidenced by their actual function and risk exposure; the duration of existence of the business model and organizational structure; the replicability of the transaction by direct transfer of PRC taxable assets; and the tax situation of such indirect transfer and applicable tax treaties or similar arrangements. In respect of an indirect offshore transfer of assets of a PRC establishment, the resulting gain is to be included with the enterprise income tax filing of the PRC establishment or place of business being transferred, and would consequently be subject to PRC enterprise income tax at a rate of 25%. Where the underlying transfer relates to the immovable properties located in the PRC or to equity investments in a PRC resident enterprise, which is not related to a PRC establishment or place of business of a non-resident enterprise, a PRC enterprise income tax at 10% would apply, subject to available preferential tax treatment under applicable tax treaties or similar arrangements, and the party who is obligated to make the transfer payments has the withholding obligation. Where the payor fails to withhold any or sufficient tax, the transferor shall declare and pay such tax to the tax authority by itself within the statutory time limit. Late payment of applicable tax will subject the transferor to default interest. Bulletin 7 does not apply to transactions of sale of shares by investors through a public stock exchange where such shares were acquired from a transaction through a public stock exchange. Bulletin 7 may be determined by the tax authorities to be applicable to some of Gyre

Pharmaceuticals' offshore restructuring transactions or sales of the shares of Gyre Pharmaceuticals' offshore holding companies or investments where PRC taxable assets are involved. The transferors and the transferees may be subject to tax filing or withholding and tax payment obligations, while Gyre Pharmaceuticals may be requested to assist in such filings. Furthermore, the transferors or the transferees (as withholding agent) may be required to spend valuable resources to comply with Bulletin 7 or to establish that the transferors should not be taxed under Bulletin 7, for Gyre Pharmaceuticals' previous and future restructuring or disposal of shares of Gyre Pharmaceuticals' offshore subsidiaries. The PRC tax authorities have the discretion under Bulletin 7 to adjust the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. If the PRC tax authorities adjust the taxable income of the transactions under Bulletin 7, income tax costs on the transferor side associated with such potential acquisitions or disposals will increase. Gyre Pharmaceuticals faces uncertainties on the reporting and consequences on future private equity financing transactions, share exchange or other transactions involving the transfer of shares in Gyre Pharmaceuticals by investors that are non- PRC resident enterprises. The PRC tax authorities may pursue such non- resident enterprises with respect to a filing or the transferees with respect to withholding obligation, and request Gyre Pharmaceuticals to assist in the filing. As a result, non- resident enterprises in such transactions may become at risk of being subject to filing obligations or being taxed, under Circular 59 or Bulletin 7 and Bulletin 37, and may be required to expend valuable resources to comply with Circular 59, Bulletin 7 and Bulletin 37 or to establish that its non- resident enterprises should not be taxed under these circulars. The PRC tax authorities have the discretion under SAT Circular 59, Bulletin 7 and Bulletin 37 to adjust the taxable capital gains based on the difference between the fair value of the taxable assets transferred and the cost of investment. Although Gyre Pharmaceuticals currently has no plans to pursue any acquisitions in the PRC or elsewhere in the world, Gyre Pharmaceuticals may pursue acquisitions in the future that may involve complex corporate structures. Because Gyre Pharmaceuticals is a PRC tax resident by default, and if the PRC tax authorities adjust the taxable income of the transactions under SAT Circular 59 or Bulletin 7 and Bulletin 37, Gyre Pharmaceuticals' income tax costs associated with such potential acquisitions will be increased, which may have an adverse effect on Gyre Pharmaceuticals' financial condition and results of operations.

**The enacted " Holding Foreign Companies Accountable Act " and the " Accelerating Holding Foreign Companies Accountable Act " call for additional and more stringent criteria to be applied to emerging market companies upon assessing the qualification of their auditors, especially the non- U. S. auditors who are not inspected by the Public Company Accounting Oversight Board. These developments could add uncertainties to the market for our common stock. The Holding Foreign Companies Accountable Act (the " HFCAA ") requires certain issuers of securities to establish that they are not owned or controlled by a foreign government. Specifically, an issuer must make this certification if the Public Company Accounting Oversight Board (the " PCAOB ") is unable to audit specified reports because the issuer has retained a foreign public accounting firm not subject to inspection by the PCAOB. Furthermore, if the PCAOB is unable to inspect the issuer' s public accounting firm for three consecutive years, the issuer' s securities are banned from trading on a national exchange or through other methods. In December 2022, the Accelerating Holding Foreign Companies Accountable Act amended the HFCAA by decreasing the number of non- inspection years from three to two, thus reducing the time period before our common stock may be prohibited from trading or delisted if the PCAOB were to determine that it could not inspect our auditor. In March 2021, the SEC adopted interim final amendments to implement congressionally mandated submission and disclosure requirements of the HFCAA. The interim final amendments will apply to registrants that the SEC identifies as having filed an annual report on Forms 10- K, 20- F, 40- F or N- CSR with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction and that the PCAOB has determined it is unable to inspect or investigate completely because of a position taken by an authority in that jurisdiction. In December 2021, the SEC adopted amendments finalizing such rules to require that any such identified registrant is required to submit documentation to the SEC establishing that it is not owned or controlled by a governmental entity in that foreign jurisdiction, and is also required to disclose in the registrant' s annual report the audit arrangements of, and governmental influence on, such a registrant. In December 2021, the PCAOB issued a Determination Report which found that the PCAOB was then unable to inspect or investigate completely registered public accounting firms headquartered in: (1) mainland China of the PRC, because of a position taken by one or more authorities in mainland China; and (2) Hong Kong, a Special Administrative Region and dependency of the PRC, because of a position taken by one or more authorities in Hong Kong. The PCAOB has made such designations as mandated under the HFCAA. Pursuant to each annual determination by the PCAOB, the SEC will, on an annual basis, identify issuers that have used non- inspected audit firms and thus are at risk of such suspensions in the future. In August 2022, the CSRC, the Ministry of Finance of the PRC, and the PCAOB signed a Statement of Protocol (the " Protocol "), governing inspections and investigations of audit firms based in the PRC and Hong Kong. Pursuant to the Protocol, the PCAOB shall have independent discretion to select any issuer audits for inspection or investigation and has the unfettered ability to transfer information to the SEC. In December 2022, the PCAOB determined that the PCAOB was able to secure complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong and voted to vacate 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 will consider the need to issue a new determination. Notwithstanding the foregoing, if the PCAOB is not able to inspect and investigate completely our auditor' s work papers in China, you may be deprived of the benefits of such inspection which could result in limitation or restriction to our access to the U. S. capital markets and trading of our securities may be prohibited under the HFCAA. Our auditor, Grant Thornton Zhitong Certified Public Accountants LLP, an independent public accounting firm registered with the PCAOB, and an auditor of publicly traded companies in the U. S., is subject to laws in the U. S. pursuant to which the PCAOB conducts regular inspections to assess its compliance with the applicable**

**professional standards. Our auditor is headquartered in mainland China and was inspected by the PCAOB for the first time in July 2024 and was identified as a firm subject to the determinations announced by the PCAOB in December 2021. Should the PCAOB be unable to fully conduct inspection of our auditor's work papers in mainland China, it will make it difficult to evaluate the effectiveness of our auditor's audit procedures or equity control procedures. Investors may consequently lose confidence in our reported financial information and procedures or quality of the financial statements, which would adversely affect us and our securities. Moreover, if trading in our securities is prohibited under the HFCAA in the future because the PCAOB determines that it cannot inspect or fully investigate our auditor at such future time, if our securities were then traded on an exchange, that exchange may determine to delist our securities.**

Risks Related to Commercialization of Our Product and Product Candidates **We may fail to achieve the degree..... crucial for their commercial viability.** Many of our product candidates are years away from regulatory approval. Our development candidates are not expected to be commercially available for several years, if at all. Further, the commercial success of product candidates will depend upon its acceptance by physicians, individuals, third-party payors and other key decision-makers as a therapeutic and cost-effective alternative to products available at the time, which may include competing products currently under development by others. See the risk factor titled “ — We face substantial competition that may result in others discovering, developing or commercializing products before or more successfully than we do. ” If we are unable to successfully develop, obtain regulatory approval in a timely manner (including due to reasons that are beyond our control, such as changes in regulations or a shutdown of the federal government, including the FDA) and commercialize our development candidates, our ability to generate revenue from product sales with respect to any product candidates that ultimately obtain approval may be delayed and our business, growth and financial prospectus may be materially and adversely affected. For instance, no anti-fibrosis product for the treatment of pneumoconiosis has been approved in the PRC. Although ETUARY is approved in the PRC for the treatment of IPF, we cannot be certain that the NMPA, FDA or other comparable regulatory authority will approve ETUARY for the treatment of other indications, such as pneumoconiosis. In addition, the regulatory authorities in the PRC, United States and the EU have not approved any products for the treatment of **NASH-MASH**, and while there are guidelines issued by the NMPA and FDA for the development of drugs for the treatment of **NASH-MASH** and an NMPA and FDA surrogate endpoint table for drug approval, respectively, it is unclear whether the requirements for approval will change in the future or whether the NMPA or FDA will rely on regulatory precedent for future regulatory approvals. Any such changes may require us to conduct new trials that could delay our timeframe and increase the costs of our programs related to F351 or any future product candidate for the treatment of **NASH-MASH**. In addition, we cannot be certain which efficacy endpoints or presentation thereof clinical or regulatory agencies may require in a Phase 3 clinical trial of **NASH-MASH** or for approval of our product candidates. Even if the NMPA, FDA or other regulatory agency approves our product candidates, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and / or production of such product and may impose ongoing commitments or requirements for post-approval studies, including additional research and development and clinical trials. The NMPA, FDA and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval. Regulatory approval from authorities in foreign countries will be needed to market our product candidates in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. For example, ETUARY is approved for the treatment of pulmonary fibrosis in the PRC but may not be approved in any other jurisdiction, such as the United States, for such indication. If we fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited. We face substantial competition that may result in others discovering, developing, commercializing or marketing products, including our commercialized product, ETUARY, which is approved in the PRC, before or more successfully than we do. The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Although there **is one** ~~are no currently~~ approved therapeutic drug ~~treatments~~ **treatment** for liver fibrosis **in the United States**, several companies are developing product candidates in clinical studies. For details, see “ — Business — Competition ” in this Annual Report. We face competition with respect to our current product, generic drugs and product candidates and will face competition with respect to any future product candidates from segments of the pharmaceutical, biotechnology and other related industries that pursue targeted therapies for patients with organ fibrosis, such as IPF, **NASH-MASH**, **PDSSc-ILD**, **DM-ILD**, ~~pneumoconiosis~~, **DKD**, **ALF / ACLF** or **COPD**. If ETUARY, F351, F573, F528, F230, or our future product candidates do not offer sustainable advantages over competing products, we may not be able to successfully compete against current and future competitors. Our competitors may obtain regulatory approval of their products more rapidly than we may or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our product, ETUARY, which is approved in the PRC, and future products, if approved, and these competitors may also be more successful than us in manufacturing and marketing their products. Our commercial opportunity in different indications could be reduced or eliminated if competitors develop and market products or therapies that are more convenient to use, more effective, less expensive, and safer to use than our product, ETUARY, and future products, if approved. Furthermore, if competitors gain NMPA, FDA or other foreign regulatory authority approval earlier than we do, we may be unable to establish a strong market presence or to gain market share. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the level of generic competition, and the availability of reimbursement from government and other third-party payors. Our product candidates, if any are approved,

may compete with these existing drug and other therapies but may not be competitive with them in price. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic, including branded generic, products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our product candidates that we successfully introduce to the market will pose challenges. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and individual registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercialized product, ETUARY, which is approved in the PRC, and any other future product, if approved, **including nintedanib and avatrombopag, which we expect to commercialize in 2025**, may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives that would harm our business. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. 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 product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products 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 U. S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for certain medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we or our collaborators commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate that receives marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. We may be required to conduct expensive pharmaco-economic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the NMPA, FDA or similar regulatory authorities outside the PRC and United States. Moreover, eligibility for reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers its costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover its costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs 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 relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the PRC or United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that it develops could have a material adverse effect on our operating results, ability to raise capital needed to commercialize products and overall financial condition. **Moreover, our marketed ETUARY is subject to the risk of being included in the PRC's centralized volume-based procurement scheme. For details, see " — In the future, the policies of centralized volume-based procurement set by the PRC government may cover our commercialized product, ETUARY, future commercialized products, including nintedanib and avatrombopag, which we expect to commercialize in 2025, and any other future products, if approved, and the prices of such product may decrease, which in turn may have a material adverse impact on our revenue, financial condition and results of operation " in this Risk Factors section.** The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products in the United States and decrease our ability to generate revenue. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments in the United States. Sales of our product candidates will depend substantially, both domestically in the United States and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If

reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

**Risks Related to Our Common Stock**

The market price of our common stock could be subject to significant fluctuations. Some of the factors that may cause the market price of our common stock to fluctuate include:

- timing and results of INDs, preclinical studies and clinical trials of our product candidates, or those of our competitors or our existing or future collaborators;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- if we do not achieve the perceived benefits of the Contributions as rapidly or to the extent anticipated by financial or industry analysts;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- actions taken by regulatory agencies with respect to our product, product candidates, clinical studies, manufacturing process or sales and marketing terms;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue adverse or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;
- geo-political developments, general market or macroeconomic conditions including inflation and interest rates;
- market conditions in the pharmaceutical and biotechnology sectors;
- changes in the structure of healthcare payment systems;
- announcement of expectation of additional financing efforts;
- sales of securities by us or our securityholders in the future;
- if we fail to raise an adequate amount of capital to fund our operations and continued development of our product candidates;
- trading volume of our common stock;
- publicity or announcements by competitors of new commercial products, clinical progress or lack thereof, significant contracts, commercial relationships or capital commitments;
- the impact of any natural disasters or public health emergencies;
- the introduction of technological innovations or new products or product candidates that compete with our product, ETUARY, and product candidates and our services; and
- period-to-period fluctuations in our financial results.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In addition, macroeconomic conditions, a recession, depression or other sustained adverse market event or otherwise could materially and adversely affect our business and the value of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies. Furthermore, market volatility may lead to increased shareholder activism if we experience a market valuation that activists believe is not reflective of our intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. Fluctuations in operating results could adversely affect the price of our common stock. Our operating results are likely to fluctuate significantly from quarter to quarter and year to year. These fluctuations could cause our stock price to decline. Some of the factors that may cause operating results to fluctuate on a period-to-period basis include the scope, progress, duration results and costs of preclinical and clinical development programs, as well as non-clinical studies and assessments of product candidates and programs, restructuring costs, implementation or termination of collaboration, licensing, manufacturing or other material agreements with third parties, non-recurring revenue or expenses under any such agreement, the cost, timing and outcomes of regulatory compliance, approvals or other regulatory actions, the likelihood of regulatory approval, failure of regulators to grant regulatory approval and general and industry-specific economic conditions, particularly as it affects the pharmaceutical, biopharmaceutical or biotechnology industries in the PRC or United States. Period-to-period comparisons of our historical and future financial results may not be meaningful, and investors should not rely on them as an indication of future performance. Fluctuating losses may fail to meet the expectations of securities analysts or investors. Failure to meet these expectations may cause the price of our common stock to decline. Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock. Our current trading volumes are modest, and sales of a substantial number of shares of our common stock in the public market, or the perception that these sales could occur, could cause the market price to decline. Any additional sales in the public market of our common stock or other securities under these shelf registration statements could adversely affect prevailing market prices for our common stock. In addition, we have outstanding options to purchase 18,280,077,548,869 shares of common stock at a weighted average exercise price of \$ 1.49-75 as of December 31, 2023-2024. If such options are exercised and the shares are sold into the open market, such sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Conversion or exercise of these securities into shares of our common stock will cause dilution to the other holders of our common stock, and all such stock may be sold in the public market after conversion or exercise, subject to restrictions under the securities laws, which may lead to a decline in the market price of our common stock. Provisions in our certificate of incorporation and bylaws and provisions under Delaware law could make an acquisition of the Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our management. Provisions that will be included in our

certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the Company that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors will be responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions will:

- continue the use of a classified board of directors such that not all members of our board of directors are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our board of directors;
- limit who may call stockholder meetings;
- limit actions by our stockholders by written consent;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the votes that all stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which generally prohibits a person who, together with their affiliates and associates, owns 15% or more of the company’s outstanding voting stock from, among other things, merging or combining with the company for a period of three years after the date of the transaction in which the person acquired ownership of 15% or more of the company’s outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our certificate of incorporation and bylaws generally provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees. Our certificate of incorporation and bylaws provide that, unless the company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our **current or former** directors, officers, employees or stockholders to the company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our restated certificate of incorporation or our bylaws (in each case, as they may be amended from time to time) or **that is** governed by the internal affairs doctrine. This choice of forum provision will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which **the** federal courts have exclusive jurisdiction. This exclusive forum provision may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees or stockholders, which may discourage such lawsuits against us and our directors, officers and other employees and stockholders. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

~~We are a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors. We have been a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and thus have been allowed to provide simplified executive compensation disclosures in our filings. We have also had certain other decreased disclosure obligations in our SEC filings. We cannot predict whether investors find our common stock less attractive because of our reliance on any of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.~~

We do not anticipate that we will pay any cash dividends in the foreseeable future. The current expectation is that we will retain our future earnings, if any, to fund the growth of our business as opposed to paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain, if any, for the foreseeable future. If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. Lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

~~The Contributions involved the combination of two companies which previously operated as independent companies. We may fail to realize some or all of the anticipated benefits of the Contributions if the integration process takes longer than expected or is more costly than expected. Potential difficulties we may encounter in the integration process include the following:~~

- the inability to successfully combine the businesses of Catalyst and Gyre Pharmaceuticals in a manner that permits us to achieve the anticipated benefits from the Contributions, which would result in the anticipated benefits of the Contributions not being realized partly or wholly in the time frame currently anticipated or at all;
- creation of uniform standards, controls, procedures, policies and information systems; and
- potential unknown liabilities

and unforeseen increased expenses, delays or regulatory conditions associated with the Contributions. It is possible that the integration process also could result in the diversion of our management's attention, the disruption or interruption of, or the loss of momentum in, our business or inconsistencies in standards, controls, procedures and policies, any of which could adversely affect our ability to maintain our business relationships or the ability to achieve the anticipated benefits of the Contributions, or could otherwise adversely affect our business and financial results.

**General Risk Factors** Our ability to utilize our net operating loss carryforwards and tax credit carryforwards may be subject to limitations. As of December 31, 2023-2024, after consideration of certain limitations (see below), we had approximately \$ 193.54 million of federal and \$ 1013.59 million of California state net operating loss carryforwards ("NOLs") available to reduce future taxable income. Under Section 382 and Section 383 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," its ability to use its pre-change NOLs and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 "ownership change" is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. We have experienced several ownership changes. Approximately \$ 156.5 million and \$ 75.2 million of the NOLs will expire unutilized for federal and California state income tax purposes, respectively. The Contributions resulted in an additional ownership change and we may experience additional ownership changes in the future due to subsequent shifts in our stock ownership (some of which are outside of our control). In addition, our ability to use our NOLs to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs. Even if we achieve profitability, we may not be able to utilize a material portion of our NOLs and other tax attributes, which could have a material adverse effect on cash flow and results of operations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. Changes in tax laws or in their implementation may adversely affect our business and financial condition. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U. S. Treasury Department. Changes in tax law may adversely affect our business or financial condition or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. It cannot be predicted whether, when, in what form or with what effective dates tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Prospective investors should consult their tax advisors regarding the potential consequences of changes in tax law on our business and on the ownership and disposition of our common stock. We are a "controlled company" within the meaning of the Nasdaq listing standards and, as a result, qualify for, and rely on, exemptions from certain corporate governance requirements. Our stockholders do not have the same protections afforded to stockholders of companies that are subject to such requirements. The GNI Parties control a majority of the voting power of our outstanding common stock. As a result, we qualify as a "controlled company" within the meaning of the corporate governance standards of Nasdaq. Under these rules, a listed company of which more than 50 % of the voting power with respect to the election of directors is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirements that (i) a majority of our board of directors consist of independent directors, (ii) director nominees be selected or recommended to our board of directors entirely by independent directors and (iii) our compensation committee be composed entirely of independent directors. We rely on these exemptions. As a result, we do not have a majority of independent directors, director nominees are not selected or recommended to our board of directors by entirely independent directors and our compensation committee does not consist entirely of independent directors. Accordingly, you may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of Nasdaq. In the event we cease to be a "controlled company" and our shares continue to be listed on Nasdaq, we will be required to comply with these provisions within the applicable transition periods. Our executive officers, directors and principal stockholders have the ability to control or significantly influence all matters submitted to our stockholders for approval. As of December 31, 2023-2024, our executive officers, directors and principal stockholders, in the aggregate, beneficially owned a majority of our outstanding common stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of us on terms that other stockholders may desire. We may be exposed to increased litigation, including stockholder litigation, which could have an adverse effect on our business and operations. We may from time to time become subject to various litigation, legal or contractual disputes, investigations or administrative proceedings arising in the ordinary course of our business, including, but not limited to, various disputes with or claims from our suppliers, customers, contractors, licensors, business partners and other third parties that we engage for our business operation. In addition, we may be exposed to increased litigation due to the combination of Catalyst's business and Gyre Pharmaceuticals' business as a result of the consummation of the Contributions. Such litigation may have an adverse impact on our business and results of operations or may cause disruptions to our operations. In addition, in the past, stockholders have initiated class action lawsuits against biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources, which could have a material adverse effect on our business, financial condition and results of operations. If any verdict or award is rendered against us or if we agree to settle with an

adverse party, we could be required to pay significant monetary damages, assume other liabilities and / or suspend or terminate the related business projects. Negative publicity arising from litigation, legal disputes, investigations or administrative proceedings may damage our reputation and adversely affect the image of our brands and products. We may be subject to product liability claims that could expose us to costs and liabilities. We are exposed to product liability risks as a result of developing, producing, marketing, promoting and selling pharmaceutical products in the PRC, United States and other jurisdictions. Such claims may arise if our product, ETUARY, and future products, if approved, are deemed or proven to be unsafe, ineffective, defective or contaminated, or if we are alleged to have engaged in practices such as insufficient or improper labeling of products or providing inadequate, insufficient or misleading warnings or disclosures regarding side effects. A product liability claim brought against us may, regardless of merit or outcome, result in reputational harm and strain on financial resources and may consume the time and attention of our management. If we are unable to successfully defend itself against such claims, we may, among others, be subject to product recalls, civil liability for physical injury, death or other losses caused by our product, ETUARY, and future products, if approved, criminal liability and the revocation of our business licenses. PRC laws and regulations currently do not require us to, and we do not, maintain liability insurance to cover product liability claims. As a result, we may not be able to recover our losses resulting from future product liability claims. Breach, failure or disruption in or to our information system could compromise sensitive information related to our business and expose us to liability or reputational harm, and our ability to effectively manage our business operations could be adversely affected. Our information systems may fail and are subject to risks of breakdown, breach, interruption or damage from computer viruses, **ransomware and other cyber- attacks**, computer hackers, malicious code, employee error or malfeasance, theft or misuse, denial- of- service attacks, sophisticated nation- state and nation- state- supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromise. Any system damage or failure that interrupts data input, retrieval or transmission or increases service time could disrupt our normal operations, including the loss of clinical trial data from completed or future clinical trials. Loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. There can be no assurance that we will be able to effectively handle a failure of our information systems, or that we will be able to restore our operational capacity in a timely manner or at all to avoid disruption to our business. **Further, cybersecurity breaches or other cybersecurity incidents may allow hackers access to our preclinical compounds, strategies, discoveries, trade secrets, and / or other confidential information. Additionally, sensitive data could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel' s, vendors' or partners' use of generative AI technologies.** To the extent that any disruption or **security cybersecurity breach incident** were to result in a loss of, or damage to, our data or applications, or inappropriate use, disclosure of or access to confidential or proprietary information, we could incur liability **, including under laws and regulations governing the protection of protected health information and other personal data**, our competitive position could be harmed and the further development and commercialization of our product, ETUARY, and product candidates could be hindered or delayed. **The risk of a cybersecurity incident or other informational technology disruption, particularly through cyber- attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.** We may collect and store sensitive personal data in the ordinary course of our business. For details, see “ — Risks Related to Our Business Operations in the PRC — Compliance with the PRC’ s new Data Security Law, Cyber Security Law, Cybersecurity Review Measures, Personal Information Protection Law, regulations and guidelines relating to the multi- level protection scheme on cyber security and any other future laws and regulations may entail significant expenses and could affect our business ” in this Risk Factors section. If personal data are compromised due to a material breach of our information, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be subject to regulatory actions and / or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations. You may have difficulty enforcing judgments obtained against us. Substantially all of our assets are located outside of the United States. Most of our operations and administrative and corporate functions are conducted in the PRC. In addition, several of our directors and officers are nationals and residents of countries other than the United States. A substantial portion of the assets of these persons are located outside the United States. As a result, due to the lack of reciprocity and treaties between the United States and some of these foreign jurisdictions, together with cost and time constraints, it may be difficult for you to effect service of process within the United States upon these persons. In particular, several of our officers and directors are generally located in the PRC, and it will be more difficult to enforce liabilities and enforce judgments on those individuals. **If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired. Pursuant to Section 404 (a) of the Sarbanes- Oxley Act of 2002 (the “ Sarbanes- Oxley Act ”), our management is required to report upon the effectiveness of our internal control over financial reporting. Beginning with our annual report for our fiscal year ending December 31, 2024, we have become an “ accelerated filer. ” By becoming an “ accelerated filer, ” Section 404 (b) of the Sarbanes- Oxley Act will require our independent auditors to express an opinion on our internal control over financial reporting. Ensuring that we have adequate internal controls in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort that will need to be evaluated frequently. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, our independent registered public accounting firm may issue a report that is adverse, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the SEC or the Sarbanes- Oxley Act. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory**

requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. We may identify material weaknesses or significant deficiencies in our internal control over financial reporting in the future or fail to maintain effective internal control over financial reporting, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of the registrant's financial reporting. Remediation measures to remediate a material weakness or significant deficiency may be time consuming, may result in us incurring significant costs, and may place significant demands on our financial and operational resources. Our failure to identify and address any material weaknesses or significant deficiencies that may be identified in the future could result in material misstatements to our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our securities.