UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the year ended December 31, 2023

OR

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

For the transition period from _____ to

Commission file number: 000-51173

Gyre Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**56-2020050**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
12770 High Bluff Drive Suite 150 San Diego, CA	**92130**
(Address of principal executive offices)	**(Zip Code)**

(619) 949-3681

(Registrant's Telephone Number, Including Area Code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	**GYRE**	**The Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant (based on the closing price of such stock on The Nasdaq Capital Market on June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter) was approximately $11.1 million. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding common stock have been excluded because such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 19, 2024, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 85,423,246.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, is incorporated by reference from the registrant's definitive proxy statement relating to the Annual Meeting of Stockholders to be held in 2024 (the "Proxy Statement"), which shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

Gyre Therapeutics, Inc.
Annual Report on Form 10-K
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PART I

Forward-Looking Statements and Market Data

This Annual Report on Form 10-K (this "Annual Report") and the documents incorporated by reference herein contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements, other than statements of historical facts, included or incorporated by reference in this Annual Report regarding our strategy, future results of operations, future financial condition, future revenues, projected costs, prospects, plans, intentions and objectives of management, as well as the assumptions that underlie these statements, are forward-looking statements. These forward-looking statements should not be relied upon as predictions of future events as we cannot assure you that the events or circumstances reflected in these statements will be achieved or will occur. Forward-looking statements are identified by words such as "believes," "expects," "may," "will," "should," "seeks," "intends," "plans," "pro forma," "estimates," or "anticipates" or the negative of these words and phrases or other variations of these words and phrases or comparable terminology, although not all forward-looking statements contain these identifying words. Such forward-looking statements are based on our management's assumptions and assessments in light of information currently available to our management, its experience and its perception of historical trends, current conditions, expected future developments and other factors our management believes to be appropriate.

You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. For example, forward-looking statements include any statements regarding:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates and other positive results;
- our ability to develop a pipeline of product candidates to address unmet needs in the treatment of organ fibrosis and other inflammatory diseases;
- the timing, progress and results of clinical trials for F351 (Hydronidone) from the Phase 2a trial, F573 from the Phase 2 clinical trial, ETUARY from the Phase 2/3 clinical trial, and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the studies or trials will become available and research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of investigational new drugs (an "IND" or "INDs") and final FDA approval of F351 for the treatment of liver fibrosis associated with nonalcoholic associated steatohepatitis ("NASH") and chronic hepatitis B ("CHB"), ETUARY for the treatment of dermatomyositis-related interstitial lung disease ("DM-ILD") and sclerosis-related interstitial lung disease ("SSc-ILD"), F528 for the treatment of chronic obstructive pulmonary disease ("COPD"), F230 for the treatment of pulmonary arterial hypertension ("PAH"), and any other future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- our expectations regarding the future pursuit of product development efforts, including whether we will pursue such efforts, estimates regarding the expenses, future revenue, timing of any future revenue, capital requirements and need for additional financing related to such efforts, the timing of and our ability to pursue such efforts and our plans to develop and, if approved, subsequently commercialize any product candidates resulting from such efforts;
- our expectations regarding our ability to fund our operating expenses and capital expenditure requirements with our cash and investments;
- our ability to develop and advance current product candidates and programs into, and successfully complete, clinical studies;
- our manufacturing, commercialization and marketing capabilities and strategy;

- plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including estimates of the number of patients who suffer from the diseases we are targeting;
- expectations regarding the approval and use of our product candidates in combination with other drugs;
- expectations regarding the potential for accelerated approval or other expedited regulatory designation;
- our competitive position and the success of competing therapies that are or may become available;
- estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics and the potential safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates and our expectations regarding particular lines of therapy;
- plans relating to the further development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the People's Republic of China (the "PRC"), the United States, Europe, and other jurisdictions;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering ETUARY, F351, F573, F528, and F230, and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates and for the manufacture of our product candidates for clinical trials;
- our relationships with patient advocacy groups, key opinion leaders, regulators, the research community and payors;
- our ability to obtain and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of ETUARY, F351, F573, F528, and F230, and other product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of F351, and other product candidates the Company may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash will be sufficient to fund our planned operating expenses and capital expenditure requirements;
- expectations about the continued listing of our common stock on The Nasdaq Capital Market;
- the impact of laws and regulations; and
- expectations regarding the period during which we will qualify as a smaller reporting company under the Exchange Act.

Any such forward-looking statements are not guarantees of future performance and are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in or contemplated by such forward-looking statements. Factors that might cause such a difference include, but are not limited to, the risks and uncertainties described in this Annual Report, including those risks described in Part I, Item 1A, "*Risk Factors*," and Part II, Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations*,"" as well as others that we may consider immaterial or do not anticipate at this time. The risks and uncertainties described in this Annual Report, including in Part I, Item 1A, "*Risk Factors*," and Part II, Item 7, "*Management's Discussion and Analysis of Financial Condition and Results of Operations*," are not exclusive and further information concerning our company and our businesses, including factors that potentially could materially affect our operating results or financial condition, may emerge from time to time. All forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this Annual Report, speak only as of their date, and we undertake no obligation to update or revise these statements considering future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties, and you should carefully consider the factors set forth in other reports or documents that we file from time to time with the Securities and Exchange Commission (the "SEC").

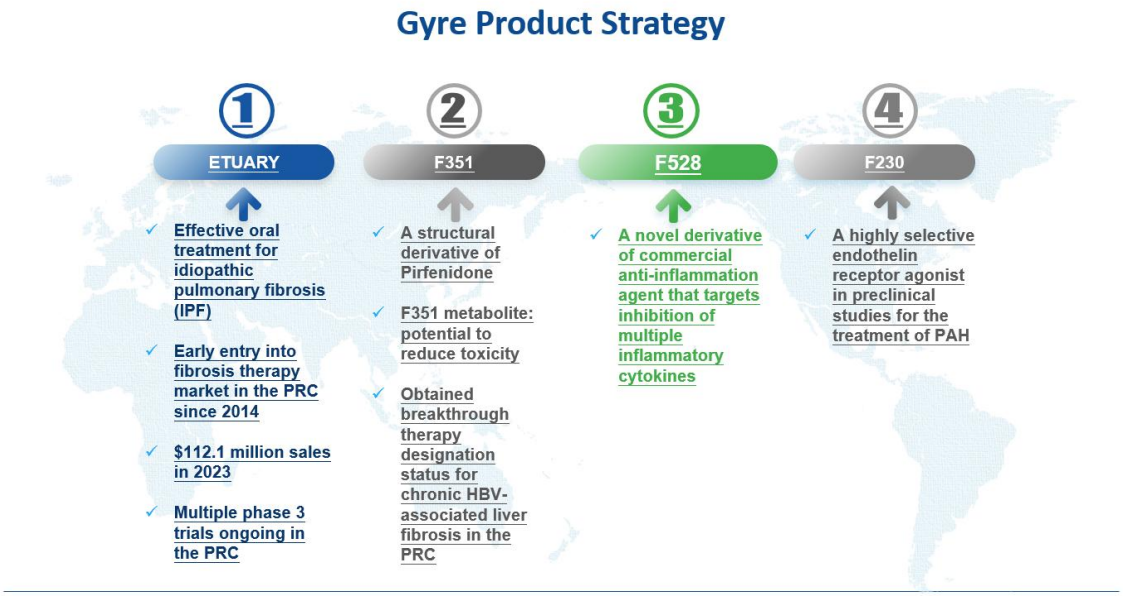
This Annual Report also contains estimates, projections and other information concerning our industry, our business, and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in such information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

Item 1. BUSINESS.

In this section, unless otherwise specified, references to "we," "our," "us" and "our company" refer to Gyre Therapeutics, Inc. and our majority indirectly owned subsidiary, Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals Co., Ltd.) ("Gyre Pharmaceuticals").

Summary

We are a financially-sustainable pharmaceutical company with a record of financial success that develops and commercializes small-molecule anti-inflammatory and anti-fibrotic drugs targeting organ diseases, focusing specifically on organ fibrosis. Fibrotic diseases represent a large patient population with significant unmet medical needs. Fibrosis involves a complex, multi-stage process with multiple pathways. While there are numerous potential targets for anti-fibrotic therapy, both established and emerging, addressing a single molecular pathway may not be sufficient to prevent, halt, or reverse fibrosis. Our strategy is to use our experience in the successful development and commercialization of ETUARY®(Pirfenidone) to expand into new indications and develop similar drug candidates.



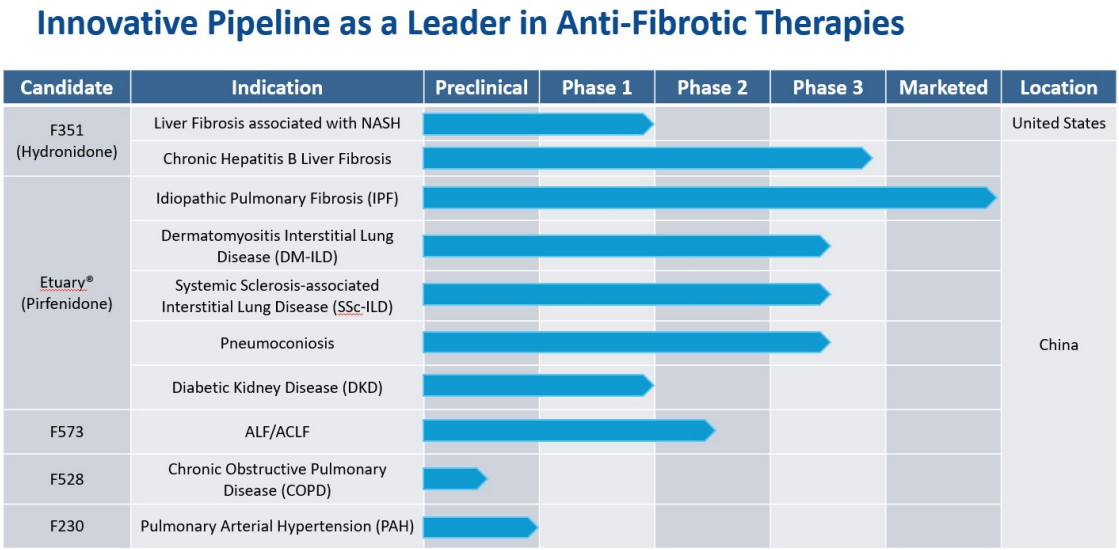
Pirfenidone, the first anti-fibrotic drug approved for idiopathic pulmonary fibrosis ("IPF") in Japan, the European Union ("EU"), the United States ("U.S."), and the PRC, is a small molecule drug that inhibits the synthesis of Tumor Growth Transforming ("TGF")-ß1, TNF-α, and other fibrosis and inflammation modulators. We have obtained approval for ETUARY (pirfenidone) in the PRC for IPF.

Gyre Pharmaceuticals successfully advanced Pirfenidone from research and development ("R&D") to commercialization in the PRC for the treatment of IPF. ETUARY's annual sales have consistently grown each year, reaching $112.1 million in 2023. In addition to IPF, Pirfenidone is undergoing three additional Phase 3 studies for connective tissue disease associated with interstitial lung disease ("CTD-ILD") to broaden its indications and market: SSc-ILD, DM-ILD and pneumoconiosis ("PD").

F351, our lead development candidate, is a structural derivative of ETUARY (Pirfenidone). It is a new oral chemical entity with an anti-fibrotic, TGF-ß1-targeting mechanism of action, for which we hold patents in major markets. Studies suggest that F351 and its major metabolites have minimal drug-drug interaction risks. Despite potential efficacy in IPF, we are prioritizing F351 for the treatment of liver fibrosis due to the large potential addressable market and significant unmet need.

Gyre Pharmaceuticals has completed a Phase 2 trial of F351 in the PRC for CHB-associated liver fibrosis. The Phase 2 trial showed that F351 was well-tolerated without notable toxicity and patients treated showed statistically-significant improvement of liver fibrosis, with the best efficacy results achieved at 270 mg/day dosing. Based on these results, a confirmatory Phase 3 trial is ongoing in the PRC. The enrollment of 248 patients for the confirmatory Phase 3 trial has been completed, with last patient out expected in 2024 and clinical results expected by early 2025.

In the U.S., we have completed a Phase 1 clinical trial of F351 in healthy volunteers. We are preparing an IND application and expect to submit it in late 2024. Following results from the PRC Phase 3 trial in CHB-associated liver fibrosis and pending approval of our IND, we expect to initiate a Phase 2a trial to evaluate F351 for the treatment of liver fibrosis associated with NASH in 2025.



Business Combination

On December 26, 2022, Catalyst Biosciences, Inc., a Delaware corporation ("Catalyst"), acquired (the "F351 Acquisition") the F351 Assets (as defined below) from GNI Group Ltd., a company incorporated under the laws of Japan with limited liability ("GNI Japan"), and GNI Hong Kong Limited, a company incorporated under the laws of Hong Kong with limited liability ("GNI Hong Kong" and, together with GNI Japan, the "Sellers"), pursuant to that certain Asset Purchase Agreement, dated December 26 2022 (the "F351 Agreement"), by and among Catalyst and the Sellers. Pursuant to the F351 Agreement, Catalyst acquired all of the assets and intellectual property rights primarily related to the Sellers' proprietary F351 compound (collectively, the "F351 Assets"), other than such assets and intellectual property rights located in the PRC. Under the terms of the F351 Agreement and upon the effective time of the transactions contemplated by the F351 Agreement, Catalyst paid the Sellers $35,000,000 in the form of: 6,266,521 shares of Catalyst common stock, par value $0.001 per share (the "Common Stock"); and 12,340 shares of Catalyst Series X Convertible Preferred Stock, par value $0.001 per share (the "Convertible Preferred Stock").

Also on December 26, 2022, Catalyst, GNI USA, Inc., a Delaware corporation ("GNI USA"), GNI Japan, GNI Hong Kong, Shanghai Genomics, Inc., a company organized under the laws of the PRC, the individuals (each, a "Minority Holder" and collectively, the "Minority Holders") listed on Annex A to that certain Business Combination Agreement (as amended, the "Business Combination Agreement"), and Continent Pharmaceuticals Inc., a Cayman Islands company limited by shares ("CPI"), entered into the Business Combination Agreement, pursuant to which, among other matters, Catalyst would acquire an indirect controlling interest in Beijing Continent Pharmaceuticals Co., Ltd, a company organized under the laws of the PRC (now doing business as Gyre Pharmaceuticals Co., Ltd.) ("BC" or "Gyre Pharmaceuticals"), pursuant to the following transactions: (a) GNI USA would contribute all of its ordinary shares in the capital of CPI, par value $0.0001 per share to Catalyst (the "CPI Contribution"), (b) GNI USA would contribute its interest in Further Challenger International Limited, a company incorporated and existing under the laws

of the British Virgin Islands with company number 1982271 ("FC"), to Catalyst (the "FC Contribution") and (c) each Minority Holder would contribute 100% of the interest he or she holds in his or her respective Entity (as defined in the Business Combination Agreement) to Catalyst (together with the CPI Contribution and the FC Contribution, the "Contributions").

On October 27, 2023, Catalyst entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") for a private placement with GNI USA (the "Private Placement"). Pursuant to the Securities Purchase Agreement, GNI USA agreed to purchase an aggregate of 8,110,000 units (the "Units") representing (i) 811 shares of Convertible Preferred Stock and (ii) warrants to purchase up to 811 shares of the Convertible Preferred Stock (the "Warrants"). The purchase price for each Unit was $0.6165, for an aggregate purchase price of approximately $5.0 million. The Private Placement closed on October 30, 2023. The Warrants were immediately exercisable at an exercise price of $4,915.00 per share of Convertible Preferred Stock, subject to adjustments as provided under the terms of the Warrants, and expire October 30, 2033. The references to share and per share amounts in this paragraph do not reflect the Reverse Stock Split (as defined below).

Effective at 12:01 a.m. Eastern Time on October 30, 2023 (the "Closing Date"), Catalyst (i) increased the number of authorized shares of Common Stock from 100,000,000 shares to 400,000,000 shares, (ii) effected a reverse 1-for-15 reverse stock split (the "Reverse Stock Split") and (iii) changed its name to "Gyre Therapeutics, Inc."

Also on the Closing Date, Gyre consummated the previously announced business combination pursuant to the certain Business Combination Agreement and, after giving effect to the Reverse Stock Split, (i) GNI USA contributed all of its ordinary shares in the capital of CPI to Gyre in exchange for 45,923,340 shares of Common Stock, (ii) GNI USA contributed its interest in FC, to Gyre in exchange for 17,664,779 shares of Common Stock and (iii) each Minority Holder contributed 100% of the interest he or she holds in his or her respective Entity to Gyre in exchange for an aggregate of 10,463,627 shares of Common Stock. Immediately after the Contributions, Catalyst's stockholders as of immediately prior to the Contributions owned approximately 2.5% of the outstanding shares of Gyre, GNI USA owned approximately 85.3% of the outstanding shares of Gyre and the Minority Holders owned approximately 12.3% of the outstanding shares of Gyre, in each case, assuming conversion of the Convertible Preferred Stock issued in connection with the F351 Agreement and the Convertible Preferred Stock issued in connection with the Private Placement and subject to certain assumptions.

Following the completion of the Contributions, the business conducted by the registrant became primarily the business conducted by Gyre, which is a biopharmaceutical company committed to the research, development, manufacturing and commercialization of innovative drugs for organ fibrosis.

Overview

We are committed to bringing better treatments through innovation to patients with organ fibrosis. We seek to implement the following strategies to achieve our mission and goals:

Leverage our resources and expertise in the PRC to attain rapid proof-of-concept through cost-effective and efficient pre-clinical studies and early-stage clinical development and apply them elsewhere in the world

Founded in 2002, Gyre Pharmaceuticals became a part of our company in 2023 through a business combination transaction. In the PRC, it has established a strong presence by successfully developing and commercializing ETUARY (pirfenidone capsule) for the treatment of IPF, capturing a significant market share. The success of ETUARY enabled Gyre Pharmaceuticals to develop comprehensive pharmaceutical capabilities, including robust and cost-efficient R&D resources for conducting various clinical trials, manufacturing capabilities, and an extensive nationwide sales and marketing network in the PRC. Additionally, the availability of government support for biotechnology projects in the PRC enhances Gyre Pharmaceuticals' ability to undertake pre-clinical and clinical development processes effectively and economically. We expect to leverage the knowledge and know-hows from Gyre Pharmaceuticals' studies in the PRC as a basis for conducting clinical studies to address unmet medical needs in organ fibrosis elsewhere in the world.

Build our position in the treatment of fibrosis diseases, develop our product portfolio and explore indication expansion

We have successfully commercialized ETUARY for the treatment of IPF in the PRC and we expect to continue to research and develop the use of ETUARY in other indications to build our market position, including ongoing Phase 3 clinical trials for the treatment of SSc-ILD, DM-ILD and PD in the PRC. We have also successfully completed a Phase 1 clinical trial in ETUARY for our diabetic kidney disease ("DKD") program.

In addition to expanding indications for ETUARY, our clinical-stage pipeline includes F351, our lead product candidate, for the treatment of CHB-associated liver fibrosis, the prevalence of which reached 63.6 million patients in 2022 in the PRC according to Frost & Sullivan, and for the treatment of NASH-associated liver fibrosis in the U.S. We commenced patient enrollment for our Phase 3 clinical trial of F351 in the PRC in January 2022 and fully enrolled the 248-patient study in October 2023. We have completed our Phase 1 clinical trial of F351 in the U.S. and expect to submit an IND in late 2024. Our clinical-stage pipeline also includes F573 for the treatment of acute/acute-on-chronic liver failure ("ALF/ACLF"). We initiated our Phase 2 clinical trial of F573 in the PRC in March 2023.

Our preclinical-stage product pipeline includes F528 for the treatment of COPD, and F230 for the treatment of PAH. We believe that F528 could provide a first-line therapy for COPD and reduce long-term lung function degradation. On March 13, 2024, we submitted an IND application for F230 to the PRC Center for National Medical Products Administration ("NMPA").

Further enhance our academic promotion and expand our sales network

Enhancing academic promotion is one of our key sales approaches. We work to maintain close and long-term collaboration with academic organizations, promote expert consensus, attend international and domestic academic conferences, closely communicate with Key Opinion Leaders ("KOLs") and improve our brand recognition. We actively participate in online and offline academic activities and host academic conferences to promote market education, raise our brand recognition and increase the clinical use of our products.

We have established a comprehensive sales network in the PRC which positions us to quickly realize sales once a product candidate is approved. We provide on-the-job training to our sales team to educate them on the latest research and clinical practice and gain an in-depth understanding of the clinical benefits of our product portfolio. To expand the geographic coverage of product sales, precisely target the clinical needs and improve our market penetration, we deploy our sales teams and resources to hospitals and expand our reach to additional small and medium-sized cities across the PRC.

Prudently build our product portfolio through value accretive business development and strategic collaborations

Complementary to our in-house R&D efforts, we continue to stay abreast of cutting-edge technology and product developments in the industry by bringing in products and technology that are in line with our development strategies and R&D principle through acquisition, in-licensing or collaboration. We intend to build a dedicated and seasoned business development team to seek value accretive opportunities to support our growing business development needs.

We proactively yet prudently source, identify, and execute promising in-licensing or acquisition opportunities. We have acquired or in-licensed the intellectual property rights of certain drug candidates from GNI Japan, particularly the intellectual property rights to F351 outside the PRC. Leveraging our medical and pharmaceutical network, we will continue to collaborate with domestic and multinational industry leaders to optimize our pipeline structure and maximize the clinical and commercial value of our product portfolio.

We continue to focus on high-quality products that are synergistic with our existing product pipeline. For instance, to enrich our hepatic product pipeline, we have acquired promising products for the treatment of thrombocytopenia in patients with chronic liver disease. Meanwhile, leveraging our R&D and commercial experience, we are also exploring other disease areas, such as multiple sclerosis.

Expand and upgrade our facilities to increase production capacity and control production costs

To facilitate R&D of our product pipelines, meet growing market demands, and realize our plan of sales expansion, we commenced the construction of an innovative drug research, development and production center in Shunyi, Beijing

in June 2022. We plan to add additional production capacity of 500 million capsules by 2024 and continue to scale up our production capacity in accordance with our sales and the market demand for our products and product candidates.

In addition, we expect to ramp up our production capacity in line with the development and commercialization progress of our products. To secure stable and sufficient supply of active pharmaceutical ingredients ("APIs") of high quality at reasonable costs, we have built our API production center in Cangzhou, PRC and expanded our production capacity through technology upgrades. We have completed this upgrade, and our annual production capacity is 50 tons of APIs at our Cangzhou facility. Our API production capability reduces our reliance on the upper-stream suppliers of raw materials, improves our cost management and provides us pricing advantages.

Continually attract, develop and retain high-quality talent

As a profitable and innovative pharmaceutical company, maintaining a streamlined, talented team tailored to the features of our product pipeline and our development needs is crucial for our success. To attract and retain talent, we are committed to the consistent development of a cohesive and vibrant corporate culture and attach great importance to the training and development of each of our employees.

Our experienced sales and marketing team is crucial to our continuous growth. To expand our national network and penetrate into small and medium-sized cities across the PRC, we intend to further strengthen our sales and marketing capabilities by gradually increasing our headcount in this area. As an innovative company, we recruit experienced and skilled production technicians and R&D talent in related fields in the PRC and the U.S. We also plan to build our business development team to coordinate and implement our strategic collaboration plans.

We believe the following strengths position us to execute on our strategies:

Long-term commitment to the treatment of organ fibrosis, with ETUARY being one of the first three drugs approved for the treatment of IPF globally

Our pipeline and our revenue of $112.1 million and $99.2 million for ETUARY in 2023 and 2022, respectively, has laid a solid foundation for us in organ fibrosis treatment. ETUARY is the first drug in the PRC and among the first three drugs in the world approved to treat IPF.

In addition, we have a pipeline of drug candidates focusing on the treatment of fibrosis of various organs, including lung, liver and kidney. Among them, F351 is being developed for the treatment of CHB- and NASH-associated liver fibrosis. We are also expanding the indication of our ETUARY to various other diseases.

Development of F351 as potentially the first approved drug for CHB-associated liver fibrosis in the PRC and development candidate for the treatment of NASH-associated liver fibrosis in the U.S.

With nearly 20 years of dedicated research in pulmonary fibrosis diseases and deep know-how accumulated in organ fibrosis treatment, coupled with the fact that fibrosis occurs in different organs with a similar pathogenic mechanism, we have expanded from pulmonary fibrosis to the treatment of liver fibrosis to address unmet clinical needs and a growing market. Our innovative small molecule drug, F351, has demonstrated a favorable profile for the treatment of CHB-associated liver fibrosis in clinical trials. It is designed to reverse liver fibrosis by inhibiting hepatic stellate cell proliferation while simultaneously blocking the TGF-ß1 signaling pathway, both of which play important roles in CHB-associated liver fibrosis. Due to the severity of the disease and the clinical trial progress of F351 compared with the currently available treatments, in March 2021, the Center for Drug Evaluation ("CDE") of the NMPA in the PRC granted F351 a Breakthrough Therapy designation, which helps to accelerate the review of drugs that have early evidence to suggest that the drug may demonstrate a substantial improvement over currently available therapies. We commenced patient enrollment for our Phase 3 clinical trial in January 2022. As of October 2023, we have completed the full enrollment of 248 subjects and we expect to have the last patient out in 2024 and to submit an NMPA application for F351 in the PRC in early 2025.

In the U.S., we are actively preparing to file an IND application in late 2024 for a Phase 2 clinical trial to evaluate F351 for the treatment of NASH-associated liver fibrosis.

Professional sales and marketing team and nationwide sales network

There is an extremely high barrier for commercializing orphan drugs due to the scarcity of patients. We have established a professional sales and marketing team and a broad sales network during the commercialization of ETUARY, which are evidenced by its strong sales track record and dominant market position. Currently, our sales network covers 30 provinces, autonomous regions and municipalities in the PRC. Our sales network has grown significantly, covering 2,901 and 35,512 hospitals and pharmacies in 2022 and 2023, respectively.

As of December 31, 2023, our sales and marketing team had 391 employees with an average of nine years of experience. Among them, our vice president in charge of sales has more than 25 years of experience in multinational pharmaceutical companies and the PRC's innovative pharmaceutical companies, and our core regional managers have an average of 17 years of industry experience and 11 years of management experience. One-third of the other members of our sales team worked for international pharmaceutical companies and one-fourth have a bachelor's degree or above in biology, medicine or pharmacy. We believe that our integrated sales network and accumulated management and sales experience will allow us to continue to be a dominant player in the IPF market in the PRC and to achieve rapid sales of new products once if and when they are launched.

Large in-house manufacturing facilities and strict quality control

Our ability to produce both APIs and drug products internally provides us with stringent control over the supply chain, which enables us to maintain cost-effective production and lower our exposure to unforeseen supply chain disruptions. For more details about our two manufacturing centers, manufacturing capabilities and processes, see "*—Properties—Gyre Pharmaceuticals' Properties*" and "*—Production and Quality Control—In-House Manufacturing Facilities.*"

Experienced senior management team with strong execution capability

We have an experienced management team with strong execution capability and an average of more than 20 years of industry experience both in the U.S. and the PRC.

Intellectual Property

Our success depends in part upon our ability to protect our core technology and intellectual property. Our intellectual property is critical to our business and we strive to protect it through a variety of approaches, including by obtaining and maintaining patent protection in the United States and internationally for our product candidates, new targets, indications and applications and other inventions important to our business. For our product candidates, we generally pursue patent protection covering compositions of matter, methods of manufacture and methods of use. As we further develop our product candidates, we plan to identify additional novel candidates for patent protection that may potentially enhance commercial success, including pursuit of claims directed to new therapeutic indications. We enter into collaboration agreements and other relationships with pharmaceutical companies and other industry participants to leverage our intellectual property or gain access to the intellectual property of others.

Patents

As of the date of this Annual Report, Gyre owns 15 granted patents globally, 11 pending patent applications in the PRC and eight Patent Cooperation Treaty ("PCT") patent applications. As of the date of this Annual Report, we are the owner of all the patents and patent applications which are material to our business.

The term of individual patents depends on the legal term for patents in the jurisdictions in which they are granted. In most jurisdictions, the patent term for inventions is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable jurisdiction. The actual protection afforded by a patent varies on a claim-by-claim and country-by-country basis and depends upon many factors, including the type of patent, the scope of its coverage, the availability of any patent term extensions or adjustments, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Although ETUARY's (Pirfenidone) substance patent expired in August 1993, Gyre currently holds one process patent that expires in 2038 and one dosage and administration patent that expires in 2024 regarding Pirfenidone. In addition,

Gyre holds a family of patents for methods using Pirfenidone compositions to treat certain cytotoxic- or radiation-induced injuries, such as pneumonitis, consisting of granted patents in Europe, Japan, the PRC, Canada, and the U.S.

Our F351 patent portfolio currently consists of six patent families, including patents and/or patent applications in various countries and under the PCT. The first patent family is for pharmaceutical compositions thereof, as well as methods for preparing or using F351 to treat fibrosis, of which one U.S. patent expires on September 22, 2024. The second patent family is for a method of preparing F351 and consists of one granted patent in the PRC that expires in 2028, two granted pants in Japan, both of which expire in 2037, and 2 PCT patent applications and 6 pending patent applications in the PRC. The third patent family is for a method of preparing a crystal form of F351 and consists of one granted patent in the PRC that expires in 2041. The fourth patent family relates to methods for using F351 to treat and/or prevent chronic hepatitis B with hepatic fibrosis and consists of one PCT patent application and one pending patent application in each of the PRC, Canada, and Australia. The fifth patent family pertains to the use of pharmaceutical compositions or drug kits in the preparation of drugs to treat or relieve pulmonary fibrosis or to improve the symptoms of pulmonary fibrosis and consists of one pending patent application in the PRC and one PCT patent application. The sixth patent family is for F351 compositions and methods of using F351 for treating liver fibrosis, liver cirrhosis, advanced hepatitis B and NASH and consists of one PCT patent application and one pending patent application in each of the PRC, Australia, Canada, Europe, Israel, Japan, South Korea, Mexico, New Zealand, Singapore, and the U.S.

For F573, Gyre owns two granted patents in the PRC, which both expire in 2031, one patent application in the PRC and one PCT patent application. For F528, Gyre owns one PCT patent application and one patent application in each of the PRC, Japan, Europe, and the U.S.

We expect to continue to file patent applications to cover methods of treating additional indications, as well as new forms, formulations, and methods of manufacturing F351 and other drug candidates.

Trade Secrets

We may rely, in some circumstances, on trade secret and/or confidential information to protect aspects of our technology. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with consultants, scientific advisers and contractors. We have entered into confidentiality agreements and non-competition agreements with our senior management and key members of our R&D team and other employees who have access to trade secrets or confidential information about our business.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. For details of risks related thereto, see "*—Risk Factors—Risks Related to Our Intellectual Property*".

Trademarks and Domain Names

We conduct our business under the brand name of "Continent" or "康蒂尼". As of December 31, 2023, we own four registered artwork copyrights, 23 registered software copyrights and 35 registered trademarks in the PRC. We also own seven registered trademarks in Hong Kong, one international trademark of "ETUARY" and the trademark application of "ETUARY" in seven countries and regions including the United States, EU and Japan. As of the same date, we also hold 28 active domain names.

Our Operations in the United States

In this section, references to "we," "our," "us" and "our company" refer to Gyre Therapeutics, Inc.

Our U.S. operations are headquartered in San Diego, CA, and primarily focus on the development and commercialization of F351 (Hydronidone) for the treatment NASH-associated liver fibrosis. The development strategy for F351 in NASH-associated liver fibrosis is based on results obtained in mechanistic studies in NASH rodent models and results of Gyre Therapeutics' Phase 2 clinical trial evaluating F351 for the treatment of CHB-induced liver fibrosis in the PRC, which met the primary endpoints of safety and efficacy and led to Breakthrough

Therapy designation by the NMPA. We have completed a Phase 1 clinical trial of F351 in the U.S. and intend to submit an IND for our Phase 2 clinical trial in the fourth quarter of 2024.

Disease Overview - NASH

NASH (also known as metabolic dysfunction-associated steatohepatitis, or "MASH"), a severe form of non-alcoholic fatty liver disease ("NAFLD"), also known as metabolic dysfunction-associated steatotic liver disease ("MASLD"), an umbrella of conditions caused by the build-up of extra fat in the liver that is not caused by alcohol intake, is characterized histologically by the additional presence of inflammation and hepatocellular injury, such as visible ballooning, and has a significantly worse prognosis, with the potential to progress to liver fibrosis, cirrhosis or hepatocellular carcinoma ("HCC").

NASH represents a large and rapidly growing problem in the U.S. and worldwide. Diagnoses have been on the rise and are expected to increase dramatically in the next decade. The prevalence of NAFLD, which affects approximately 25% of the global population, and NASH, which develops in approximately 20% to 30% of NAFLD patients, is driven primarily by the worldwide obesity epidemic. As a result, the prevalence of NASH has increased significantly in recent decades, paralleling similar trends in the prevalence of obesity, insulin resistance and Type 2 diabetes. The prevalence of these conditions is expected to increase further due to unhealthy nutrition habits, such as consumption of a diet high in fructose, sucrose and saturated fats, and sedentary behavior.

The critical pathophysiologic mechanisms underlying the development and progression of NASH include reduced ability to metabolize clear lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. NASH patients have an excessive accumulation of fat in the liver resulting primarily from a caloric intake above and beyond energy needs. A healthy liver contains less than 5% fat, but a liver in someone with NASH can contain more than 20% fat. This abnormal liver fat contributes to the progression to NASH, a liver necro-inflammatory state, that can lead to scarring, also known as fibrosis, and, for some, can progress to cirrhosis and liver failure—cirrhosis develops in approximately 20% to 45% of patients. In some cases, cirrhosis progresses to decompensated cirrhosis, which results in permanent liver damage that can lead to liver failure. In addition, it is estimated that 8% of patients with advanced fibrosis will develop HCC. NASH is a complex, multifaceted disease that does not just affect the liver. Patients with NASH frequently have other significant metabolic co-morbidities such as obesity, hyperglycemia, dyslipidemia and systemic hypertension (a constellation of which is commonly referred to as metabolic syndrome) and these further contribute to the risk of cardiovascular disease.

Etiology of NASH

Understanding of the pathophysiologic mechanisms that lead to NASH has evolved in recent years but still remain insufficiently elucidated. Excessive caloric overload, metabolic dysregulation, cardio-metabolic co-morbidities and genetic risk factors increase the likelihood of developing NASH, with a multitude of potential mechanistic contributors to pathophysiology. In NASH, the liver's capacity to handle the primary metabolic energy substrates, carbohydrates and fatty acids, is overwhelmed. This occurs when there is an excess of free fatty acids deposited in the liver or their disposal from the liver is impaired. The accumulation of surplus free fatty acids leads to the formation of toxic lipid species. These toxic lipids then induce endoplasmic reticulum stress, oxidative stress and an inflammatory response, which can result in hepatocellular injury and death. This may lead to fibrosis and genomic instability, which may worsen over time to cirrhosis and HCC, respectively. The critical pathophysiologic mechanisms underlying development and progression of NASH include (1) reduced ability to handle lipids, (2) increased insulin resistance, (3) injury to hepatocytes and (4) development and progression of liver fibrosis in response to hepatocyte injury.

Diagnosis

Most people with NASH are asymptomatic and their disease is often discovered incidentally following a liver imaging procedure, such as an ultrasound, prescribed for other reasons or as part of an investigation for elevated liver enzymes. Once suspected clinically, a liver biopsy is required to definitively diagnose NASH, which necessitates the joint presence of steatosis, ballooning, and lobular inflammation. Once pathologically confirmed, the severity of NAFLD and NASH is determined using the histologically validated NAS, which grades disease activity on a scale of 0 to 8. The NAS is the sum of the individual scores for steatosis (0 to 3), lobular inflammation (0 to 3), and hepatocellular ballooning (0 to 2) but does not include a score for fibrosis. Fibrosis staging (F0-F4) relies on the Kleiner classification

(F0 = no fibrosis; F1 = perisinusoidal or periportal fibrosis (not both); F2 = both perisinusoidal and periportal fibrosis; F3 = bridging fibrosis; F4 = cirrhosis).

Histological diagnosis remains the gold standard for assessment of NASH and fibrosis. However, given that liver biopsy is associated with risks of pain, bleeding and other morbidity, as well as significant cost, the procedure is not practical for general patient screening. Additionally, histology diagnosis is confounded by evaluation of a small sliver of a large heterogenous organ that may not represent the full organ, and significant variability in reading of slides including inter- and intra-reader variability. Several non-invasive tools such as clinical risk scores, serum markers and imaging techniques are increasingly used to assess NASH patients. Non-invasive tests ("NITs") such as the Fibroscan-AST score, Fibrosis-4 index, the Enhanced Liver Fibrosis score and vibration-controlled transient elastography, have been validated and are increasingly used. These NITs have an excellent negative predictive value and an acceptable positive predictive value for detection of advanced (≥ F3) fibrosis and are increasingly used in clinical settings. Additionally, evidence is emerging that shows a correlation between reduction in steatosis as measured by MRI-proton density fat fraction (MRI-PDFF) and reduction in ALT ≥17 U/L and histologic improvement on liver biopsy. In their draft guidance, the FDA encouraged sponsors to identify biochemical or noninvasive imaging biomarkers that, once characterized and agreed by the FDA, could replace liver biopsies for patient selection and efficacy assessment in clinical trials.

We expect that the validation and subsequent adoption of these NITs will result in an increase in the diagnosis and treatment rates for NASH in the future.

Our Clinical-Stage Product Candidate: F351

Overview of F351

F351, our Phase 1 clinical-stage drug candidate, has the potential to treat NASH-associated liver fibrosis. We anticipate filing an IND application and initiating a Phase 2a clinical trial for the treatment of NASH-associated liver fibrosis in the United States in 2024.

F351 is a structural analogue of the approved anti-fibrotic (pulmonary fibrosis) drug ETUARY, but with medicinal chemistry that has been modified to potentially reduce the safety liabilities associated with Phase 1 metabolism. F351 is designed to treat liver fibrosis by inhibiting the activation of hepatic stellate cells ("HSCs") through Smad7-mediated TGF-ß degradation, as well as decreasing the expression of fibrosis-related genes. The TGF-ß is a central mediator of fibrogenesis in tissues. Activation of the HSCs is recognized as a central event in the progression of liver fibrogenesis, with the TGF-ß as one of the key mediators.

F351 has been shown to inhibit *in vitro* both p38γ kinase activity and TGF-ß1-induced excessive collagen synthesis in HSCs. This is further supported by its anti-proliferative effects on the HSCs in the liver. *In vitro* anti-fibrotic effects of F351 were also confirmed in several established *in vivo* rodent models of liver fibrosis, such as carbon tetrachloride ("CCl_4")-induced liver fibrosis mouse model, DMN-induced liver fibrosis rat model, and HSA-induced liver fibrosis rat model, as well as mouse model of NASH fibrosis (CCl_4 +Western [High Fat] Diet). In the NASH mouse model, F351 significantly reduced the severity of fibrosis, as well as demonstrated improvements in the functional, biochemical and histopathological attributes of the affected liver tissue, including a significant reduction of hydroxyproline content and liver enzymes (ALT), aspartate (AST), a decrease in liver fat degeneration, and decreases in the levels of several of inflammatory cytokines at doses of 3-10 mg/kg/day, as well as a decrease in the NAS score in the CCl_4 and WD-induced fibrosis and cell ballooning NASH models at doses of 15-50 mg/kg bid (HEDs of 144 – 480 mg) which are relevant to human exposure. Thus, the key attributes of F351's molecular mechanisms of action in animal models of liver fibrosis support its efficacy potential in liver fibrosis of various etiologies including those associated with NASH.

Phase 1

The clinical development of F351 in the United States includes a completed Phase 1 clinical trial that evaluated the safety, tolerability, and PK of single and multiple doses of F351 in U.S. healthy volunteers, and collected bridging data to the data obtained in healthy volunteers in the PRC. This Phase 1 clinical trial of F351 was conducted on the

basis of an IND that was filed in 2016 for F351 as an anti-fibrotic agent with a focus on liver fibrosis associated with a spectrum of chronic liver diseases.

Following single oral doses of F351 30 mg or 120 mg in Part I of the trial, F351 was rapidly absorbed, showing a linear PK pattern of exposure with mean elimination half-life of five to six hours, and five to seven hours for M3 and M4 metabolites. Following repeated oral doses of F351 30 mg or 120 mg TID for seven days in Part II of the trial, F351 capsules were rapidly absorbed with a similar PK pattern of exposure and similar half-life as seen following single doses of F351. Modest accumulation (less than a 1.5-fold increase) was observed for F351, M3 and M4 with repeated 30 mg or 120 mg TID. Dose-normalized F351 C_{max} and AUC values were similar in males and females.

Overall, F351 was well tolerated when administered as a single oral dose of 30 mg or 120 mg and when administered as repeated oral doses of 30 mg or 120 mg TID for seven consecutive days. There were no premature discontinuations due to adverse events ("AEs"), no serious adverse events ("SAEs"), and no deaths reported in this trial. Treatment-emergent AEs reported following single dose administration in Part I of the trial included a single AE of rhinorrhoea and scattered, isolated, reversible laboratory abnormalities. Treatment-emergent AEs reported following repeated dose administration in Part II of the trial included headache (25.0%), constipation (16.7%) and somnolence (12.5%). Abdominal discomfort and flatulence were also reported as gastrointestinal AEs in one subject each. There were no clinically significant overall changes in safety laboratory tests that were attributable to trial drug product, including no evidence of any significant drug-induced liver injury or clinically significant overall changes in vital signs, ECG parameters or physical examinations that were attributable to trial drug product.

Phase 2

We plan to initiate Phase 2a clinical development of F351 in NASH-associated liver fibrosis. The goal of the proposed Phase 2a clinical trial is to obtain early Proof-of-Concept ("PoC") for F351 in subjects with NASH-associated liver fibrosis as a basis of expansion into a more comprehensive Phase 2/3 clinical program. This trial will be conducted under a new IND, reflecting the distinct risk-benefit profile that the drug may have in a NASH patient population. To support the IND filing and initiation of the proposed Phase 2a clinical trial, we plan to cross-reference all nonclinical and clinical data obtained in trials completed under the currently-active IND in the United States, as well as those previously completed in the PRC. We believe that the results obtained in these nonclinical and clinical studies provide adequate information on the current clinical risk/benefit profile of the drug and allow for safe initiation of the proposed Phase 2a clinical trial of F351 in NASH-associated liver fibrosis. In connection with the F351 Acquisition, GNI initiated the transfer of ownership of the IND to us.

Agreements Relating to the F351 Program

F351 Asset Purchase Agreement

On December 26, 2022, we acquired the F351 Assets from the GNI Japan and GNI Hong Kong. Pursuant to the F351 Agreement, we acquired all of the assets and intellectual property rights primarily related to GNI Japan's and GNI Hong Kong's proprietary F351 compound, other than such assets and intellectual property rights located in the PRC. The F351 Assets include 15 issued or pending patents and patent applications outside of the PRC, with the last acquired issued patent expected to expire in August 2037. Under the terms of the F351 Agreement and upon the effective time of the transactions contemplated by the F351 Agreement, we paid GNI Japan and GNI Hong Kong $35,000,000 in the form of: 6,266,521 shares of Common Stock; and 12,340 shares of Convertible Preferred Stock.

Competition

The biopharmaceutical industry is intensely competitive and subject to rapid innovation and significant technological advancements. We believe the key competitive factors that will affect the development and commercial success of F351 and any future product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price, the level of generic competition and reimbursement. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. A number of biotechnology and pharmaceutical companies are pursuing the development or marketing of pharmaceuticals that target the same diseases that we are targeting. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Given the high

incidence of NASH, it is likely that the number of companies seeking to develop products and therapies for the treatment of liver and cardio-metabolic diseases, such as NASH, will increase.

If F351 is approved for the treatment of NASH-associated liver fibrosis, future competition could also arise from five main classes of drugs aiming to reach the market in the current NASH landscape: Farnesoid X receptor agonists, fibroblast grow factor 21, thyroid hormone receptor-β agonists, glucagon-like peptide 1 ("GLP-1") agonists, and PPAR agonists, but there are others as well. Resmetirom, a beta-thyroid hormone receptor agonist from Madrigal Pharmaceuticals, Inc. became the first drug to be approved by FDA for the treatment of adults with noncirrhotic NASH with moderate to advanced liver fibrosis, to be used along with diet and exercise; other candidates include VK2809 a beta-thyroid hormone receptor agonist from Viking Therapeutics, Inc.; Aldafermin, an FGF19 analog from NGM Biopharmaceuticals, Inc.; denifanstat, novel fatty acid synthase (FASN) inhibitor from Sagimet Biosciences; MK-3655, an FGFR1c/KLB agonist antibody from Merck & Co., Inc.; Efruxifermin, a FGF21 fusion protein from Akero Therapeutics, Inc.; Pegozafermin, a FGF21 fusion protein from 89bio, Inc.; Belapectin, a Galectin-3 inhibitor from Galectin Therapeutics Inc.; Aramchol, a synthetic conjugate of cholic acid and arachidic acid from Galmed Pharmaceuticals Ltd.; Semaglutide, a GLP-1 receptor agonist from Novo Nordisk A/S; Pemvidutide/ALT-801, a dual GLP-1/glucagon agonist from Altimmune; Tirzepatide, a dual GIP/GLP-1 receptor agonist from Eli Lilly and Company; Lanifibranor, a PPAR alpha/delta/gamma agonist from Inventiva; NNC0194-0499, an FGF21 analog from Novo Nordisk; BOS-580, an FGF21 analog from Boston Pharmaceuticals; and BFKB8488A, an FGFR1/KLB agonist antibody from Genentech; and pegozafermin, a specifically engineered glycoPEGylated analog of fibroblast growth factor 21 from 89bio, Inc.

Manufacturing and Supply

The manufacturing of F351 active pharmaceutical ingredients ("API") and drug product supplies required for supporting the Phase 2a clinical trial in NASH-associated liver fibrosis was completed at WuXi STA, based in the PRC. The API and drug product are of current Good Manufacturing Practice ("cGMP") grade quality, and batch release and stability studies comply with applicable regulatory requirements.

In light of the recently introduced BIOSECURE Act, which would prohibit federal agencies from entering into procurement contracts with an entity that uses biotechnology equipment or services from a biotechnology company of concern, we have taken several measures to strengthen our supply chain in the event that Wuxi Biologics, Inc. ("Wuxi Biologics") or one of our other manufacturers is impacted. We are carefully monitoring and assessing the situation surrounding Wuxi Biologics and deliberating various options, including switching to a different CDMO for F351 clinical trials in the U.S. We will also continue to closely monitor geopolitical risk and implement additional mitigations and supply chain redundancies, as needed. See the risk factor entitled "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."

Government Regulation in the United States

Government authorities in the United States, at the federal, state and local levels, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, product approval, manufacture, quality control, manufacturing changes, packaging, storage, recordkeeping, labeling, promotion, advertising, sales, distribution, marketing, and import and export of drugs. Our current product candidates are expected to be regulated as pharmaceutical drugs. The processes for obtaining regulatory approval in the United States and in foreign countries and jurisdictions, along with compliance with applicable statutes and regulations and other regulatory authorities both pre- and post-commercialization, are a significant factor in the production and marketing of our products and our research and development activities and require the expenditure of substantial time, human capital and financial resources.

Review and Approval of Drugs

In the United States, the FDA and other government entities regulate drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and the regulations promulgated thereunder, as well as other federal and state statutes and regulations. Failure to comply with applicable legal and regulatory requirements in the United States at any time during the product development process, approval process, or after approval, may subject us to a variety of

administrative or judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, withdrawal of approvals, delay or suspension of clinical trials, issuance of warning letters and other types of regulatory letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil monetary penalties, refusals of or debarment from government contracts, exclusion from the federal healthcare programs, restitution, disgorgement of profits, civil or criminal investigations by the FDA, U.S. Department of Justice, State Attorneys General, and/or other agencies, False Claims Act suits and/or other litigation, and/or criminal prosecutions.

An applicant seeking approval to market and distribute a new drug in the United States must typically undertake the following:

- completion of pre-clinical laboratory tests, animal studies, chemical synthesis and manufacturing and formulation studies in compliance with the FDA's GLP, regulations;
- submission to the FDA of an IND for human clinical testing, which must become effective without FDA objection before human clinical trials may begin;
- approval by an independent institutional review board ("IRB"), representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with the FDA's good clinical practice ("GCP"), regulations, to establish the safety and effectiveness of the proposed drug product for each indication for which approval is sought;
- preparation and submission to the FDA of a New Drug Application ("NDA");
- review of the NDA by an FDA advisory committee, where applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the drug product, and the active pharmaceutical ingredient or ingredients thereof, are produced to assess compliance with cGMP, regulations and to assure that the facilities, methods, and controls are adequate to ensure the product's identity, strength, quality, and purity;
- payment of user fees, as applicable, and securing FDA approval of the NDA; and
- compliance with any post-approval requirements, such as any risk evaluation and mitigation strategy ("REMS"), or post-approval studies required by the FDA.

Preclinical Studies and an IND

To file an IND, an organization must produce batches of the actual material of drug substance and drug product to be used in the clinical trial. The batches of drug substance and drug product need to be characterized analytically before release and placed on stability. At least one month of stability data must be included in the IND upon submission.

Preclinical studies can include *in vitro* and animal studies to assess the potential for adverse events and, in some cases, to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations. Other studies include laboratory evaluation of the purity, stability and physical form of the manufactured drug substance or API and the physical properties, stability and reproducibility of the formulated drug or drug product. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical studies, among other things, to the FDA as part of an IND to justify that the proposed clinical study may safely proceed. Some preclinical testing, such as longer-term toxicity testing, animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Following commencement of a clinical trial under an IND, the FDA may place a clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing

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

Human Clinical Studies in Support of an NDA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

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

Phase 1: The product candidate is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.

Phase 2: The product candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. Phase 1, Phase 2, and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites in late-stage clinical trials to assure compliance with GCP and the integrity of the clinical data submitted.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. In the United States, when a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived, and some of the requirements may be waived upon the FDA's decision. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with applicable FDA regulatory requirements in order to use the study as support for an IND or application for marketing approval or licensure, including that the study was conducted in accordance with GCP, including review and approval by an independent ethics committee and use of proper procedures for obtaining informed consent from subjects, and the FDA is able to validate the data from the

study through an onsite inspection if the FDA deems such inspection necessary. The GCP requirements encompass both ethical and data integrity standards for clinical studies.

Submission of an NDA to the FDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical and clinical studies, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee, currently approximately $4.0 million for fiscal year 2024, for applications requiring clinical data, and the sponsor of an approved NDA is also subject to an annual program fee, currently approximately $0.4 million for fiscal year 2024. These fees are adjusted annually.

Under certain circumstances, the FDA will waive the application fee for the first human drug application that a small business, defined as a company with less than 500 employees, including employees of affiliates, submits for review. An affiliate is defined as a business entity that has a relationship with a second business entity if one business entity controls, or has the power to control, the other business entity, or a third-party controls, or has the power to control, both entities. In addition, an application to market a prescription drug product that has received orphan designation is not subject to a prescription drug user fee unless the application includes an indication for other than the rare disease or condition for which the drug was designated. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a disease or condition that affects fewer than 200,000 individuals in the United States, or for which there is no reasonable expectation that U.S. sales will be sufficient to recoup the development and production costs.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA also may require submission of a REMS plan to mitigate any identified or suspected serious risks. The REMS plan could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on an NDA

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific

indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information for the FDA to reconsider the application. If those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. After approval, the FDA may seek to prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. Some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track Designation, Accelerated Approval, Priority Review, Orphan Drug Designation and Breakthrough Therapy Programs

Fast Track

There are several FDA programs intended to help facilitate the development of new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and data demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug may request the FDA to designate the drug as a Fast Track product at any time during the clinical development of the product. Under a Fast Track designation, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the application.

Priority Review

A product is eligible for priority review if it is for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review to facilitate the review.

Accelerated Approval

A product that is being studied for safety and effectiveness in treating serious or life-threatening illnesses and provides meaningful advantage over existing treatments may receive accelerated approval, which means that it may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint that can be measured earlier than, and is reasonably likely to predict an effect on, irreversible morbidity or mortality. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. Under the Food and Drug Omnibus Reform Act of 2022, the FDA may require, as appropriate, that such studies be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. The FDA also has increased authority for expedited procedures to withdraw approval of a product or indication approved under accelerated approval if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for seven years. These circumstances are an inability to supply the drug in sufficient quantities or a situation in which a new formulation of the drug has shown superior safety or efficacy or a major contribution to patient care. This exclusivity, however, could also block the approval of its product for seven years if a competitor obtains earlier approval of the same drug for the same indication.

The FDA's interpretation of the scope of orphan drug exclusivity may change. The FDA's longstanding interpretation of the Orphan Drug Act is that exclusivity is specific to the orphan indication for which the drug was actually approved. As a result, the scope of exclusivity has been narrow and protected only against competition from the same "use or indication" rather than the broader "disease or condition." In the September 2021 case *Catalyst Pharmaceuticals, Inc. v. FDA*, a federal circuit court set aside the FDA's narrow interpretation and ruled that orphan drug exclusivity covers the full scope of the orphan-designated disease or condition regardless of whether the drug obtains approval only for a narrower use. The decision concerned amifampridine, a drug used to treat Lambert-Eaton myasthenic syndrome (LEMS). Depending on how the FDA applies the decision beyond this case, it may limit the drugs that can receive exclusivity.

Breakthrough Therapy Designation

A product may also be eligible for receipt of a Breakthrough Therapy designation. The Breakthrough Therapy designation is intended to expedite the FDA's review of a potential new drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease where "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a drug as a Breakthrough Therapy provides the same benefits as are available under the Fast Track program, as well as intensive FDA guidance on the product's development program. Fast Track designation, priority review, accelerated approval and Breakthrough Therapy designation do not change the standards for approval, but they may expedite the development or approval process.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented.

FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use.

Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events or problems with manufacturing processes of unanticipated severity or frequency, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

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

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Hatch-Waxman Patent Certification and the 30 Month Stay

In 1984, with passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the "Hatch-Waxman Amendments") amending the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA") to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD"). To reference that information, however, the ANDA applicant must demonstrate, and the FDA must conclude, that the generic drug does, in fact, perform in the same way as the RLD it purports to copy. Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. However, an applicant may submit an ANDA suitability petition to request the FDA's prior permission to submit an abbreviated application for a drug that differs from the RLD in route of administration, dosage form, or strength, or for a drug that has one different active ingredient in a fixed combination drug product (*i.e.*, a drug product with multiple active ingredients).

At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the RLD." Upon approval of an ANDA, the FDA indicates that the generic product is "therapeutically equivalent" to the RLD and it assigns a therapeutic equivalence rating to the approved generic drug in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider the therapeutic

equivalence rating to mean that a generic drug is fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of a therapeutic equivalence rating often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant's product or a method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

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

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA pursuant to an NDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant, and for which the applicant has not obtained a right of reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous findings of safety and effectiveness is scientifically and legally appropriate, it may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional bridging studies or measurements, including clinical trials, to support the change from the previously approved reference drug. The FDA may then approve the new drug candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

To the extent that a Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. As a result, approval of a 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments. Those Amendments permit a patent restoration of up to five years for patent term lost during product

development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of a NDA, plus the time between the submission date of an NDA and ultimate approval. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to the Centers for Medicare & Medicaid Services ("CMS"), other divisions of the U.S. Department of Health and Human Services (*e.g.*, the Office of Inspector General), the U.S. Department of Justice ("DOJ") and individual U.S. Attorney offices within the DOJ and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy provisions of the Health Insurance Portability and Accountability Act ("HIPAA") and similar state laws, each as amended.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. There are statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Our practices may not in all cases meet all the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act ("ACA") to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes

"any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved and thus non-reimbursable, uses. HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH") and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

There are also a number of U.S. state privacy laws, such as the California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020 ("CPRA"), that govern the privacy and security of personal information in certain circumstances. The CCPA/CPRA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including to provide specific disclosures in privacy notices, rights to California residents in relation to their personal information. Health information falls under the CCPA/CPRA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked with a particular consumer or household—unless it is subject to HIPAA—and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. Some of these laws and regulations impose different, and in certain instances, more stringent requirements than HIPAA. Failing to comply with these laws and regulations can result in significant civil and/or criminal penalties, as well as exposure to private litigation, all of which can result in financial and reputational risks.

Additionally, the federal Physician Payments Sunshine Act within the ACA and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

To distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with

the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing and to prohibit certain other sales and marketing practices. All our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, privately managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. This is also true of Medicare reimbursement, where different vendors process payments, so that coverage by one vendor does not assure that all other vendors will provide coverage. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. In addition, the United States federal government position on matters related to drug pricing is evolving and uncertain and any changes could have a material impact on drug pricing generally in the United States, including for our product candidates if approved. Recently, the U.S. government passed the Inflation Reduction Act, which authorizes the U.S. Department of Health and Human service to negotiate prices of certain drugs with participating manufacturers in federal healthcare programs.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The National Institute for Health and Care Excellence (NICE) in the United Kingdom also requires consideration of cost-benefit analysis. The downward pressure on healthcare costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage

and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA"), prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern the use, handling and disposal of various biological, chemical and radioactive substances used in and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Government Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug under EU regulatory systems, we must submit a marketing authorization application.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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

Employees in the United States

We consider our ability to recruit, retain and motivate our employees to be critical to our success. We are an equal opportunity employer and are fundamentally committed to creating and maintaining a work environment in which employees are treated with respect and dignity. We strive to administer all human resources policies, practices and actions related to hiring, promotion, compensation, benefits and termination in accordance with the principal of equal employment opportunity, meaning on the basis of individual skills, knowledge, abilities, job performance and other legitimate criteria and without regard to race, color, religion, sex, sexual orientation, gender expression or identity, ethnicity, national origin, ancestry, age, mental or physical disability, genetic information, any veteran status, any military status or application for military service, or membership in any other category protected under applicable law.

As of December 31, 2023, we had 4 full-time employees in the U.S. We have no collective bargaining agreements with our employees, and we have not experienced any work stoppages. We consider our relations with our employees to be good.

We aim to provide our employees with competitive salary and benefits that enable them to achieve a good quality of life and plan for the future. Our benefits are based on local norms and market preferences, but include all salary and social benefits required by local law (including paid time off for vacation and sick leave) and many additional benefits that go beyond legal requirements.

U.S. Business Organization

We commenced operations in 2002 and are a Delaware corporation. On August 20, 2015, we merged with Targacept, Inc. and on October 30, 2023, we completed the Contributions and became Gyre Therapeutics, Inc. Our corporate headquarters are in San Diego, California. We conduct our R&D activities and general and administrative functions primarily from our San Diego, California location.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports, are available for free at www.gyretx.com as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. They are also available for free on the SEC's website at www.sec.gov. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

Our Operations in the PRC: Gyre Pharmaceuticals

In this section, references to "we," "our," "us" and "our company" refer to Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals Co., Ltd.) ("Gyre Pharmaceuticals").

Gyre Pharmaceuticals was founded in 2002 and is an innovative drug development enterprise in the PRC committed to the treatment of organ fibrosis diseases, integrated R&D, production and commercialization. Gyre Pharmaceuticals is an indirect, majority-owned subsidiary of Gyre Therapeutics, Inc.

Overview of our PRC Operations

We are a commercial-stage biopharmaceutical company committed to the research, development, manufacturing and commercialization of innovative drugs for organ fibrosis. We initially focused on the treatment of IPF and have gradually broadened our therapeutic field and R&D efforts to other areas of organ fibrosis. Our flagship product, ETUARY, was approved in the PRC in 2011 and is among the first three approved drugs for IPF worldwide. Thereafter, we have developed a pipeline of additional innovative drug candidates F351, F528, F230 and F573 and have had ten years of successful commercialization of ETUARY.

As the PRC's first approved treatment for IPF, ETUARY has been included in the National Reimbursement Drug List (the "NRDL") of the PRC since 2017. Filling a vacuum in the PRC as the first approved IPF treatment, ETUARY has developed rapidly and maintained a dominant market share in the PRC. The total estimated market size for IPF treatments in the PRC was $127.4 million in 2022 and is expected to grow to $698.6 million by 2031, according to

Frost & Sullivan. Moreover, as different organ fibrosis diseases share a similar pathogenic mechanism and fibrosis process, we are seeking to expand the use of ETUARY to include other pulmonary fibrosis diseases, such as ILD and pneumoconiosis, as well as diseases causing renal fibrosis, such as DKD. The success of ETUARY in the IPF drug market lays the foundation for our R&D and registration strategy to further expand the use of such drugs to indications with large patient populations.

Through in-house R&D efforts and collaborative arrangements with GNI Japan, we have developed, in addition to ETUARY, a pipeline of pharmaceutical product candidates at various phases of clinical development, including F351, F528, F230 and F573. Specifically, liver fibrosis is an area of our focus and our key product candidate in this area is F351. F351 is currently in its Phase 3 clinical trial and has the potential to be the world's first approved drug to treat liver fibrosis associated with CHB. According to Frost & Sullivan, the number of patients with liver fibrosis in the PRC reached 140.3 million in 2022, of which approximately 45.3%, or 63.6 million, have liver fibrosis caused by CHB. Our Phase 2 clinical trials of F351 demonstrated positive results in reversing the fibrosis process and F351 was granted a Breakthrough Therapy designation by the CDE in March 2021. We commenced patient enrollment for the Phase 3 clinical trial in January 2022 and completed enrollment in the fourth quarter of 2023.

Based on our years of research into organ fibrosis, we have also expanded our R&D to include potential treatments for COPD, PAH and ALF/ACLF:

F528. We are evaluating F528 in preclinical studies for the treatment of COPD. F528 is a novel anti-inflammation agent that targets inhibition of multiple inflammatory cytokines and has the potential to modify the progression of COPD with low toxicity *in vivo*. According to Frost & Sullivan, the number of COPD patients in the PRC reached 106.4 million in 2022 and is expected to reach 110.1 million by 2031. The current standard of care is primarily used to relieve symptoms, reduce the frequency and severity of disease deterioration and improve cardio endurance. We expect that F528 could provide a first-line therapy for COPD and reduce long-term lung function degradation.

F230. We are evaluating F230, a selective endothelin receptor antagonist, in preclinical studies for the treatment of PAH. PAH is a progressive, life-threatening cardiovascular disease. According to Frost & Sullivan, the number of PAH patients in the PRC reached 57,882 in 2022 and is expected to reach 70,279 by 2031. On March 13, 2024, we submitted an IND application for F230 in the PRC.

F573. We are evaluating F573 in Phase 2 clinical trials for the treatment of ALF/ACLF. According to Frost & Sullivan, the number of patients in the PRC with ALF/ACLF reached 39,247 in 2022. The main treatment options for ALF/ACLF include comprehensive medical therapy, non-biological artificial liver support therapy and liver transplantation. However, there are currently no approved small molecule or biologic drugs for the treatment of ALF/ACLF. We enrolled the first subject for the Phase 1 clinical trial in January 2022 and initiated our Phase 2 clinical trial in March 2023.

While advancing the R&D of our pipeline products, we are one of only a few biopharmaceutical companies focusing on organ fibrosis drugs in the PRC with manufacturing and commercialization capabilities and an established track record. For further details about our two manufacturing centers, manufacturing capabilities and processes, see "*—Properties—Gyre Pharmaceuticals' Properties*" and "*—Production and Quality Control—In-House Manufacturing Facilities.*" For further details about our professional sales team and a comprehensive sales network, see "*—Sales, Marketing and Distribution.*"

We are also one of a limited number of biopharmaceutical companies in the PRC that has grown from a development-stage company to achieving sustained profitability. This growth was primarily attributable to the increased market demand for ETUARY, which is the first IPF drug marketed in the PRC. We face limited competition in the IPF drug market and we direct our marketing resources to encourage physician adoption of ETUARY.

Our Products and Product Pipeline

ETUARY: National Category 1.1 New Drug for IPF Approved in 2011

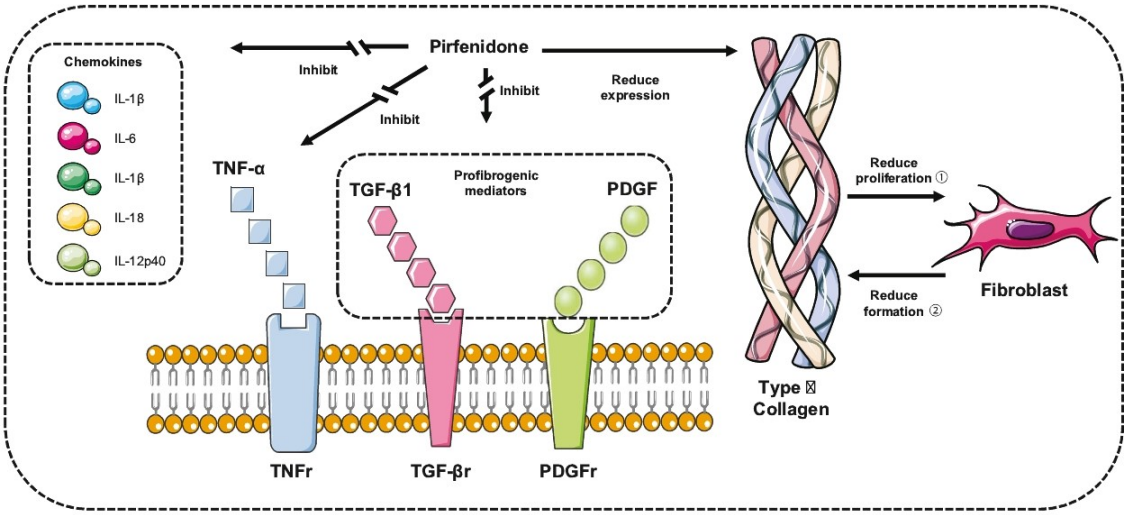
Overview

ETUARY (pirfenidone capsule) was approved as a National Category 1.1 New Drug in 2011 for the treatment of IPF, a rare disease. Given the absence of an approved IPF treatment in the PRC, ETUARY was included in the NRDL in 2017 and has since held a dominant market share. Clinical studies have shown that ETUARY can effectively slow down the decline in lung function and IPF disease progression. Moreover, given that different organ fibroses have similar pathogenic mechanisms and fibrosis processes, we are currently working to expand the therapeutic indications of ETUARY to other pulmonary fibrosis diseases, such as SSc-ILD, DM-ILD and pneumoconiosis, as well as diseases causing renal fibrosis, such as DKD.

Mechanism of Action

Pulmonary fibrosis is caused by activation of alveolar cells after epithelial damage, which secretes a series of pro-inflammatory cytokines, activating fibroblast proliferation and myofibroblast differentiation and reducing the rate of apoptosis. ETUARY reduces Type I Collagen expression by inhibiting the expression of pro-fibrogenic mediators, including TGF-ß1, platelet-derived growth factor ("PDGF") and fibroblast growth factor, which ultimately reduces fibroblast proliferation and collagen fiber synthesis and decreases extracellular matrix accumulation. It also inhibits TNF-α, IL-1 and other inflammatory mediators, thus reducing the inflammatory response.

The diagram below illustrates the mechanism of action of pirfenidone.



Source: Frost & Sullivan Analysis

Market Opportunities and Competition

IPF

IPF is a rare disease, defined as a chronic, progressive fibrotic interstitial pneumonia of unknown cause to the lungs, occurring primarily in the elderly. It is characterized by progressive worsening of dyspnea and lung function and is associated with a poor prognosis. The average five-year survival rate for patients with IPF is 32%, with the average 10-year survival rate dropping to 16%. According to Frost & Sullivan, the prevalence of IPF in the PRC increased from 83,002 patients in 2017 to 131,654 patients in 2022 at a CAGR of 9.7%, and it is expected to increase to 214,664 patients by 2027 at a CAGR of 10.3% from 2022 to 2027 and to 320,677 patients by 2031 at a CAGR of 10.6% from 2027 to 2031. The total market size of IPF in the PRC increased from $13.6 million in 2017 to $127.4 in 2022 at a CAGR of 56.3%, and is expected to reach $344.9 million by 2027 at a CAGR of 22.0% from 2022 to 2027 and $698.6 million by 2031 at a CAGR of 19.3% from 2027 to 2031.

The scarring of lung tissues is irreversible. However, proper treatment may slow the rate of fibrosis, increase the patient's survival rate, alleviate the patient's symptoms and improve the patient's quality of life. There are currently two types of IPF drugs approved in the PRC: pirfenidone and nintedanib. They are both clinically shown to slow down the formation of scar tissue in the lungs of IPF patients and are the only drugs that are considered effective for the treatment of organ fibrosis in the PRC. According to the latest guideline for the treatment of IPF issued by the American Thoracic Society, European Respiratory Society, Japanese Respiratory Society and Latin American Thoracic Association, pirfenidone and nintedanib are the only two types of IPF drug conditionally recommended with moderate-quality evidence.

Since its commercialization in the PRC, ETUARY has remained a dominant player in the IPF drug market. Sales of ETUARY have continued to grow, increasing from $99.2 million in 2022 to $112.1 million in 2023, and we expect our sales growth to continue. Although still a dominant player, the market share of ETUARY declined recently primarily due to the rising market share of new drugs, including 安博司, which had $13.5 million of sales in 2022, and OFEV (Nintednib), which had $67.0 million of sales in 2022. In 2022, the annual expenditures per patient in the PRC before NRDL reimbursement for ETUARY, 安博司, and OFEV were $13,106 to $13,378, $10,553, and $15,132, respectively. Despite the recent decrease of market share of ETUARY in the IPF market, we continue to expect a strong sales performance due to sustained increases in the prevalence of IPF and future indication expansion of ETUARY for the potential treatment of ILD, pneumoconiosis and other diseases. In addition, there are various barriers to entry for the potential market entrants. For instance, it is difficult for new entrants to build an experienced and specialized sales and marketing team in the short term given that sales and marketing strategies of organ fibrosis drugs significantly differ from that of etiological treatment drugs and long-term and stable collaboration with KOLs and hospitals is critical to developing and optimizing product portfolio, effectively educating and penetrating the market and recruiting patients for clinical trials.

SSc-ILD and DM-ILD

CTD-ILD is non-idiopathic interstitial pneumonia. Connective Tissue Diseases ("CTD") is a type of autoimmune disease that causes damage to various organs throughout the body based on chronic inflammation of blood vessels and connective tissue. Interstitial Lung Diseases ("ILD") is one of the most serious pulmonary complications and can result in significant morbidity and mortality when associated with CTD.

Scleroderma ("SSc") is a CTD characterized by degenerative microvascular phenomena and immune system activation, leading to fibrosis of the skin and internal organs. ILD is very frequent in patients affected by SSc, reaching about 50% prevalence, representing the leading SSc-related cause of death. Dermatomyositis ("DM") is characterized by proximal skeletal muscle weakness and muscle inflammation. Among patients with DM, ILD is a major cause of morbidity and mortality. The frequency of ILD in DM has been reported to range between 5% and 45%, depending on the diagnostic method.

According to Frost & Sullivan, the prevalence of CTD-ILD in the PRC increased from approximately 2.3 million patients in 2017 to 2.4 million patients in 2022, and is expected to reach 2.5 million patients in 2027 and 2.6 million patients in 2031. Among the CTD-ILD patients, approximately 8.4% are SSc-ILD and DM-ILD patients in 2022. The market size of anti-fibrosis drugs for SSc-ILD/DM-ILD patients was $9.1 million in 2022 and is expected to reach $53.1 million by 2027 and $117.6 million by 2031 at a CAGR of 42.4% from 2022 to 2027 and a CAGR of 22.0% from 2027 to 2031.

SSc-ILD and DM-ILD are induced by known factors, including specific exposure or autoimmune diseases (such as scleroderma and rheumatoid arthritis). Symptoms include chronic cough, expectoration, hemoptysis, progressive dyspnea and intermittent fever. The treatment of CTD-ILD (including SSc-ILD and DM-ILD) is a combination of the immunosuppressive treatment for CTD and the anti-fibrosis treatment for ILD, which can effectively prevent or even reverse the progression of ILD lesion and protect the pulmonary function of patients. Recommended immunological drugs include cyclophosphamide, mycophenolate mofetil and azathioprine. Anti-fibrosis treatment methods vary with different types of CTD-related ILD in terms of the timing, drug selection, dosage and treatment duration. Recommended anti-fibrosis drugs include pirfenidone and nintedanib.

Pirfenidone is an antifibrotic agent with anti-inflammatory properties, including inhibition of proinflammatory cytokines and inhibition of inflammatory cell proliferation. Despite the differences in their clinical presentation, IPF,

SSc-ILD and DM-ILD share some overlapping pathogenic mechanisms, including injury to structural cells, fibroblast activation, myofibroblast accumulation, expression of fibrogenic cytokines and growth factors and progressive ILD. Based on the results of pirfenidone's preclinical studies, we are evaluating its efficacy on patients with SSc-ILD and DM-ILD in Phase 3 clinical trials. Currently, nintedanib is approved for the treatment of anti-fibrosis in patients with SSc-ILD.

Pneumoconiosis

Pneumoconiosis refers to a spectrum of pulmonary diseases caused by inhalation of mineral dust, usually as the result of certain occupations. The main pathological features include chronic pulmonary inflammation and progressive pulmonary fibrosis, which can eventually lead to death caused by respiratory and/or heart failure. Pneumoconiosis is widespread globally and a serious global public health concern. Its high incidence and mortality result from improper occupational protection and the lack of early diagnostic methods and effective treatments.

According to Frost & Sullivan, in the PRC, the prevalence of pneumoconiosis increased from 850,299 patients in 2017 to 926,769 patients in 2022, and it is expected to increase to 962,562 patients by 2027 and 980,917 patients by 2031. The market size of anti-fibrosis drugs for pneumoconiosis is expected to reach $12.1 million by 2027 and $64.1 million by 2031 a CAGR of 51.7% from 2027 to 2031.

To date, there are two pirfenidone product candidates for the treatment of pneumoconiosis in various clinical stages in the PRC. We enrolled the first patient in our Phase 3 clinical trial of ETUARY for the treatment of pneumoconiosis in June 2022, making ETUARY the most clinically advanced anti-fibrosis drug for the treatment of pneumoconiosis in the PRC. As of December 31, 2023, no small molecule or biologic anti-fibrosis product for the treatment of pneumoconiosis had been approved in the PRC.

An experimental study on silica-induced lung fibrosis in rats demonstrated that pirfenidone can slow the transformation from epithelial to mesenchymal cells when administered for 14 days and 28 days. These treatments were associated with a significant down-regulation of vimentine and up-regulation of E-cadherin, suggesting that pirfenidone can exhibit an inhibiting effect on silica-induced epithelial-mesenchymal transition in rats.

DKD

DKD is a chronic kidney disease ("CKD") caused by diabetes mellitus. DKD is clinically manifested as specific pathological structural and functional changes in the kidney of diabetes patients. In addition, DKD has become the primary cause of progression from CKD to the end-stage renal disease and one of the main diseases causing renal fibrosis. As one of the serious complications of diabetes, DKD in the PRC is characterized by high prevalence, low awareness rate, low treatment rate and low control rate.

According to Frost & Sullivan, the prevalence of DKD in the PRC increased from 45.4 million patients in 2017 to 53.2 million patients in 2022, and it is expected to increase to 61.5 million patients by 2031. The DKD market in the PRC increased from $24.2 billion in 2017 to $37.2 billion in 2022 and it is predicted to expand to $51.5 billion by 2027 and $60.3 billion by 2031.

The standard of care for DKD has been blood glucose control, blood pressure control and blood liquid control. However, current therapeutic strategies are far from being completely effective because no available therapy successfully prevents DKD and many patients still progress to end-stage renal disease. The current available drugs for the treatment of DKD include hypoglycemic drugs, antihypertensive drugs and lipid-lowering drugs. As of December 31, 2023, there was one approved treatment for DKD in many parts of the world, finerenone (marketed under the name KERENDIA).

Pirfenidone has demonstrated positive therapeutic effects on DKD due to its unique mechanism of action. Several growth factors or cytokines that are locally produced in the kidney appear to contribute to the extracellular matrix accumulation, inflammation and scarring in progressive DKD. The TGF-ß1 system is activated and plays a pathogenetic role in DKD in animal models of type 1 and type 2 diabetes. In addition, several studies in patients with type 1 and type 2 diabetes indicate increased renal production of TGF-ß1. The TNF-α' system has also recently been linked with human DKD on the basis of circulating blood levels and gene expression in kidneys from patients with

DKD. Pirfenidone has been found to inhibit TGF-ß1 production and consequent matrix deposition in experimental animal models of kidney disease. In animal models and cell culture studies, pirfenidone also reduces TNF-α' production. Previous studies also showed that oral pirfenidone administered to db/db mice after the onset of established DKD was effective in reducing glomerulosclerosis.

Summary of Clinical Results

As of December 31, 2023, Gyre Pharmaceuticals and Shanghai Genomics, Inc. ("SG") have conducted over 10 clinical trials to explore the clinical benefits of pirfenidone in the PRC. As the first drug approved for IPF in the PRC, ETUARY was approved upon completion of Phase 2a clinical trials. Summarized below are current key clinical trials of ETUARY.

Registered Phase 2a Clinical Trial of Pirfenidone for IPF

This trial was a randomized, double-blind, multi-dose, parallel-controlled, multicenter Phase 2a clinical trial to investigate the effectiveness of pirfenidone combined with basic treatment for IPF. The objective was to evaluate the safety and efficacy of pirfenidone capsules, as well as to determine the most appropriate clinical treatment dose by observing the therapeutic effects of pirfenidone capsules on pulmonary function (including arterial blood gas analysis), the six-minute walk test ("6MWT"), survival, quality of life and high-resolution computed tomography imaging in IPF patients. The treatment group was divided into two dose treatment groups, a 400 mg/tid treatment group and a 600 mg/tid treatment group. 24 patients were enrolled in each treatment group. The placebo group was also divided into two groups, a four capsules/tid group and a six capsules/tid group, with 12 patients in each group. The treatment and placebo groups were assigned in a 2:2:1:1 ratio and patients were stratified and randomized to be assigned to receive pirfenidone or placebo. The primary endpoints were pulmonary function parameters, 6MWT results and survival rate.

This trial has been completed with a total of 72 patients enrolled.

The efficacy results of the trial were as follows:

Therapeutic Effect	Criteria	Results (FAS, after 12 months treatment)
Pulmonary function	Diffusing capacity of carbon monoxide % ("DLco%")	There was a statistically significant difference among the three groups of the change in DLco% (P=0.0306), with a mean change of -2.79±9.34% in the 600 mg treatment group and a mean change of -14.92±16.40% in the placebo group (P=0.0014 for the two groups).
	Diffusing capacity of carbon monoxide ("DLco")	There was a statistically significant difference among the three groups of the change in DLco (P=0.0049), with a mean change of -0.42±3.45% in the 600 mg treatment group and a mean change of -3.14±4.44% in the placebo group (P=0.0016 for the two groups).
	Arterial oxygen saturation ("SaO2")	There was a statistically significant difference among the three groups of the change in arterial oxygen saturation (SaO2) (P=0.0145), with a mean change of -3.83±4.02% in the placebo group and -0.30±3.05% in the 400 mg group (P=0.0055 for the two groups).
6MWT	Pulse oxygen saturation ("SpO2")	There was a statistically significant difference among the three groups of the change in SpO2 after 6MWT (P=0.0168), with a mean change of -9.08±10.66% in the placebo group and 0.22±7.30% in the 400 mg treatment group (P=0.0062 for the two groups).

Survival rate	N/A	The mortality of placebo group, 400 mg treatment group and 600 mg treatment group was 20.83%, 21.74% and 16.67%, respectively, with no statistical significance.

17 patients experienced SAEs, but none were drug-related. The incidence of adverse drug reactions ("ADRs") in the placebo group, 400 mg and 600 mg treatment groups was 41.67%, 29.17% and 45.83%, respectively, with no statistical difference between the three groups. The incidence of rash in the treatment groups was statistically different from that in the placebo group and was present in all of the 600 mg treatment groups with an incidence of 20.83%. The common ADRs included nausea (12.5% in each of the 400 mg treatment group and 600 mg treatment group), photosensitivity (4.17% in the 400 mg treatment group and 12.5% in the 600 mg treatment group) and drowsiness (8.33% in the 600 mg treatment group), but these were not statistically significant from the placebo group. The incidence of AEs in the placebo group, 400 mg and 600 mg treatment groups was 70.83%, 66.67% and 66.67%, respectively, with no statistical difference between the three groups. The average incidence of SAEs in each of the placebo group and the 400 mg and 600 mg treatment groups was 54.17%, with no statistical difference between the three groups. The incidence of SAEs (including mortality and hospitalization) in each of the placebo group and the 400 mg and 600 mg treatment groups was 29.17%, 20.83% and 20.83%, with no statistical difference between the three groups.

After 12 months of treatment, pirfenidone was effective in slowing down the decline in DLco%, DLco, SaO2 and SpO2 immediately after 6MWT. No drug-related SAEs were observed and rash and nausea were the most common ADRs. The results show that pirfenidone has potential for the treatment of IPF.

Phase 3 Clinical Trial of Pirfenidone for the Treatment of SSc-ILD

We are conducting a randomized, double-blind, placebo-controlled, multicenter Phase 3 clinical trial to evaluate the efficacy and safety of pirfenidone in the treatment of SSc-ILD. The primary endpoint is the change in FVC% at 52 weeks of treatment compared to baseline. 144 patients are planned to be enrolled in the trial, with 108 in the treatment group and 36 in the control group.

This trial enrolled the first patient in June 2018. Due to the outbreak of COVID-19 and the scarcity of eligible patients, this trial is still in the process of recruiting patients and therefore no clinical results are currently available for analysis.

Phase 3 Clinical Trial of Pirfenidone for the Treatment of DM-ILD

We are conducting a randomized, double-blind, placebo-controlled, multicenter Phase 3 clinical trial to evaluate the efficacy and safety of pirfenidone for the treatment of DM-ILD. The primary endpoint is the change in FVC% at 52 weeks of treatment compared to baseline. 152 patients will be enrolled in the trial, with 114 in the treatment group and 38 in the control group.

This trial enrolled the first patient in June 2018. Due to the outbreak of COVID-19 and the scarcity of eligible patients, this trial is still in the process of recruiting patients and no clinical results are currently available for analysis.

Phase 3 Clinical Trial of Pirfenidone for the Treatment of Pneumoconiosis

We are conducting a randomized, double-blind, placebo-controlled, multi-center Phase 3 clinical trial to evaluate the efficacy and safety of pirfenidone in the treatment of pneumoconiosis. The primary endpoint is the change in force vital capacity at 52 weeks of treatment compared to baseline. 272 patients will be enrolled in the trial, with 136 in the treatment group and 136 in the control group.

We obtained ethics committee approval as of January 2022 and enrolled the first patient in June 2022.

Phase 1 Clinical Trial of Pirfenidone for Our DKD Program

We conducted an open-label, parallel-controlled, single-center clinical trial is to evaluate the safety and PK of a single dose of pirfenidone capsules in patients with CKD stages G2 and G3a. 24 subjects were enrolled, consisting of 12 patients with renal insufficiency and 12 healthy volunteers.

The Phase 1 clinical trial was completed in March 2022. In this trial, pirfenidone was tolerated when used in patients with chronic kidney disease G2 and G3a, there were no significant changes in the main pharmacokinetic parameters compared with healthy controls, and no dose adjustment was required.

Our Clinical-Stage Product - F351: Category 1 New Drug to Reverse CHB-Associated Liver Fibrosis

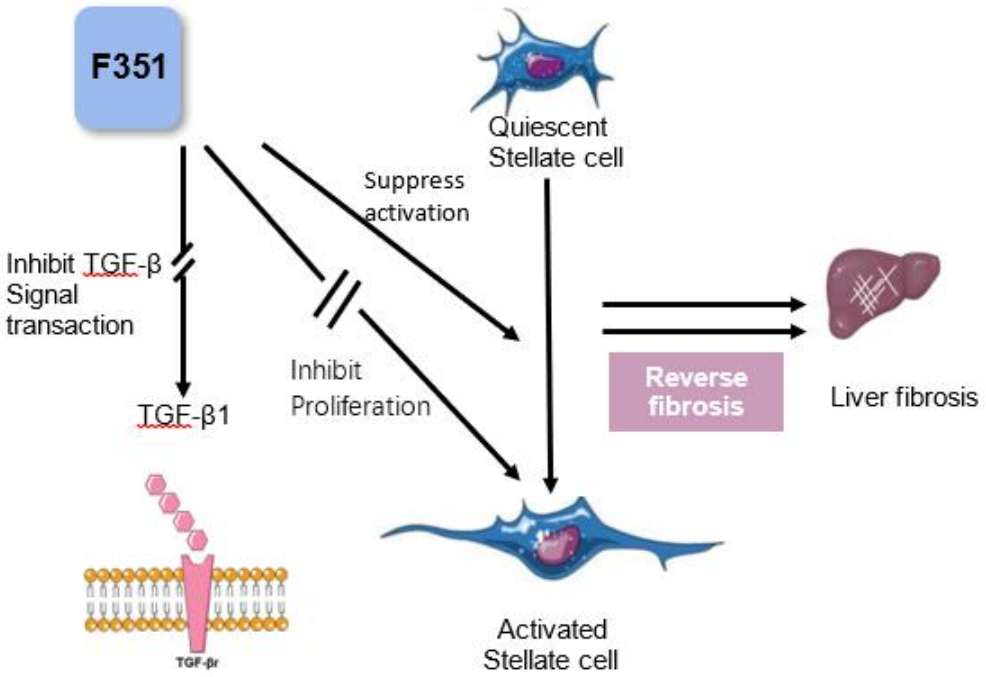
Overview

F351, our Phase 3 clinical-stage product candidate, has the potential to become the first approved drug to treat CHB-associated liver fibrosis. According to Frost & Sullivan, CHB is the number one cause of liver fibrosis in the PRC and the number of patients with liver fibrosis in the PRC reached approximately 140.3 million in 2022, of which approximately 45.3% were caused by CHB. To date, there is no effective clinical therapy for liver fibrosis and no specific therapeutic drugs have been approved worldwide. F351 demonstrated positive results the reversal of the fibrosis process in its Phase 2 clinical trial. F351 may reverse liver fibrosis by inhibiting hepatic stellate cell proliferation and the TGF-ß1 signaling pathway, both of which play major roles in the CHB-associated liver fibrosis. Due to the results of the Phase 2 clinical trial in CHB-induced liver fibrosis, and as one of the first drugs announced to treat liver fibrosis, F351 was granted a Breakthrough Therapy designation by the CDE in March 2021 and we commenced patient enrollment for the Phase 3 clinical trial in January 2022. We completed enrollment in the fourth quarter of 2023 and expect to have the last patient out in 2024 and to submit an NMPA application for F351 in the PRC in early 2025.

Mechanism of Action

When injuries occur and epithelial and/or endothelial cells are damaged, pro-inflammatory cytokines are released by the coagulation cascade for immune cell recruitment, mainly neutrophils and macrophages. These recruited immune cells function as the scavenger to remove tissue debris and dead cells, resulting in acute inflammation. Meanwhile, immune cells themselves release factors like chemokines and cytokines to amplify inflammatory reactions. Next, the released factors, such as TGF-ß1, PDGF, interleukin-13 and interleukin-4, induce the limited activation and proliferation of myofibroblasts. F351 is expected to treat and reverse liver fibrosis in chronic viral hepatitis B by inhibiting the proliferation of HSCs and the TGF-ß1 signaling pathway.

The diagram below illustrates the mechanism of action of F351:



Market Opportunities and Competition

CHB is a major cause of liver morbidity and mortality in Asia. Patients chronically infected with the hepatitis B virus tend to experience liver fibrosis and may develop end-stage liver disease, such as decompensated cirrhosis and HCC, without intervention. In the PRC, about 70% of cirrhoses were developed from HBV infection, which reflects the significant demand for the treatment of CHB-associated liver fibrosis.

According to Frost & Sullivan, the prevalence of CHB-associated liver fibrosis globally increased from 221.1 million patients in 2017 to 257.8 million patients in 2022. The prevalence of CHB-associated liver fibrosis in the PRC from 2017 to 2022 ranges from 63.6 million to 66.4 million patients and is expected to remain stable in the next 10 years. The anti-liver fibrosis drug market in the PRC has increased from $138.0 million in 2017 to $162.7 million in 2022 and we expect the market to grow to $338.0 million in 2027 and $801.2 million in 2031, at a CAGR of 15.8% and 24.1%, respectively.

Etiological treatment is currently the most common treatment of liver fibrosis. For CHB-associated liver fibrosis, antiviral therapy is only able to suppress the viral infection, but is unable to prevent, slow or reverse the progress of fibrosis, suggesting a significant unmet need for effective antifibrotic therapy. Anti-fibrotic treatment is recommended for the treatment of intermediate and advanced liver fibrosis, as well as early-stage cirrhosis. As of December 31, 2023, no chemical or biological drugs treating liver fibrosis that have been approved globally or in the PRC. Globally, there are currently a series of drugs that are in late-stage (Phase 2 or later) clinical trials for the treatment of liver fibrosis. Of these clinical-stage drugs, F351 is the most clinically advanced product candidate in the PRC that has the potential to effectively reverse the fibrosis process.

In our clinical trials, F351 showed promising results in the reversal of liver fibrosis. Our Phase 2 clinical results in CHB patients with liver fibrosis show that, using the pathological score of Ishak stage as the primary outcome measure, the treatment group showed better results in reversing liver fibrosis than the placebo group after 52 weeks of treatment. In particular, around 56.1% of the patients achieved a fibrosis regression of > 1 in the 270 mg group. We commenced the patient enrollment for the Phase 3 clinical trial in January 2022 and completed enrollment in October 2023.

Summary of Clinical Results

As of December 31, 2023, more than five clinical trials sponsored by us or SG were carried out to explore the clinical risk/benefit of F351. Summarized below are the results of selected key clinical trials of F351.

Phase 2 Clinical Trial of F351 for CHB-Associated Liver Fibrosis in the PRC

We conducted a Phase 2 randomized, double-blind, placebo-controlled, Entecavir-based (the first-line drug for the treatment of CHB virus infection), multi-center, dose-escalation trial assessing the safety and efficacy of F351 for treatment of patients in the PRC with CHB-associated liver fibrosis. The Phase 2 trial was randomized in 240 patients divided into four dose-escalating groups (placebo; 180 mg/day; 270 mg/day; and 360 mg/day) with a primary endpoint of the reduction of the liver fibrosis score (Ishak Scoring System) by greater than or equal to one grade after taking F351 in combination with Entecavir.

The trial met its primary endpoint of a statistically-significant improvement in the liver fibrosis score over the 52-week treatment versus placebo ($p=0.0245$). The percentages of patients who achieved a fibrosis regression of > 1 were 25.58% (placebo), 40.48% (180 mg/day), 56.10% (270 mg/day) and 43.90% (360 mg/day). Accordingly, the 270 mg/day treatment group showed the highest percentage of patients who were able to reach the primary endpoint.

F351 showed better safety results when compared to the placebo in this trial. In the placebo group, 180 mg treatment group, 270 mg treatment group and 360 mg treatment group, rates of SAEs were 4.65%, 2.38%, 2.38% and 7.32%, respectively, with no statistical significance. A total of seven (4.17%) subjects experienced seven SAEs throughout the trial: two (4.6%) in the placebo group, one (2.38%) in the 180 mg group, one (2.38%) in the 270 mg group and three (7.32%) in 360 mg group, with no statistical significance. The SAEs were laboratory abnormalities, elevation of transaminases, embolic infarction, comminuted fracture, osteoporosis, unplanned pregnancy and hypertension. No deaths occurred.

Phase 3 Clinical Trial of F351 for CHB-Associated Liver Fibrosis in the PRC

We are conducting a Phase 3 randomized, double-blind, placebo-controlled, Entecavir-based, multi-center trial assessing the safety and efficacy of F351 for treatment of patients in the PRC with CHB-associated liver fibrosis. The Phase 3 clinical trial was designed to be randomized in 248 patients with a primary endpoint of the reduction of the liver fibrosis score (Ishak Scoring System) by at least one grade after taking F351 in combination with Entecavir.

We commenced patient enrollment for the Phase 3 clinical trials of F351 in January 2022 and completed enrollment in October 2023. No clinical results are currently available for analysis. We expect to have top line results by early 2025.

F573: Potential Category 1 New Drug for ALF/ACLF

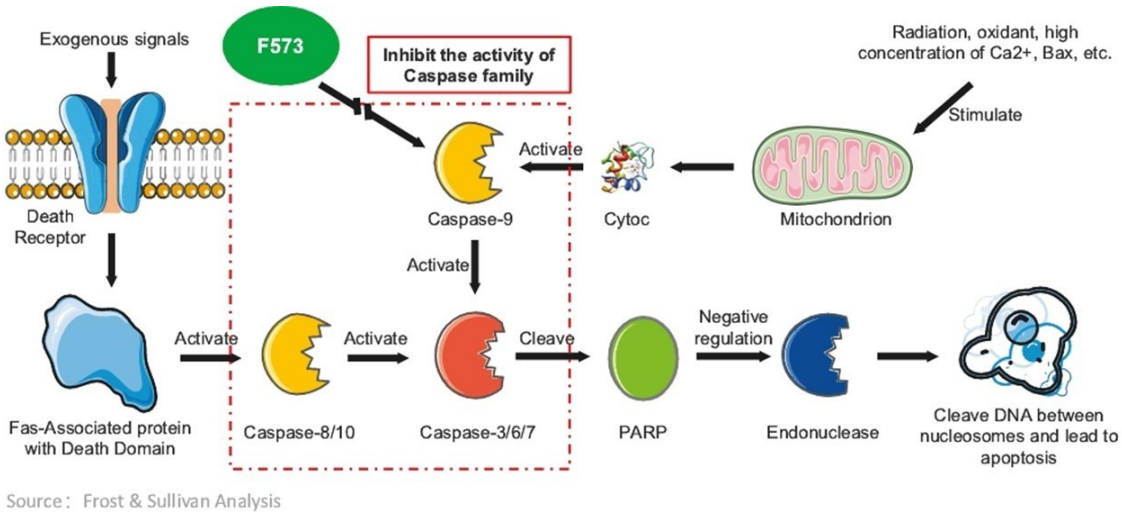
Overview

F573 is a caspase inhibitor and a potential Category 1 new drug for the treatment of ALF/ACLF. According to Frost & Sullivan, the number of patients with ALF/ACLF in 2022 reached 39,247 in the PRC. The main treatment options for ALF/ACLF include comprehensive medical therapy, non-biological artificial liver support therapy and liver transplantation. Currently, there are no drugs specifically for the treatment of ALF/ACLF. We enrolled the first subject for the Phase 1 clinical trial in January 2022 and initiated a Phase 2 clinical trial in March 2023.

Mechanism of Action

Inflammatory response and immune dysfunction can lead to massive liver cell death, which causes ALF/ACLF. Therefore, inhibiting the apoptosis process of normal hepatocytes helps to delay the progression of ALF/ACLF. The main mediating pathways of hepatocyte apoptosis include the mitochondrial pathway and the death receptors pathway, where the caspase family plays an important role as the main executive molecules. The main mechanism of F573 is to inhibit the activity of the caspase family, including caspases 1, 3, 6, 7, 8 and 9 and to reduce the cleavage effects on poly-ADP-ribose polymerase, thus blocking the cell apoptosis process mediated by endogenous or exogenous signals. As a result, hepatic failure is expected to be alleviated by F573.

The diagram below illustrates the mechanism of action of F573:



Market Opportunities and Competition

ALF/ACLF is severe liver damage caused by a variety of factors, resulting in severe impairment or loss of synthesis of detoxification, metabolism and biotransformation functions. ALF/ACLF can follow with syndromes of jaundice, coagulation dysfunction, hepatorenal syndrome, hepatic encephalopathy and ascites. The causes of ALF/ACLF are complex and include the hepatitis viruses (especially HBV) and other viruses, drugs, hepatotoxic substances (*e.g.*, alcohol and chemical agents), bacteria and parasites. In the PRC, HBV, drugs and hepatotoxic substances are the most common causes of ALF/ACLF.

According to Frost & Sullivan, the prevalence of ALF/ACLF in the PRC was 43,123 patients in 2017 and 39,247 patients in 2022 and is expected to be 34,969 patients in 2027 and 31,485 patients in 2031. The market size of ALF/ACLF in the PRC was $278.6 million in 2017 and $253.5 million in 2022 and it is expected to be $225.9 million in 2027 and $203.3 million in 2031.

The main treatment options for liver failure include comprehensive medical therapy, non-biological artificial liver support treatment and liver transplantation. Medical treatment mainly includes general supportive therapy, symptomatic treatment, etiological treatment and treatment for complications.

The efficacy profile of F573 has been demonstrated in four preclinical studies. In *in vitro* studies, F573 had a significant inhibitory effect on apoptosis in a variety of cells. Specifically, F573 had a protective effect on HeLa cells, human normal hepatocytes L02 and Jurkat cells, while inhibiting Caspase-3 enzyme activity and reducing its ability to cleave the substrate AC-DEVD-AMC. F573 improved liver function and alleviated the liver injury caused by D-GalN/LPS-induced fulminant liver failure in rats, which significantly inhibited hepatocyte necrosis and apoptosis and showed a preventive and therapeutic effect on acute and severe liver injury. In a pharmacodynamic acute liver injury experiment on D-Gal/LPS mortality in mice, F573 had a protective effect against acute liver injury caused by D-Gal and LPS in km mice and prolonged the survival time of km mice. F573 has been shown to improve liver function and reduce liver injury in ConA-induced acute liver failure in BALB/c mice. F573 significantly inhibits hepatocyte necrosis and apoptosis and has a preventive and therapeutic effect on acute and severe liver injury.

Clinical Development Plan

Phase 1 Clinical Trial of F573 for ALF/ACLF

We enrolled the first subject for our Phase 1 clinical trial to assess the tolerance and PK of single and multiple doses of F573 in January 2022. We recruited 100 healthy subjects for this trial and completed the Phase 1 clinical observations of tolerability and PK in July 2022. The Cmax of F573 was not dose-dependent at the dose range from 0.5 mg/kg to 2.0 mg/kg, and AUC0-t and AUC0-∞ of F573 showed linear pharmacokinetics. The rate of absorption of F573 showed sex differences. F573 was administered once a day for seven days without accumulation in the human body.

Phase 2 Clinical Trial of F573 for ALF/ACLF

We initiated our Phase 2 clinical trial in March 2023. The Phase 2 clinical trial is designed to be a randomized, double-blind, placebo-controlled clinical trial. The main objective of this trial is to assess the efficacy and safety of F573 for injection in the treatment of liver injury/failure. The Phase 2 trial is divided into three stages:

- *First Stage*: 16 patients with 1/2 grade DILI or other liver injury patients and 9 patients with CHB are expected to enroll. First, DILI or other liver injury patients will be treated with the trial drug at either 0.5 mg/kg, 1.0 mg/kg, 2.0 mg/kg or placebo in a 1:1:1:1 ratio. CHB patients will receive the trial drug.
- *Second Stage*: 12 cases in each of the 2/3 grade DILI or other liver injury patients and the CHB patient groups are expected to enroll and are expected to be assigned to the experimental group and the control group in a ratio of 3:1.

After obtaining subject consent, pharmacokinetic blood samples will be collected for CHB patients in stages 1 and 2 in this trial.

- *Third Stage*: This stage is expected to use a randomized, double-blind, placebo-controlled design. The stage is designed to be divided into screening period (14 days), treatment period (28 days) and follow-up period (90 days).

48 screen-eligible subjects are expected to receive trial drug or placebo in a ratio of 3:1, once a day for 28 days. Subjects are also expected to receive concurrent drug acetylcysteine injection. After withdrawal, the subjects will be followed up for 90 days for safety.

Our Preclinical-Stage Product Candidates

F230: Selective Antagonist of EPA for PAH

F230 is a selective endothelin-receptor A antagonist to treat PAH. PAH is a rare disease and a progressive, life-threatening disorder characterized by increased pressure in the pulmonary arteries that carry blood from the heart to the lungs. A common pathological hallmark of PAH is vascular remodeling, including increased stiffening and thickening of pulmonary arteries. This restricts blood flow through the lungs, causing pulmonary hypertension and making the heart work harder to pump blood to the lungs. The exact cause of PAH is unknown and there is no known cure for PAH. PAH is a serious disease that has a short life expectancy if left untreated. The prognosis for the treatment of PAH is poor, with a high mortality rate and survival of less than three years in the absence of standard therapy.

According to Frost & Sullivan, the prevalence of PAH in the PRC increased from 49,004 patients in 2017 to 57,882 patients in 2022 and it is expected to increase to 67,682 patients by 2027 and 70,279 patients by 2031. The market size of PAH in the PRC increased from $0.29 billion in 2017 to $0.37 billion in 2022 and it is expected to increase to $0.47 billion by 2027 and $0.52 billion by 2031.

In the study of Hypoxia-induced PAH in rats, F230 resulted in significant decreases of, or exhibited a decrease trend based on different dose groups in, mean pulmonary arterial pressure, right ventricular systolic pressure, right ventricular/left ventricular plus septum and pulmonary artery wall thickness. Even at minimum effective dosage, the differences of those indexes between treatment group and PAH group are statistically significant.

F528: A Potential First-line Therapy for COPD

F528 is an anti-inflammatory small molecule drug candidate developed for the treatment of COPD. F528 is a novel anti-inflammation agent that targets inhibition of multiple inflammatory cytokines and could modify the progression of COPD with extreme low toxicity *in vivo*. COPD is a chronic inflammatory lung disease which causes obstructed air flow from the lungs. It consists of three separate illnesses: emphysema, chronic bronchitis and chronic obstructive asthma. COPD causes the destruction of barriers between alveoli inside the lungs, causing airways to get swollen and clogged with mucus. In most cases, COPD develops very slowly and symptoms may emerge for years before being diagnosed.

According to Frost & Sullivan, prevalence of COPD in the PRC increased from 102.7 million patients in 2017 to 106.4 million patients in 2022 and is expected to increase to 108.6 million patients in 2027 and 110.1 million patients in 2031. The COPD market in the PRC was $0.9 billion in 2017 to $1.1 billion in 2022. The market is predicted to expand to $1.3 billion by 2027 and $1.5 billion by 2031.

The drug treatment of COPD is mainly used to relieve symptoms, reduce the frequency and severity of disease deterioration and improve cardio endurance and health. Currently, there is no conclusive clinical trial evidence showing that existing drugs can slow down the long-term decline in lung function. For late-stage COPD patients, currently-available treatment options achieve limited therapeutic effects. As clinical research results from external parties indicated, 2% of patients were reported to gain improvement in exercise capability after 24 months of standard medical treatment and none were reported to gain improved health-related quality of life. Thus, there are significant unmet clinical needs for COPD patients.

We believe F528 could become first-line therapy for COPD. In a preclinical study of the effect of F528 in rats with COPD induced by smoke exposure and LPS tracheal injection, the lung index, the alveolar space and the lung injury score were significantly decreased after the treatment of F528.

Other Drug Candidates

To supplement and enrich our product candidate pipeline, we acquire the marketing rights to certain generic drugs, including avatrombopag maleate for the treatment of CLD-associated thrombocytopenia, fingolimod hydrocholoride for the treatment of multiple sclerosis, minocycline hydrochloride foam for the treatment of moderate to severe acne and acetylcysteine injection for the treatment of respiratory diseases with excessive thick mucus discharge.

Occupational, Health, Safety and Environmental Matters

We are subject to various health, safety, social and environmental laws and regulations and our operations are regularly inspected by local government authorities. We are committed to social responsibility and consider environmental, social and governance essential to our continuous development and we believe we have adequate policies to promote compliance with applicable health, safety, social and environmental protection regulations.

Under the oversight of the senior management, we actively identify and monitor the actual and potential impact of environmental, social and climate-related risks on our business, strategy and financial performance and incorporate considerations for these issues into our business, strategic and financial planning with a particular focus on areas such as employee responsibility, environment responsibility and public responsibility. Corporate social responsibility is viewed as part of our core growth philosophy and pivotal to our ability to create sustainable value for our stockholders.

In addition, we monitor and enforce the compliance of our operations with environment, health and safety laws and regulations. This responsibility is executed through training, formulation and implementation of strategies, policies, standards and metrics, communication of environmental, health and safety policies and procedures through a team of coordinators, environmental, health and safety audits and incident response planning and implementation. With the oversight of our management, our quality control team assesses the likelihood of such risks occurring and the estimated magnitude of any potential impact.

Permits and Other Approvals

As of December 31, 2023, we have received all material permissions and approvals required for our business operations. As of December 31, 2023, our wholly-owned subsidiary (Beijing Continent Biomedical Technology Co., Ltd., a company organized under the laws of the PRC) has obtained a business license but has no business operations. The following table sets forth the details of material licenses, permits and approvals:

License/Permit	Validity Period	Authority
Drug Production License	September 2022 – September 2025	Beijing Medical Products Administration
Information Service Qualification Certificate	January 2021 – January 2026	Beijing Medical Products Administration
Zhongguancun High- tech Enterprise	December 2022 – December 2024	Administrative Commission of Zhongguancun Science Park
High-tech Enterprise Certificate	November 2022 – November 2025	Beijing Municipal Science & Technology Commission, Beijing Municipal Finance Bureau, Beijing Municipal Administration of Taxation
Drug Registration Approval (pirfenidone)	Valid until August 2028	Beijing Medical Products Administration
Drug Registration Approval (pirfenidone capsule)	Valid until August 2028	Beijing Medical Products Administration
GMP Certificate for Pharmaceutical Products (Pirfenidone APIs)	July 2019 – July 2024	Beijing Medical Products Administration
Foreign Trade Operators Registration Form	From February 2022	Beijing Municipal Commission of Commerce

Our Research and Development

We consistently devote resources to R&D to achieve long-term growth. We believe the diversification and expansion of our product pipeline through both in-house R&D and external collaboration are critical to our long-term competitiveness and success.

We have a dedicated in-house R&D team of 85 employees in the PRC as of December 31, 2023. Our R&D department is comprised of the following departments: drug discovery, chemistry, manufacturing and control ("CMC"), clinical development, medical affairs and regulatory affairs. Our R&D employees possess significant expertise in molecular biology, chemistry regulatory affairs and clinical development. Through cross-functional collaboration, our R&D organization has enabled us to develop new drug products to address unmet clinical needs.

We employ a clinical-demand-oriented and market-driven approach to our R&D efforts. We first identify suitable drug development targets and carry out project evaluation and overall project design based on our development strategies and then explore and establish experimental methodology by coordinating across different experimental platforms. We carefully select drug development programs by balancing the commercial potential of each drug candidate and its likelihood of successful development, its potential competition, and the ultimate market size.

Drug Discovery

Our molecule screening and design capabilities increase the possibility of success of advancing molecules from preclinical studies to market, enable innovative therapeutic approaches and support rich pipeline assets built around key pathways and targets. We have built an efficient system to conduct target identification and validation, compound design and screen and lead compound optimization. During the discovery stage, drug candidates are tested for their

absorption, distribution, metabolism, excretion and toxicological properties, and promising compounds are optimized through structure modification to achieve maximum efficacy and minimum toxicity. Our R&D centers support a targeted drug discovery and screening platform, which can efficiently complete target identification and validation, compound design and lead optimization.

During the drug discovery stage, we explore new R&D opportunities, conduct feasibility research and provide evaluation for the opportunities. We also design and prepare new chemical compounds, conduct systematic research related to the manufacturing process and quality management of the new drugs and develop technology platforms to support, manage and supervise the related technologies.

Chemistry, Manufacturing & Controls

CMC Group

The CMC group is a critical link between discovery and clinical study. It is responsible for developing chemical and pharmaceutical processes, so that drug substances can be made with the desired physical and chemical properties and formulated to achieve maximum bio availability and stability. During the CMC stage, the synthesis of each API molecule is investigated thoroughly to ensure that the drug substance can reach pre-determined quality standards, the manufacturing processes are safe, robust, economical and environmentally friendly and the drug products have good stability and suitable storage conditions and shelf life.

Clinical Development Group

Our clinical development team oversees clinical trials for drug development, sets up the procedural standard of clinical affairs and handles clinical medicine matters. Our clinical development team also focuses on clinical development strategy, clinical trial protocol design, clinical trial operation coordination, pharmacovigilance and clinical trial quality control. Our clinical development team members specialize in management of all stages of our clinical trials, including clinical trial design, implementation, drug supply and the collection and analysis of trial data. We collaborate with top clinical experts in various areas as our principal investigators, leverage the operational capabilities of industry leading clinical research organizations and rely on well-known academic medical institutions and clinical trial centers in the PRC and abroad to promote the high quality and efficient implementation of our clinical trials in the PRC.

Clinical Trial Design and Implementation

Our clinical development group manages all stages of clinical trials, including protocol design, operation and the collection and analysis of clinical data. Our rapid trial advancements are driven by (i) our strategic decision to initiate clinical phase trials with our outstanding preclinical results, (ii) rigorous trial design, (iii) long-term partnership with numerous hospitals and principal investigators from different regions and (iv) high-quality execution. Leveraging our extensive knowledge and experience in clinical trials, our clinical development experts identify unique therapeutic opportunities for our drug candidates based on the differentiating properties observed in clinical trials and improve clinical plans accordingly.

Competition

The organ fibrosis market is subject to rapid change. While we believe that our robust pipeline of innovative products and drug candidates, strong sales and marketing capability and experienced leadership team provide us with competitive advantages, we face potential competition from many different sources working to develop therapies targeting the same indications which our marketed drug or our drug candidates target. These include major pharmaceutical companies, specialty pharmaceutical and biotechnology companies of various sizes, academic institutions, government agencies and research institutions. Any drug candidates that we successfully develop and commercialize will compete both with existing drugs and with any new drugs that may become available in the future.

Our products primarily compete with products that are indicated for similar conditions on the basis of efficacy, price and general market acceptance by medical professionals and hospitals. The identities of our key competitors vary by product or drug candidate, and in certain cases, our competitors may have greater financial resources and expertise in

R&D, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do.

We believe our continued success will primarily depend on our ability to develop innovative products and advanced technologies, apply technologies to all production lines, continuously develop an extensive product portfolio and pipeline, effectively commercialize and market our existing and future products, expand our distribution network and maintain customer relationships, attract and retain seasoned and talented technology development personnel, maintain high quality standards, maintain a highly efficient operational model and obtain and maintain regulatory approvals.

Production and Quality Control

In-House Manufacturing Facilities

Our manufacturing facilities are situated in Beijing and Cangzhou, Hebei province, in the PRC. During the years ended December 31, 2022 and 2023, 100% of pirfenidone we sold was manufactured at our Beijing and Cangzhou facilities. Our manufacturing facilities are designed and operated in compliance with cGMP regulations.

Quality Management

We believe that the product quality is fundamental to ensure the safety of patients and achieve our long-term development. Our quality management team monitors every stage of our operations in accordance with NMPA's regulations. We implement quality management measures throughout our production process, including supplier examination, raw material inspection and testing and process control, and all products are thoroughly inspected and tested before release.

Procurement Quality Control

We have established internal procedures governing the selection for raw material suppliers and quality control to meet the requirements of relevant cGMP and pharmaceutical registration regulations. We select our raw material suppliers based on a variety of factors, including their economic status, capital, reputation, quality control management, production scale and technological strengths and evaluate them based on their qualification, feedback to our questionnaire and our on-site examination.

Logistics and Delivery Management

We have entered into logistics service agreements with third parties. Pursuant to the arrangement, logistics service providers provide delivery services in a safe and timely manner pursuant to our requirements, while we are responsible for the quality of goods. Our logistics service providers are responsible for any loss caused by their negligence during their provision of the logistics service, including transfer, loading, unloading, transportation and delivery. Our logistics service providers also liaise and handle the insurance aspects, while we arrange the payment of insurance premiums together with the freight charges.

Inventory Management

Our inventory principally consists of raw materials, work-in-progress, semi-finished goods (representing APIs) and finished products. We endeavor to maintain our inventory at a reasonable level that is sufficient to sustain our production without interruption. We enter into supply agreements with reference to our annual sales plan, manufacturing plan and procurement plan.

Sales, Marketing and Distribution

Our In-House Sales and Marketing Team

As of December 31, 2023, our in-house sales and marketing team had market coverage of 30 provinces, autonomous regions and municipalities in the PRC. Our sales and marketing team is primarily responsible for establishing and maintaining relationships with outlets in their covered regions.

We believe the relatively high level of medical knowledge and skill of our sales and marketing team are important to the implementation of our academic marketing approach and maintenance of our reputation as a leading pharmaceuticals company. As of December 31, 2023, our in-house sales and marketing team included 391 employees, with an average of more than nine years of experience in pharmaceutical sales. Our more experienced staff also share their academic promotion networking experience on a regular basis.

For more details regarding the qualifications of our employees, see "*—Employees and Human Capital*" in this section.

Academic Promotion

We emphasize academic promotion and patient service in our sales and marketing efforts. We strive to promote and strengthen our academic recognition and brand awareness among medical experts by educating doctors and other medical professionals on ETUARY, our other product candidates and their respective indications. We believe that our working relationships with medical experts help to raise our profile, enhance awareness of ETUARY in the medical community and among patients, increase the clinical capabilities of healthcare providers and provide us with valuable clinical data to improve ETUARY, all of which help us more effectively market and sell ETUARY.

Distribution

Distributors are our direct customers and they resell our products to the outlets, including hospitals, other medical institutions and pharmacies. Distributors are primarily responsible for the delivery of products and their payments, while our in-house sales and marketing team is responsible for conducting academic marketing activities and other promotional efforts.

From time to time, we have terminated or opted to not renew our collaboration relationships with certain distributors due to consolidation of distribution channels and unstable business management of the distributors. At the same time, we add new distributors primarily as a result of the continued expansion and optimization of our sales network. In general, our relationships with our major distributors have remained stable.

Product Pricing

We take into account a number of factors in determining our prices, which primarily includes our R&D, production and marketing costs and expenses, the perceived value of products, our market share and the competitive landscape. In addition, our pricing strategies are also affected by the regulations and policies imposed on the pharmaceutical industry, including medical insurance reimbursement standards and regulation of medical and pricing practices. Our commercialization team closely monitors new policies affecting the pricing of pharmaceutical products in the PRC and keeps updating our pricing strategies to navigate in the evolving regulatory environment and cope with local policies and competition in different provinces, with the goal of maintaining the price levels of our products and maximizing our overall sales in the PRC. For details, see "*—Our Operations in the PRC: Gyre Pharmaceuticals—Regulatory Requirements in the PRC—Other PRC Regulations in Relation to the Pharmaceutical Industry—Price Controls*".

National Reimbursement Drug List

Participants in the national public medical insurance program are eligible for full or partial reimbursement of the purchase price of drugs included in the NRDL, which sets forth the payment standard for drugs under the basic medical insurance, work-related injury insurance and maternity insurance funds. The government started to regularly adjust the NRDL since 2017 and ETUARY successfully entered into the NRDL within the same year. The latest version of the NRDL has been implemented from March 1, 2023. For further details, see "*—Our Operations in the PRC: Gyre Pharmaceuticals—Regulatory Requirements in the PRC—Other PRC Regulations in Relation to the Pharmaceutical Industry—Coverage of the National Medical Insurance Program*".

Two-Invoice System

On December 26, 2016, the State Counsel Healthcare Reform Committee, National Health and Family Planning Commission, the National Development and Reform Commission and other relevant government authorities jointly issued the Circular on Issuing the Implementing Opinions on Carrying out the Two-Invoice System for Drug Procurement among Public Medical Institutions (for trial implementation), which provides detailed rules regarding the implementation of the Two-Invoice System at a national level. For details, see "*—Our Operations in the PRC: Gyre Pharmaceuticals—Regulatory Requirements in the PRC—Other PRC Regulations in Relation to the Pharmaceutical Industry—Drug Distribution and Two-Invoice System*". To comply with relevant regulations, we primarily adopt the single-layer distribution model with distributors who directly on-sell our products to hospitals and public medical institutions. Certain distributors may engage sub-distributors for the sales to pharmacies, which were not subject to the regime of the Two-Invoice System.

Centralized Tender Process and Centralized Volume-Based Procurement System

Prices of most pharmaceutical products in the PRC sold to public hospitals and public medical institutions are determined through a competitive centralized tender process at the provincial or municipal level with varying terms and procedures. In the centralized tender process, the winning pharmaceutical production companies will be allowed to sell their products to public hospitals and other public medical institutions at the bid prices. The centralized tender process can create pricing pressure among substitute products or products that are perceived by the market to be substitute products and resulted in significant change in how drugs are priced and procured in the PRC.

Raw Materials and Suppliers

In addition to the suppliers in our "Qualified Supplier Directory," each of our significant raw material suppliers have backup suppliers. In addition, each material has more than one manufacturer, and each manufacturer has multiple distributors. These distributors have reasonable inventory reserves. If we need to find a new supplier, we conduct comparative research and, after confirming, the supplier is added to our Qualified Supplier Directory to ensure product supply.

Regulatory Requirements in the PRC

Government authorities in the PRC extensively regulate, among other things, the research, development, testing, product approval, manufacture, quality control, manufacturing changes, packaging, storage, recordkeeping, labeling, promotion, advertising, sales, distribution, marketing, and import and export of drugs and biologic products. Our current product candidates are expected to be regulated as drugs. The processes for obtaining regulatory approval in the PRC, along with compliance with applicable statutes and regulations and other regulatory authorities both pre- and post-commercialization, are a significant factor in the production and marketing of our products and our research and development activities and require the expenditure of substantial time and financial resources.

Drug Regulatory Regime

The drug regulatory regime in the PRC consists of the Standing Committee of the National People's Congress, the State Council and several ministries and agencies under the State Council's authority including, among others, the NMPA, the predecessor of which is the China Food and Drug Administration ("CFDA"), the National Health Commission (the "NHC"), the predecessors of which are the National Health and Family Planning Commission of the PRC and the National Healthcare Security Administration (the "NHSA").

The NMPA, is a regulatory authority responsible for registration and supervision of pharmaceutical products, cosmetics and medical equipment under the supervision of State Administration for Market Regulation ("SAMR").

The NHC is the chief healthcare regulator of the PRC, and is primarily responsible for drafting national healthcare policy, regulating public health, medical services and the health contingency system of the PRC, coordinating healthcare reform in the PRC and overseeing the operation of medical institutions and practicing of medical personnel in the PRC.

The NHSA is responsible for drafting and implementing policies, plans and standards of medical insurance, maternity insurance and medical assistance, administering the PRC's healthcare fund, formulating a uniform medical insurance catalogue and payment standards for drugs, regulating medical disposables and healthcare services, and formulating and administering the bidding and tendering policies for drugs and medical disposables.

Laws and regulations in relation to Drugs

Pharmaceutical Product Development

In the PRC, the NMPA monitors and supervises the administration of pharmaceutical products, as well as medical devices and equipment. The local provincial medical products administrative authorities in the PRC are responsible for the supervision and administration of drugs within their respective administrative regions. According to the Drug Administration Law of the PRC (the "Drug Administration Law"), drugs refer to articles which are used in the prevention, treatment and diagnosis of human diseases and intended for the regulation of the physiological functions of human beings, for which indications or functions, usage and dosage are specified, including traditional PRC drugs, chemical drugs and biological products. The Drug Administration Law and the Implementing Regulations of the Drug Administration Law of the PRC, have established the legal framework for the administration of pharmaceutical products and applies to entities and individuals engaged in the research, production, trade, application, supervision and administration of pharmaceutical products.

Non-Clinical Research and Animal Testing

The State Administration for Market Regulation requires preclinical data to support registration applications for imported and domestic drugs. Pursuant to the Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory Studies, the NMPA is responsible for the certification of non-clinical research institutions across the PRC and the local provincial medical products administrative authorities are in charge of the daily supervision of non-clinical research institutions in the PRC. The NMPA decides whether an institution is qualified for undertaking pharmaceutical non-clinical research by evaluating such institution's organizational administration, research personnel, equipment and facilities and operation and management of non-clinical pharmaceutical projects. A GLP Certification will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website. When the GLP requirements are met, the State Drug Administration will approve and issue the drug GLP certification which is valid for five years.

The Administrative Regulations on Experimental Animals, the Administrative Measures on Good Practice of Experimental Animals and the Administrative Measures on the Certificate for Experimental Animals (for Trial Implementation) regulates the use and breeding of experimental animals and performing experimentation on animals requires a Certificate for Use of Laboratory Animals.

Approval and Reform for Clinical Trials of New Drugs

Under the Administrative Measures for Drug Registration, the PRC Drug Administration Law and Implementing Regulations of the PRC Drug Administration Law, new drug applications are subject to clinical trials. The NMPA has taken a number of steps to increase efficiency for approving clinical trial applications and has also significantly increased monitoring and enforcement of the Good Clinical Practice for Drug Trials (the "PRC's GCP"), to ensure data integrity.

The Administrative Measures for Drug Registration confirms a number of reform actions, including but not limited to: (i) the full implementation of marketing authorization holder system and implied approval of the commencement of clinical trials; (ii) implementing associated review of drugs, excipients and packaging materials; and (iii) introducing procedures for expedited registration of drugs. Upon completion of nonclinical research, clinical trials must be conducted for the application of a new drug registration and applicants must apply for approval of IND from the NMPA, or the CDE before conducting clinical trials.

The Opinions of the State Council on the Reform of Evaluation and Approval System for Drugs and Medical Devices, established a framework for reforming the evaluation and approval system for drugs and medical devices.

The Announcement of the CFDA on Several Policies on the Appraisal and Approval of Drug Registration, further simplifies the approval process of drugs and provides that the IND of new drugs is subject to one-off umbrella approval and the declaration review or approval by stages will no longer be adopted. According to the Announcement of the State Drug Administration on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs, within 60 days after the acceptance of and the fees paid for the IND, the applicant may conduct the clinical trials for the drug in accordance with the clinical trial protocol submitted, if the applicant has not received any negative or questioning opinion from the CDE.

The Priority Review and Approval Procedures for Drug Marketing Authorizations (for Trial Implementation) further clarified that a fast track IND or drug registration pathway will be available to the innovative drugs.

Regarding International Multi-Center Clinical Trials

Pursuant to the International Multi-Center Clinical Trial Guidelines (for Trial Implementation), promulgated by the NMPA, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement the International Multi-center clinical trials in the PRC, the applicants must comply with the Drug Administration Law, the Regulations for the Implementation of the PRC Drug Administration Law and the Measures for the Administration of Drug Registration. Additionally, applicants must execute the GCP, make reference to universal international principles such as the ICH-GCP and comply with the laws and regulations of the countries involved in the International Multi-Center clinical trials. Where the applicants plan to use the data derived from the International Multi-Center clinical trials for approval of a drug registration in the PRC, the application must involve at least two countries, including the PRC, and must satisfy the requirements for clinical trials set forth in the Notice on Issuing the International Multi-Center Clinical Trial Guidelines (for Trial Implementation) and the Administrative Measures for Drug Registration and other related laws and regulations.

Drug Clinical Trial Registration

According to the Administrative Measures for Drug Registration, upon obtaining the approval of its IND, the applicant must, prior to conducting the clinical trial of drugs, register on the registration and information announcement platform for clinical trials of drugs, information regarding the scheme of the clinical trial.

Pursuant to the Announcement on Drug Clinical Trial Information Platform, all clinical trials approved by the NMPA and conducted in the PRC must complete a clinical trial registration and publish trial information through the Drug Clinical Trial Information Platform. The applicant must complete the trial pre-registration within one month after obtaining the approval of the IND in order to obtain the trial's unique registration number and complete registration of certain follow-up information before the first subject's enrolment in the trial. If the registration is not completed within one year after the approval of the IND, the applicant must submit an explanation and if applicant's first submission is not completed within three years, the approval of the IND will automatically expire.

Phases of Clinical Trials and the Communication with the CDE

According to the Administrative Measures for Drug Registration, a clinical trial consists of Phases 1, 2, 3, 4 and bioequivalence trial. In addition to the characteristics of a drug and the research purpose, the research contents must also include clinical pharmacological research, exploratory clinical trial, confirmatory clinical trial and post-marketing research under the Administrative Measures for Drug Registration.

Pursuant to the Administrative Measures for Communication on Drug Research, Development and Technical Reviews, during the research and development periods and in the registration applications of the innovative new drugs (among others), the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development periods of drugs, and mainly include meetings before the IND application, meetings upon the completion of Phase 2 trials and before the commencement of Phase 3 trials, meetings

before submitting a marketing application for a new drug and meetings for risk evaluation and control. Type III meetings refer to meetings not classified as Type I or Type II.

Sampling and Collecting Human Genetic Resources Filing

The Administrative Regulations of the PRC on the Administration of Human Genetic Resources, further stipulates that in order to obtain marketing authorization for relevant drugs and medical devices in the PRC, no approval is required in international clinical trial cooperation using the PRC's human genetic resources at clinical institutions without export of human genetic resource materials. However, the two parties must file the type, quantity and usage of the human genetic resource to be used with the administrative department of science and technology under the State Council before clinical trials may commence. According to the Service Guide for Administrative Licensing Items Concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (the "Service Guide"), the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor falls within the scope of international cooperation and the cooperating organization of the PRC must apply for approval of the China Human Genetic Resources Management Office.

Pursuant to the Administrative Regulations of the PRC on Human Genetic Resources, no approval is required in international clinical trial cooperation using the PRC's human genetic resources at clinical institutions without export of human genetic resource materials in order to obtain marketing authorization for relevant drugs and medical devices in the PRC. However, the two parties must file the type, quantity and usage of the human genetic resource to be used with the administrative department of science and technology under the State Council before clinical trials commence.

On June 1, 2023, The Ministry of Science and Technology promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (the "HGR Implementation Rules"), which became into effect on July 1, 2023. The HGR Implementation Rules have refined the Regulations of the PRC on the Administration of Human Genetic Resources, including, but not limited to, refining the definition of "human genetic resources information", clarifying the identification standard of "foreign entities", adjusting the scope of collection licensing, and adjusting and improving the approval procedures for international cooperative scientific research and administrative supervision rules.

Registration of Drug Marketing

According to the Administrative Measures for Drug Registration, an applicant must complete studies in pharmacy, pharmacology and toxicology, as well as clinical trials of pharmaceuticals. The applicant must submit an application for drug marketing authorization and the relevant research materials in accordance with the submission requirements after determining quality standards, verifying commercial scale manufacturing process and preparing to undergo examination and inspection for drug registration. Once an application is submitted, the CDE will assemble pharmacists, medical professionals and other technical specialists to analyze the drug's safety, effectiveness and quality control. After the comprehensive review, the drug will be approved for marketing and a drug registration certificate shall be issued.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law, the state implements the drug marketing authorization holder system for drug management. The drug marketing authorization holder is an enterprise or a drug development institution that has obtained the drug registration certificate and is responsible for non-clinical research, clinical trials, production and operation, post-marketing research, adverse reaction monitoring, reporting and processing of drugs in accordance with the provisions of the Drug Administration Law.

Under the Circular of the CFDA on the Matters Relating to Promotion of the Pilot Program for the Drug Marketing Authorization Holder System (the "Circular on Drug Marketing Authorization Holder System"), the drug marketing authorization holder must establish a drug quality assurance system and be equipped with special personnel to take charge of quality management on drugs independently. Additionally, the drug marketing authorization holder must regularly review the quality management system of the drug manufacturer and the drug distributor and supervise its continuous quality assurance and control capabilities. A drug marketing authorization holder who manufactures drugs on its own shall obtain a drug production license in accordance with the Circular on Drug Marketing Authorization

Holder System and entrust a qualified drug manufacturer. The drug regulatory authority of the State Council has formulated guidelines for the quality of pharmaceuticals entrusted manufacturing, to guide and supervise the drug marketing authorization holder and the entrusted manufacturer to fulfill their drug quality assurance obligations. The Announcement of the State Drug Administration on Strengthening the Supervision and Administration on Entrusted Manufacturing by the Drug Marketing Authorization Holder, which came into effect on October 17, 2023, reiterates the importance of supervision over entrusted manufacturing and stipulates more stringent and detailed requirements on aspects of license, quality and supervision of the entrusted manufacturing of the drug marketing authorization holder.

Drugs' Registration Classification

Under the Measures for the Administration of Drug Registration, drugs are classified into PRC medicine, chemical medicine, biological products and others. According to the Notice of the NMPA about the Issuing of the Reform Plan for the Registration Classification of the Chemical Drugs, the registration classification of the chemical drugs are adjusted to five categories. Category 1 drugs refer to innovative chemical drugs that have not been marketed anywhere in the world. Improved new chemical drugs that are not marketed anywhere in the world fall into Category 2 drugs. Generic chemical drugs that have equivalent quality and efficacy to the originator's drugs that have been marketed abroad but not yet in the PRC are classified as Category 3 drugs. Generic drugs that have equivalent quality and efficacy to the originator's drugs and have been marketed in the PRC fall into Category 4 drugs. Category 5 drugs are drugs which have already been marketed abroad, but are not yet approved in the PRC. Category 1 and 2 drugs must follow the registration application procedure for new drugs according to the Measures for the Administration of Drug Registration; Category 3 and 4 drugs must follow the procedure for generic drugs; and Category 5 drugs must follow the application and regulation requirements for importing drugs.

According to the Chemical Drug Registration Classification and Application Data Requirements, innovative chemical drugs and improved new chemical drugs are categorized as Category 5.1 drugs, while generic chemical drugs, all of which shall have been already marketed abroad but not yet approved in the PRC are categorized as Category 5.2 drugs.

Special Examination and Fast Track Approval for Drugs Targeting Rare Diseases

Pursuant to the Notice on Publishing the Procedures of Developing the Rare Disease List, the following four criteria must be met at the same time for rare disease designation: (i) the disease has a low incidence or prevalence in PRC and abroad; (ii) the disease significantly impacts the patient and his or her family; (iii) there is a clear diagnosis method; and (iv) the disease can be treated or intervened in an economically feasible way, or it has been included in a national scientific research project if there is no effective treatment or intervention for such disease. With certain drugs targeting rare diseases being listed in National Rare Disease List, a company may be eligible for the priority review and approval of new drugs for these diseases from the NMPA.

According to the Administrative Provisions on Special Examination and Approval of the Registration of New Drugs, special examination and approval for new drugs registration applications applies when (1) the effective constituent of a drug extracted from plants, animals and minerals, as well as the preparations thereof, have never been marketed in the PRC and the material medicines and the preparations thereof are newly discovered; (2) the chemical raw materials for medicines as well as the preparations thereof and the biological product have not been approved for marketing, either in the PRC or aboard; (3) new drugs with distinctive clinical treatment advantages for diseases such as AIDS, malignant tumor or other rare diseases; or (4) new drugs for diseases that currently lacking effective treatment.

According to the Opinions of the State Council on the Reform of Evaluation and Approval System of Drugs and Medical Devices, a special evaluation and approval system shall be adopted for innovative drugs to accelerate the evaluation and approval process for innovative drugs for prevention and treatment of AIDS, cancer, major infectious diseases, rare diseases and other diseases.

According to the Announcement of the State Drug Administration and the NHC on Optimizing the Evaluation and Approval of Drug Registration, the CDE will prioritize the allocation of resources for review, inspection, examination and approval of registration applications that have been included in the scope of priority evaluation and approval.

Good Manufacturing Practices

Pursuant to the Drug Administration Law, one engaged in drug manufacturing activities shall comply with the GMP and establish a sound GMP management system, to ensure that the entire process of drug manufacturing is maintained to meet the statutory requirements and the GMP requirements enacted by the drug regulatory authority under the State Council in accordance with the Drug Administration Law. The legal representative of and principal person in charge of a drug manufacturer are fully responsible for the drug manufacturing activities of the enterprise.

The Good Manufacturing Practice for Drugs provided guidance for the quality management, organization and staffing, production premises and facilities, equipment, material and products, recognition and inspection, documentation maintenance, manufacture management, quality control and quality assurance, contractual manufacture and contractual inspection for the products, product delivery and recalls of a manufacturer.

Drug Production License

Under the Measures for the Supervision and Administration of Drug Production promulgated by SAMR, persons engaging in pharmaceutical manufacturing activities shall be subject to approval by the pharmaceuticals administrative authorities of the province, autonomous region or centrally-administered municipality where the persons engaging in pharmaceutical manufacturing activities are located, obtain a Drug Production License pursuant to the Measures for the Supervision and Administration of Drug Production promulgated by SAMR, comply strictly with the pharmaceutical manufacturing quality control norms and ensure that the manufacturing process complies with statutory requirements at all times. The period of validity of Drug Production License is five years. In the event the license holder needs to continue to manufacture pharmaceuticals upon the expiration of the Drug Production License, it shall apply to the original issuing authorities for reissuance of a Drug Production License six months before the expiration date of the Drug Production License.

Drug Business License and Good Supply Practice Requirements

According to Drug Administration Law and the Regulations for the Implementation of the PRC Drug Administration Law, in order to be engaged in the drug wholesale distribution and retailing of drugs, a company must obtain a Drug Business License with an appropriate "scope of distribution" from the local drug regulatory authority and comply with the Good Supply Practice for Pharmaceutical Products promulgated by the CFDA under the State Council. Under the Measures for the Supervision and Administration of Drug Quality in Trading and Usage, which became effective on January 1, 2024, a Pharmaceutical Trading License is valid for five years. Each holder of the Pharmaceutical Trading License must apply for an extension of its permit during the period from two months to six months prior to expiration. Otherwise, the holder shall cease its trading activities upon expiration until a new Pharmaceutical Trading License is granted by the drug regulatory authority.

Other PRC Regulations in relation to the Pharmaceutical Industry

Drug Recall

According to the Measures on the Administration of Drug Recalls, the term "drug recalls" refers to the activities of a drug marketing authorization holder to recall drugs that have been marketed, but have quality problems or other potential safety hazards under the prescribed procedures and take corresponding measures to timely control risks and eliminate potential hazards. The term "quality problems or other potential safety hazards" refers to non-compliance of drugs with statutory requirements, or other unreasonable risks that may endanger human health and life safety caused by drugs due to research and development, production, storage and transportation, labeling and other reasons.

Administrative Protection and Monitoring Periods for New Drugs

Pursuant to the Implementing Regulations for the Drug Administration Law of the PRC, based on the needs for protection of public health, the NMPA may set an observation period of not more than five years for new drugs produced by drug manufacturers; and no approval shall be given to any other manufacturers to produce or import the said drugs during the observation period.

Packaging of Pharmaceutical Products

Pursuant to the Drug Administration Law, drug packaging must be printed or affixed with a label and include the literature pursuant to the provisions. According to the Measures for The Administration of Pharmaceutical Packaging, pharmaceutical packaging must comply with national and professional standards. Drugs that have not been developed and approved for packaging standards cannot be sold or marketed in the PRC (except for drugs for the military). According to the PRC's GCP, the packaging labels of the investigational product must indicate the information on the use only for clinical trial, clinical trial information and information on the drug for clinical trial, but the blinded state may be kept in blind trials.

Insert Sheet and Labels of Pharmaceutical Products

Pursuant to Administrative Provisions on Pharmaceutical Directions and Label, the insert sheets and labels of drugs should be reviewed and approved by the NMPA. A drug insert sheet should include the important scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug's name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, description, indication or function, strength, dose and usage, adverse reaction, contraindications, precautions, storage, production date, batch number, expiry date, approval number and drug manufacturer.

Advertising of Pharmaceutical Products

Pursuant to the Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purpose, the contents of a drug advertisement must be based on the drug instructions approved by the drug administrations under the State Council. Where a drug advertisement involves drug name, indications or major functions and pharmacological effects, the drug advertisement shall not go beyond the scope of instructions and must state contraindications and adverse reactions in a prominent position. Prescription drug advertisements must also state that "the advertisement is meant to be read only by medical and pharmaceutical professionals" in a prominent position and OTC drug advertisements must also add the non-prescription drug label (OTC) in a prominent place and state that "please purchase and use the drugs in accordance with the drug instructions or under the guidance of a pharmacist" in a prominent position.

Drug Technology Transfer

Drug technology transfer refers to the transfer of drug production technology by the owner to a drug manufacturer as the transferee and the application for drug registration by the drug manufacturer as the transferee pursuant to the provisions under Administrative Provisions for Registration of Drug Technology Transfer. The NMPA promulgated the Administrative Provisions for Registration of Drug Technology Transfer, to standardize the registration process of drug technology transfer, which includes application for, evaluation, review, approval and supervision of drug technology transfer registration. An application for drug technology transfer must be submitted to the provincial drug regulatory authority and the SFDA will ultimately make an approval decision based on the comprehensive opinions of the drug review center. Eligible applications will receive a letter of approval and a drug approval number for the supplementary application.

Online Drug Information Services

According to the Administrative Measures for Internet-based Drug Information Service, the operational internet drug information service refers to the activities of providing medical information (including medical devices) and other services through the internet. Where any website intends to provide internet drug information services, the website must file an application with the local provincial counterparts of NMPA and will be subject to the examination and approval thereof for obtaining the qualifications for providing internet drug information services. The validity term for a Qualification Certificate for Internet Drug Information Services is five years and may be renewed at least six months prior to its expiration date upon a re-examination by the relevant authority.

Centralized Drug Procurement and Use

According to the Circular of the General Office of the State Council on Issuing the Pilot Program for Conducting Centralized Drug Procurement and Use by the State and the Opinions of the National Healthcare Security Administration on Supporting Measures Concerning Medical Insurance for the Pilot Program for Conducting Centralized Procurement and Use of Drugs by the State, eleven pilot cities are selected as the pilot cities for the centralized procurement and use of drugs under the organization of the country. The scope of drugs to be procured in a centralized manner includes selected varieties from the generic names corresponding to generic drugs passing consistency evaluation of quality and efficacy. After completing the purchases by the public medical institutions in the pilot regions, the public medical institutions will use the selected drugs as the priority drugs and the quantity of the selected drugs used during the pilot procurement period will be no less than that of the non-selected drugs.

According to the Implementation Opinions on Expanding the Regional Scope in the Pilot Program for Conducting Centralized Procurement and Use of Drugs by the State to Wider Areas issued by several authorities including the National Healthcare Security Administration and NMPA, among others, the mode of centralized procurement of drugs with quantity for centralized procurement and use of drugs organized by the country is being promoted throughout the country. Such mode is applicable to 25 designated generic drugs in the pilot program of centralized drug procurement and use of drugs organized by the country.

Coverage of the National Medical Insurance Program

Under the Decision of the State Council on Establishing the Urban Employees' Basic Medical Insurance System, all employers in urban cities are required to enroll their employees in the basic medical insurance program and employers and employees must jointly contribute to the insurance premiums. Under the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance, urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. The Opinions of the State Council on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents requires the integration of the urban resident basic medical insurance and the new rural cooperative medical care system. Additionally, the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance established a unified basic medical insurance system, which covers all urban and rural residents other than rural migrant workers and persons in flexible employment arrangements who participate in the basic medical insurance for urban employees. Program participants are eligible for full or partial reimbursement of the cost of medicines included in the medical insurance catalogue.

Pursuant to the Notice Regarding the Tentative Measures for the Administration of the Scope of Basic Medical Insurance Coverage for Pharmaceutical Products for Urban Employee, a pharmaceutical product listed in the medical insurance catalogue must be clinically necessary, safe, effective, reasonably priced, easy to use, available in sufficient quantity and must meet one of the following requirements: (1) be set forth in the pharmacopoeia of the PRC, (2) satisfy the standards promulgated by the NMPA and (3) be approved by the NMPA for imported pharmaceutical products.

The PRC Ministry of Labor and Social Security, together with other government authorities, has the power to determine the medicines included in the National Medical Insurance Catalog. The Western medicine and Chinese patent medicine included in the National Medical Insurance Catalog are divided into two parts, Part A and Part B. Provincial governments are required to include all Part A and Part B medicines listed on the National Medical Insurance Catalog in their provincial Medical Insurance Catalog in the National Medical Insurance Catalog. Fees incurred for the use of Part A medicines are entitled to reimbursement in accordance with the regulations in respect of basic medical insurance. Fees incurred by the use of Part B are shared by the patient and basic medical insurance. The percentage of reimbursement by basic medical insurance for Part B medicines is stipulated by local authorities and in result may differs from region to region in the PRC.

National Essential Drug List

According to the Opinions of the General Office of the State Council on Improving the National Essential Drugs System, Circular on the Issuance the Administrative Measures for the List of National Essential Drugs, and the National Essential Drug List (2018) (the "National Essential Drug List"), basic healthcare institutions funded by government (primarily county-level hospitals, county-level PRC medicine hospitals, rural clinics and community clinics), must store and use drugs listed in the National Essential Drug List. The drugs listed in the National Essential Drug List must be purchased by centralized tender process and shall be subject to the price control by NDRC. Remedial

drugs in the National Essential Drug List are listed in the National Basic Medical Insurance Catalogue and the entire amount of the purchase price of such drugs is entitled to reimbursement.

Medical Insurance Reimbursement Standards

According to the Decision of the State Council on Establishing the Urban Employees' Basic Medical Insurance System, Opinions on the Establishment of the New Rural Cooperative Medical System, the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance and the Opinions of the State Council on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents, medical insurance would be available to all employees and residents in both rural and urban areas.

According to the Notice of Opinion on the Diagnosis and Treatment Management, Scope and Payment Standards of Medical Service Facilities Covered by the National Urban Employees Basic Medical Insurance Scheme, the basic medical insurance scheme would cover a portion of the costs of diagnostic and treatment devices, as well as diagnostic testing. The scope and rate of reimbursement are determined by provincial policies.

The major aim of the Guidance on Further Deepening the Reform of the Payment Method of Basic Medical Insurance released by the General Office of the State Council is to develop a diverse reimbursement mechanism that includes diagnosis-related groups, per-capita caps and per-bed-day caps. These new reimbursement systems have been implemented across the country, replacing the previous reimbursement method, which is based on service category and product price.

Price Controls

For drugs with their prices determined by the market, the Drug Administration Law of the PRC requires that these drugs' prices are determined by the market and marketing authorization holders, manufacturers and distributors of drugs and medical institutions must conduct pricing under the principles of fairness, rationality, good faith and consistency between quality and prices. Marketing authorization holders, manufacturers and distributors of drugs and medical institutions must comply with the price management rules for drugs of the medicinal product price department of the State Council to determine the prices of drugs and are prohibited from making exorbitant profits, price monopoly and price fraud, among others.

According to Price Law of the PRC, drug prices must be set in compliance with the law of value. Prices of most commodities and services are market-adjusted prices and prices of a very small number of commodities and services are government- guided prices or government-set prices. The prices of pharmaceutical products are mainly determined by market competition. Instead of direct governmental price controls, the government primarily regulates prices by establishing a centralized procurement mechanism, revising medical insurance reimbursement standards and strengthening regulation of medical and pricing practices.

The Opinions on Effectively Carrying out Drug Price Administration at Present promulgated by National Healthcare Security Administration seek to further improve the drug pricing formation mechanism and emphasizes the market-oriented drug pricing mechanism. Although narcotic drugs and Category 1 psychotropic drugs are subject to government pricing, other drugs are priced by drug operators according to the market. Meanwhile, the national and provincial medical security departments may implement or delegate third parties to implement price cost investigation on drug suppliers and the results can be used as the basis for determining whether the drugs were sold at unfair prices.

Drug Distribution and Two-Invoice System

The Implementing Opinions on Promoting the "Two-Invoice System" for Drug Procurement By Public Medical Institutions (For Trial Implementation) ("Two-Invoice System Notice") is a system that mandates only two invoices shall be issued during the drug distributions, i.e., pharmaceutical manufacturers to issue one invoice to pharmaceutical distributors and pharmaceutical distributors to provide another one invoice to public medical institutions. The Two-Invoice System excludes the sale of products through a chain of distributors which will, in result, increase the ultimate drug price of the public medial institutions. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

According to the Several Opinions of the General Office of the State Council on Further Reform and Improvement in Policies of Drug Production, Circulation and Use, the Two-Invoice System would be promoted in pilot areas for public hospital reform, and has been implemented nationwide by 2018. Pharmaceutical companies must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

Regulation in Relation to Intellectual Property Rights

Patents

Pursuant to the Patent Law of the PRC and the Implementation Rules of the Patent Law of the PRC, an invention-creation shall mean an invention, utility model or design. Inventions and utility models for which patent rights are granted and an invention-creation must possess novelty, creativity and practicality. The Patent Office under the State Intellectual Property Office is responsible for receiving, examining and approving patent applications. The protection period is 20 years for an invention patent, 10 years for a utility model patent and 15 years for a design patent, commencing from such patent's application date. Any patentee or interested party may file a lawsuit with a people's court against any individual or entity that utilizes a patent or conducts any other activity that infringes a patent without the patent holder's authorization, and may request regulatory authorities to order the infringer to stop the infringement act forthwith or impose a fine on the infringer. If the patent infringement is found to constitute a crime, the patent infringer shall be held criminally liable in accordance with applicable laws. According to the PRC Patent Law, for public health purposes, the State Intellectual Property Office of the PRC may grant a compulsory license for manufacturing patented drugs and exporting them to countries or regions covered under relevant international treaties to which PRC has acceded. In addition, according to the Patent Law, any organization or individual that applies for a patent in a foreign country for an invention or utility model patent established in the PRC is required to report to the State Intellectual Property Office for confidentiality examination.

Trademarks

Pursuant to the Trademark Law of the PRC and the Regulations on the Implementation of the Trademark Law of the PRC, the validity period of registered trademarks is 10 years, calculated from the date of approval of the registration. A trademark registrant intending to continue to use the registered trademark upon expiry of the period of validity must undergo the renewal formalities within 12 months before expiry according to the relevant provisions. If it fails to do so, the trademark registrant may be granted a six-month grace period. The period of validity of each renewal is 10 years, commencing from the day after the expiry date of the last period of validity. If the renewal formalities are not satisfied within the grace period, the registration of the trademark is canceled.

Copyright

Copyright in the PRC is protected by the Copyright Law of the PRC and Regulations for the Implementation of the Copyright Law of PRC. These laws and regulations provide provisions on the classification of works and the obtaining and protection of copyright and its related rights.

Domain Names

Domain names are protected under the Measures for the Administration of Internet Domain Names issued by the Ministry of Industry and Information Technology (the "MIIT") and Implementing Rules on Registration of China Country Code Top-level Domain Names issued by China Internet Network Information Center. The MIIT is the regulatory body responsible for the administration of PRC internet domain names. The China Internet Network Information Center is responsible for the administration of registration of China country code top-level domain names.

Trade Secrets

According to the Anti-Unfair Competition Law of the PRC and Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Trade Secret Infringement, the term "trade secrets" refers to technical and business information that is unknown to the public, has utility, may create business interests or profits for its legal owners or holders and is maintained as a secret by its legal owners or holders. Under the PRC Anti-Unfair Competition Law, business persons are prohibited from infringing others' trade secrets

by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion or any other illicit means; (2) disclosing, using or allowing another person to use a trade secret acquired from the right holder by any means as specified in the preceding subparagraph; (3) disclosing, using or allowing another person to use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; and (4) abetting a person, or tempting or aiding a person into or in acquiring, disclosing, using or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential.

Regulations on Environmental Protection

According to the Environmental Protection Law of the PRC, the Regulations on the Administration of Construction Project Environmental Protection and the Environmental Impact Assessment Law of the PRC and Law of the PRC on the Prevention and Control of Environment Pollution Caused by Solid Wastes, an enterprise, which causes environmental pollution and discharges other materials that endanger the public, must implement environmental protection methods and procedures into its business operations. Where effects may be exerted on the environment after the completion of construction projects, the construction enterprise must submit an environmental impact report (form) or environmental impact registration form to the relevant environmental protection department. Any project that is required to prepare the environmental impact report (form) in accordance with the law must obtain the approval from the relevant environmental protection department for its environmental impact assessment documents; otherwise, construction on the project may not begin. Pursuant to the Administrative Measures for Pollutant Discharge Licensing (for Trial Implementation) and the Regulations on the Administration of Pollutant Discharge Permits, a pollutant-discharging entity must legally hold a pollutant discharge license and discharge pollutants in compliance with the pollutant discharge license. Any entity must obtain a pollutant discharge license prior to discharging any pollutants. A discharge license issued for the first time shall be valid for three years and a renewed license shall be valid for five years.

Pursuant to the Notice of the General Office of the State Council on Issuing the Implementation Plan for the Permit System for Controlling the Discharge of Pollutant Emission and the Classification Administration List of Pollutant Discharge Permitting for Fixed Pollution Sources (2019 Version), the state implements a focused management, a simplification management and a registration management of emission permits based on the pollutant discharging enterprises and other manufacturing businesses' amount of pollutants, emissions and the extent of environmental damage. The manufacturing of drug substance and manufacturing dose for chemical drugs (except for manufacturing of dose for chemical drugs that are simply mixed or repackaged) fall within the industries that are strictly regulated, and must obtain the discharge permit in accordance with the prescribed time limit.

Hazardous Chemicals

Regulations on Safety Administration of Hazardous Chemicals, provides regulatory requirements on the safe production, storage, use, operation and transportation of hazardous chemicals. The PRC government exerts strict control over implementing overall planning and rational layout for the production and storage of hazardous chemicals and exam safety conditions of construction project concerning manufacturing or storing hazardous chemicals. An enterprise that manufactures and stores hazardous chemicals is required to appoint a qualified institution to conduct safety evaluations of its safety production conditions once every three years and to prepare a safety evaluation report.

According to the Administrative Measures for the Registration of Hazardous Chemicals, the state adopts a registration system for hazardous chemicals. The registration of hazardous chemicals are subject to the principles of application by enterprises, two-level review, unified issuance of certificates and hierarchical administration. Where any registering enterprise fails to go through the registration formalities for hazardous chemicals or fails to go through the formalities for altering the registration contents of hazardous chemicals when the type of registration changes or the hazardous chemicals it manufactures or imports have new hazardous characteristics, the registering enterprise must make corrections and may be subject to a fine of not more than 50,000 yuan. If the registering enterprise refuses to make corrections, it shall be given a fine of not less than 50,000 yuan but not more than 100,000 yuan. If the circumstance is serious, the registering enterprise will be ordered to suspend production and business for rectification.

Product Liability

Pursuant to the Product Quality Law of the PRC, manufacturers shall be liable for the quality of products they produce and guarantee that the product quality meets the requirements stipulated by laws and shall not mix impurities or imitations into products, pass fake goods off as genuine ones or shoddy products as good ones or sub-standard products as standard ones. Sellers are required to take measures to ensure the quality of the products sold by them. The manufacturer shall be liable to compensate for any bodily injuries or damage to property other than the defective product itself resulting from the defects in the product, unless the manufacturer is able to prove that: (1) the product has never been circulated; (2) the defects causing injuries or damage did not exist at the time when the product was circulated; or (3) the science and technology at the time when the product was circulated were at a level incapable of detecting the defects.

According to the Civil Code of the PRC, where a defect of a product endangers the personal or property safety of another person, the manufacturer or the seller shall assume civil liabilities in accordance with the law.

Labor Protection

According to the Labor Law of the PRC, employers must develop and improve their rules and regulations in accordance with the law to ensure that workers enjoy their labor rights and perform their labor obligations. Employers must develop and improve the system of labor safety and sanitation and strictly implement the national protocols and procedures on labor safety. Employers must guard against labor safety accidents and reduce occupational hazards and labor safety and sanitation facilities must meet the relevant national standards. Employers must provide workers with the necessary labor protection equipment that meets the safety and hygiene conditions stipulated under national regulations by the State and conduct regular health checks for workers who engage in operations with occupational hazards. Laborers engaged in special operations must have received specialized training and obtained the pertinent qualifications.

According to Labor Contract Law of the PRC and the Implementation Regulations of the Labor Contract Law of the PRC, employers and employees must enter into written labor contracts to establish their employment relationships. With respect to a circumstance where a labor relationship has already been established but no formal contract has been made, a written labor contracts must be entered into within one month from the date when the employee begins to work. In addition, wages shall not be lower than the local minimum wage standard.

According to Interim Provisions on Labor Dispatch, employers may employ dispatched workers only for temporary, auxiliary or substitutable positions and must strictly control the number of dispatched workers which may not exceed 10% of the total number of its workers.

Social Insurance and Housing Fund Regulations

According to the PRC Social Insurance Law (the "Social Insurance Law"), the Interim Regulation on Levying Social Insurance Premiums, the Regulation on Work-Related Injury Insurance, the Regulation on Unemployment Insurance and the Trial Measures for Maternity Insurance of Enterprises Employees, the employer must contribute to social insurance plans covering basic pensions insurance, basic medical insurance, maternity insurance, work injury insurance and unemployment insurance. Basic pension, medical and unemployment insurance contributions shall be paid by both employers and employees, while work-related injury insurance and maternity insurance contributions shall only be paid by employers. Employers who fail to promptly contribute social security premiums in full shall be ordered by the social security premium collection agency to make or supplement contributions within a prescribed time limit and shall be subject to a late payment fine computed from the due date at the rate of 0.05% per day; where payment is not made within prescribed time limit, the relevant administrative authorities shall impose a fine ranging from one to three times the outstanding amount.

According to the Regulation on the Administration of Housing Provident Fund, employers must register with the competent managing center for housing provident funds and upon the examination by such center, these employers shall complete procedures for opening an account at the bank for the deposit of employees' housing provident funds. Employers are also required to pay and deposit housing funds on behalf of their employees in full and in a timely manner. Employers that violate the Regulation on Housing Provident Fund and fail to open housing provident fund accounts for their employees with the housing fund administration center within a designated period or fail to go

through the formalities of opening housing provident fund accounts for their employees shall be subject to a fine ranging from approximately $1,412 to $7,062.

Foreign Investment

The Foreign Investment Law of the PRC and the Implementing Regulation for the Foreign Investment Law, applies to any investment activities directly or indirectly conducted by a foreign natural person, enterprise or other organization and a foreign-invested enterprise established prior to the effective date of the Foreign Investment Law shall adjust its legal form or governance structure to comply with the provisions of the Company Law of the PRC or the Partnership Enterprises Law of the PRC, as applicable and complete amendment registration before January 1, 2025. According to the Foreign Investment Law of the PRC, the state applies the administrative system of pre-establishment national treatment plus negative list to foreign investment and accords national treatment to foreign investment outside of the negative list. Furthermore, the Implementing Regulation for the Foreign Investment Law provides implementing measures and detailed rules to ensure the effective implementation of the Foreign Investment Law.

On December 30, 2019, the Ministry of Commerce of the PRC ("MOFCOM") and the State Administration for Market Regulation, or the SAMR, jointly promulgated the Measure for Reporting of Information on Foreign Investment, which came into effect on January 1, 2020 and pursuant to which, the establishment of the foreign-invested enterprises, including establishment through purchasing the equities of a domestic non-foreign-invested enterprise or subscribe to the increased capital of a domestic non-foreign funded enterprise and its subsequent changes are required to submit an initial or change report through the Enterprise Registration System.

The Special Administrative Measures for Foreign Investment (2021 Edition) ("Negative List") sets out in a unified manner the special management measures for the access of foreign investments such as requirements for equity and senior management. Any field falling outside the Negative List shall be administered under the principle of equal treatment to domestic and foreign investment. Domestic enterprises engaged in businesses in fields prohibited from investment by the Negative List must be reviewed and approved by the relevant competent authorities of the state before issuing shares abroad and listing for trading. Foreign investors are not allowed to participate in the operation and management of the enterprises and their equity ratio are governed with reference to the relevant regulations on the management of domestic securities investment by overseas investors.

Regulations on Outbound Investment

Pursuant to the Administrative Measures on Outbound Investments, the MOFCOM and the commerce departments at provincial levels shall subject the overseas investment of enterprises to recordation or confirmation management, depending on the actual circumstances of investment. Overseas investment involving any sensitive country or region, or any sensitive industry is subject to confirmation management. Overseas investment under other circumstances is subject to recordation management.

Pursuant to the Administrative Measures for the Outbound Investment of Enterprises, an enterprise in the territory of the PRC ("the PRC Investor") shall, in overseas investment, undergo the formalities for the confirmation or recordation, among others, of an overseas investment project (the "Investment Project"), report the relevant information and cooperate in supervisory inspection. Sensitive Investment Projects conducted by PRC Investors directly or through overseas enterprises controlled by them shall be subject to approval, and non-sensitive Investment Project directly conducted by PRC Investors, namely, non-sensitive Investment Projects involving PRC Investors' direct contribution of assets or rights and interests or provision of financing or security, shall be subject to filing. The aforementioned sensitive Investment Project means an Investment Project involving a sensitive country or region or a sensitive industry. The NDRC promulgated the Catalogue of Sensitive Sectors for Outbound Investment (2018 Edition) to list the sensitive industries in detail.

Enterprise Income Tax

Pursuant to the PRC Enterprise Income Tax Law (the "EIT Law") and its implementation rules, a PRC resident enterprise is subject to EIT at the current uniform rate of 25% commencing from January 1, 2008 unless reduced under

certain specific qualifying criteria. The term "resident enterprise" refers to any enterprise established in the PRC and any enterprise established outside the PRC with a "place of effective management" within the PRC.

In 2018, we obtained a certificate from the Beijing government for a High and New Technology Enterprise ("HNTE") qualification and the certificate was renewed in 2021. This renewed certificate entitled the us to enjoy a preferential income tax rate of 15% for a period of three years from 2021 to 2023 if all the criteria for HNTE status could be satisfied in the relevant year.

Non-resident Enterprises Taxation Arrangement

Dividends (if any) paid by our subsidiaries in the PRC to their direct offshore parent companies are subject to PRC withholding income tax at the rate of 10%, provided that such dividends are not effectively connected with any establishment or place of the offshore parent company in the PRC. The 10% withholding income tax rate may be reduced or exempted pursuant to the provisions of any applicable tax treaties or tax arrangements. Hong Kong has a tax arrangement with mainland PRC that provides for a 5% withholding tax on dividends upon meeting certain conditions and requirements, including, among others, that the Hong Kong resident enterprise directly owns at least 25% equity interests of the PRC enterprise and is a "beneficial owner" of the dividends. Under the EIT Law and its implementation rules, gains derived by non-resident enterprises from the sale of equity interests in a PRC resident enterprise are subject to PRC withholding income tax at the rate of 10%. The 10% withholding income tax rate may be reduced or exempted pursuant to applicable tax treaties or tax arrangements. The gains are computed based on the difference between the sales proceeds and the original investment basis. Stamp duty is also payable upon a direct transfer of equity interest in a PRC resident enterprise. The stamp duty is calculated at 0.05% on the transfer value, payable by each of the transferor and transferee.

The Announcement of the State Taxation Administration on Issues Relating to Withholding at Source of Income Tax of Non-resident Enterprises ("Circular 37") purports to clarify certain issues in the implementation of the above regime, by providing, among others, the definitions of equity transfer income and tax basis, the foreign exchange rate to be used in the calculation of withholding amounts and the date of occurrence of the withholding obligation. Specifically, Circular 37 provides that where the transfer income subject to withholding at its source is derived by a non-PRC resident enterprise by way of installments, the installments may first be treated as recovery of costs of previous investments; upon recovery of all costs, the tax amount to be withheld shall then be computed and withheld.

Value-added Tax ("VAT")

According to the Provisional Regulations on VAT of the PRC and its implementation rules, unless otherwise specified by relevant laws and regulations, any enterprise or individual engaged in the sale of goods, provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods in the PRC are generally required to pay VAT.

According to the Circular of the Ministry of Finance and the State Taxation Administration on Adjustment to Value-Added Tax Rates ("Circular 32") for VAT taxable sales acts or importation of goods originally subject to VAT rates of 17% and 11%, respectively, such tax rate shall be adjusted to 16% and 10%, respectively. For exported goods originally subject to a tax rate of 17% and an export tax refund rate of 17%, the export tax refund rate shall be adjusted to 16%. For exported goods and cross-border taxable acts originally subject to a tax rate of 11% and an export tax refund rate of 11%, the export tax refund rate shall be adjusted to 10%. Circular 32 became effective on May 1, 2018 and supersedes existing provisions which are inconsistent with Circular 32.

Pursuant to the Announcement on Policies for Deepening the VAT Reform ("Circular 39") for VAT taxable sales acts or importation of goods originally subject to VAT rates of 16% and 10%, respectively, such tax rate shall be adjusted to 13% and 9%, respectively. For exported goods originally subject to a tax rate of 16% and an export tax refund rate of 16%, the export tax refund rate shall be adjusted to 13%. For exported goods and cross-border taxable acts originally subject to a tax rate of 10% and an export tax refund rate of 10%, the export tax refund rate shall be adjusted to 9%. Circular 39 became effective on April 1, 2019 and supersedes existing provisions which are inconsistent with Circular 39. According to the Circular on the Value-added Tax Policies for Rare Disease Drugs, for the production and sale of drugs for rare diseases, VAT shall be calculated and paid at the rate of 3% under the simplified method.

Foreign Exchange

According to the Regulation of the PRC on Foreign Exchange Administration, the foreign exchange income and expenditure and foreign exchange business operations of PRC institutions and individuals, as well as the foreign exchange income and expenditure and foreign exchange business operations conducted within the territory of the PRC by overseas institutions and individuals, shall be subject to Foreign Exchange Administration. The Renminbi is freely convertible for payments of current account items such as trade and service-related foreign exchange transactions and dividend payments, but is not freely convertible for capital expenditure items such as direct investments, loans or investments in securities outside of the PRC unless approval from the SAFE or its local counterpart is obtained in advance.

According to the Administrative Regulation regarding Foreign Exchange Settlement, Sales and Payment, foreign exchange receipts under the current account of foreign-invested enterprises may be retained to the fullest extent specified by the foreign exchange bureau. Any portion in excess of such amount shall be sold to a designated foreign exchange bank or through a foreign exchange swap center.

According to the Circular on Further Simplifying and Improving Policies on Foreign Exchange Administration for Direct Investment, banks shall directly examine and handle foreign exchange registration under overseas direct investment. The State Administration of Foreign Exchange and its branches shall indirectly regulate the foreign exchange registration of direct investment through banks.

Pursuant to the Decision of the State Council on Matters relating to Canceling and Adjusting a Group of Administrative Examination and Approval Items, the administrative approval by the SAFE and its branches for matters concerning the repatriation and settlement of foreign exchange of overseas-raised funds through overseas listing was canceled. According to the Notice on Issues Concerning the Foreign Exchange Administration of Overseas Listing, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of SAFE at the place of its establishment. The proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the prospectus and other disclosure documents.

According to the Notice on Revolutionizing and Regulating Capital Account Settlement Management Policies, foreign currency earnings in capital accounts that maintain relevant policies of willingness to exchange settlement and have been clearly implemented on (including the recalling of raised capital by overseas listing) may undertake foreign exchange settlement in the banks according to actual business needs of the domestic institutions. The tentative percentage of foreign exchange settlement for foreign currency earnings in capital account of domestic institutions is 100%, subject to adjust of the SAFE in due time in accordance with international revenue and expenditure situations.

Circular 37 requires PRC residents to register their legally owned assets or equity interests in domestic enterprises or offshore assets or interests 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. Failure to comply with the various SAFE registration requirements described above could result in liability under the PRC law for evasion of foreign exchange controls. The Circular on Further Simplifying and Improving Policies for Foreign Exchange Administration for Direct Investment allows banks to directly examine and handle the initial foreign exchange registration and amendment registration under the Circular 37 on behalf of the SAFE.

Regulations relating to stock incentive plans

The SAFE promulgated 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, which prescribed that PRC citizens or non-PRC citizens residing in the PRC for a continuous period of no less than one year (except for foreign diplomatic personnel in the PRC and representatives of international organizations in the PRC) who participate in any stock incentive plan of an overseas publicly-listed company shall, through the domestic company to which the said company is affiliated, collectively entrust a domestic agency (as such agency may be the PRC affiliate of the overseas publicly listed company which participates in stock incentive plan, or other domestic institutions qualified for asset trust business lawfully designated by such company) to handle foreign exchange registration and entrust an overseas institution to handle issues such as the exercise of options, the purchase and sale

of corresponding stocks or equity and transfer of corresponding funds. In addition, the domestic agency is required to amend the SAFE registration with respect to the stock incentive plan if there is any material change to the stock incentive plan.

Regulations on Dividend Distribution

The principal laws, rules and regulations governing dividend distributions by foreign-invested enterprises in the PRC are the PRC Company Law and the Foreign Investment Law and its Implementation Regulations. Under these requirements, foreign-invested enterprises may only pay dividends out of their accumulated profits, if any, as determined in accordance with PRC accounting standards and regulations. A PRC company is required to set aside at least 10% of its after-tax profits each year, after making up previous years' accumulated losses, if any, to fund certain capital reserve funds until the aggregate amount of these reserve funds have reached 50% of its registered capital.

The EIT Law and its implementation rules provide that since January 1, 2008, a withholding income tax rate of 10% will be applicable to dividends declared to non-PRC resident enterprises, unless otherwise reduced according to treaties or arrangements between the PRC central government and the governments of other countries or regions where the non-PRC resident enterprises are incorporated.

Hong Kong has a tax arrangement with mainland China that provides for a 5% withholding tax on dividends distributed to a Hong Kong resident enterprise, upon meeting certain conditions and requirements, including, among others, that the Hong Kong resident enterprise directly owns at least 25% equity interests of the Chinese enterprise and is a "beneficial owner" of the dividends.

Dividends, Distributions and Other Transfers

Generally, cash is transferred through our organization in the following manner: (i) funds are transferred to us from CPI as needed through BJContinent Pharmaceuticals Limited, a company incorporated under the laws of Hong Kong with limited liability ("BJC Limited"), or from other domestic shareholders, in the form of capital contributions or shareholder loans; and (ii) dividends or other distributions may be paid by us to CPI through BJC Limited, or to other domestic shareholders.

In the future, cash proceeds raised from overseas financing activities, may be transferred to us via capital contribution or shareholder loans, as the case may be.

Since BC's inception to the date of this Annual Report, there were no transfers, dividends, or distributions between BJC Limited, BC, BC Biomedical, or to investors (except as disclosed above and excluding shareholder capital contributions). We intend to retain all available funds and any future earnings for use in the operation of its business and does not anticipate paying any cash dividends on its capital stock in the foreseeable future. Notwithstanding the foregoing, any determination to pay cash dividends are at the discretion of Gyre's board of directors and will depend upon a number of factors, including Gyre's results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors Gyre's board of directors deems relevant. For additional information, see *Audited Financial Statements of Gyre Therapeutics, Inc.* included elsewhere in this Annual Report.

Under Cayman Islands law, CPI is permitted to provide funding to its subsidiaries through loans or capital contributions without restrictions on the amounts of the funds, provided that such funding is in the best interests of CPI and for proper purpose. Subject to compliance with applicable solvency requirements, there is no further Cayman Islands statutory restriction on the amount of funds that may be distributed by BC by dividend provided that no dividend shall be paid other than out of profits or, subject to certain statutory restrictions, the share premium account of CPI. The Cayman Islands does not impose a withholding tax on payments of dividends to shareholders.

Our largest shareholder is BJC Limited. Under Hong Kong law, if BJC Limited were able to declare dividends, such dividends could only be paid by BJC Limited out of its distributable profits (that is, accumulated realized profits, so far as not previously utilized by distribution or capitalization, less accumulated realized losses, so far as not previously written off in a reduction or reorganization of capital), as permitted under Hong Kong law. Dividends cannot be paid out of share capital. There are no restrictions or limitation under the laws of Hong Kong imposed on the conversion

of HKD into foreign currencies and the remittance of currencies out of Hong Kong. Under the current practice of the Inland Revenue Department of Hong Kong. Payments of dividends by BJC Limited are not subject to withholding tax in Hong Kong.

Under PRC laws and regulations, we are subject to restrictions on foreign exchange and cross-border cash transfers, including to the parent companies and U.S. shareholders. The ability to distribute earnings to the parent companies and U.S. shareholders is also limited. Current PRC regulations permit us to pay dividends to BJC Limited only out of our accumulated profits as determined in accordance with PRC accounting standards and regulations. We are required to set aside at least 10% of our after-tax profits as the statutory common reserve fund until the cumulative amount of the statutory common reserve fund reaches 50% or more of our registered capital, if any, to fund our statutory common reserves, which are not available for distribution as cash dividends. In addition, our revenue and assets are generally denominated in Chinese Renminbi ("RMB"), which is not freely convertible into other currencies. The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of the PRC. As a result, shortages in foreign currencies may limit our ability to remit sufficient foreign currency to offshore entities related to us for such offshore entities to pay dividends or make other payments or otherwise to satisfy its foreign-currency-denominated obligations. Our offshore shareholders are Gyre, which is an indirect shareholder, and Nepenthe Holdings Limited, a company incorporated under the laws of Hong Kong with limited liability ("Nepenthe"), Ratel Holdings Limited, a company incorporated in the British Virgin Islands with limited liability ("Ratel"), Aaring Limited, a company incorporated under the laws of Hong Kong with limited liability ("Aaring"), Rosefinch Holdings Limited, a company incorporated in the British Virgin Islands ("Rosefinch"), CPI and Further Challenger, each of which are wholly-owned by Gyre.

We have established stringent controls and procedures for cash flows within our organization. Each transfer of cash between entities, across borders, and to U.S. shareholders, is subject to internal approval. To effect a cash transfer, a number of steps are needed, including but not limited to the issuance of payment receipt, logging into the online banking system and completing its verification process, inspection of the invoice, and payment execution. A single employee is not permitted to complete each and every stage of a cash transfer, but rather only portions of the whole procedure. Only the finance department is authorized to make cash transfers. Within the finance department, the roles of payment approval, payment execution, record keeping, and auditing are segregated to minimize risk.

According to the Foreign Investment Law of the PRC and its implementing rules, which jointly established the legal framework for the administration of foreign-invested companies, a foreign investor may, in accordance with other applicable laws, freely transfer into or out of the PRC its contributions, profits, capital earnings, income from asset disposal, intellectual property, royalties acquired, compensation or indemnity legally obtained, and income from liquidation, made or derived within the territory of the PRC in renminbi, or RMB, or any foreign currency, and any entity or individual shall not illegally restrict such transfer in terms of the currency, amount and frequency. According to the Company Law of the PRC and other PRC laws and regulations, we may pay dividends only out of their respective accumulated profits as determined in accordance with PRC accounting standards and regulations. In addition, we are required to set aside at least 10% of our accumulated after-tax profits, if any, each year to fund a certain statutory reserve fund, until the aggregate amount of such fund reaches 50% of its registered capital. Where the statutory reserve fund is insufficient to cover any loss we incurred in the previous financial year, our current financial year's accumulated after-tax profits shall first be used to cover the loss before any statutory reserve fund is drawn therefrom. At our discretion, we may allocate a portion of our after-tax profits based on PRC accounting standards to a discretionary reserve fund.

RMB is not freely convertible into other currencies. The PRC government imposes controls on the convertibility of RMB into foreign currencies and, in certain cases, the remittance of currency out of the PRC. Shortages in availability of foreign currency may then restrict our ability to remit sufficient foreign currency to offshore entities related to us for such offshore entities to pay dividends or make other payments or otherwise to satisfy our foreign-currency-denominated obligations. Our offshore shareholders are Gyre, which is an indirect shareholder, and Nepenthe, Ratel, Aaring, Rosefinch, CPI and Further Challenger, each of which is wholly-owned by Gyre. The RMB is currently convertible under the "current account," which includes dividends, trade and service-related foreign exchange transactions, but not under the "capital account," which includes foreign direct investment and foreign currency debt, including loans we may secure for our onshore subsidiaries.

Currently, we may purchase foreign currency for settlement of "current account transactions," without the approval of the State Administration of Foreign Exchange of the PRC, or SAFE, by complying with certain procedural requirements. However, the relevant PRC governmental authorities may limit or eliminate our ability to purchase foreign currencies in the future for current account transactions. The PRC government may continue to strengthen its capital controls, and additional restrictions and substantial vetting processes may be instituted by SAFE for cross-border transactions falling under both the current account and the capital account. Any existing and future restrictions on currency exchange may limit our ability to utilize revenue generated in RMB to fund our business activities outside of the PRC or pay dividends in foreign currencies to holders of our securities. Foreign exchange transactions under the capital account remain subject to limitations and require approvals from, or registration with, SAFE and other relevant PRC governmental authorities. This could affect our ability to obtain foreign currency through debt or equity financing for BC and its subsidiaries.

Employees and Human Capital

As of December 31, 2023, we had 593 total employees, including 168 employees in Beijing, 40 employees in Cangzhou and 385 employees in other regions, which were primarily our sales and marketing employees located across the nation. We recruit our employees based on a number of factors, including work experience, educational background and the requirements of a relevant vacancy. We provide internal and external training for our management staff and other employees in various areas, such as product knowledge, project development and team building. We provide our employees with regular feedback and assess our employees based on their performance to determine their salary, promotion and career development.

In compliance with the relevant PRC labor laws, we enter into individual employment contracts with our employees covering matters such as terms, wages, bonuses, employee benefits, workplace safety and grounds for termination. The remuneration package of our employees includes salary and bonus, which are generally based on their qualifications, industry experience, position and performance. We consider the remuneration package of our employees to be competitive among our domestic competitors. The social insurance and housing provident funds for our employees have been paid in full during the years ended December 31, 2022 and 2023.

We are also subject to safety laws and regulations of the PRC. We have implemented various internal occupational health and safety procedures to maintain a safe work environment, including adopting protective measures at our production centers, inspecting our equipment and facilities regularly to identify and address safety hazards and providing regular training to our employees on safety awareness.

As of December 31, 2023, we have formed a labor union to represent our employees. We believe that we have maintained good working relationships with our employees. During the year ended December 31, 2023, we were not subject to any material claims, lawsuits, penalties or administrative actions relating to non-compliance with occupational health and safety laws or regulations and had not experienced any strikes, labor disputes or industrial actions which have had a material effect on our business.

PRC Taxation

Under Article 2 of the PRC Enterprise Income Tax Law, a resident enterprise is an enterprise that is established in the PRC under the PRC laws, or an enterprise that is established under the laws of foreign countries (regions) but whose place of effective management is located in the PRC. We are a PRC resident enterprise for PRC tax purposes because we are a legal entity registered in Beijing, PRC.

Because we are a PRC resident enterprise for Enterprise Income Tax purposes, dividends (if any) paid by us to direct offshore parent companies are subject to PRC withholding income tax at the rate of 10%, provided that such dividends are not effectively connected with any establishment or place of the offshore parent company in the PRC. In addition, gains derived by non-resident enterprises from the sale of equity interests in a PRC resident enterprise are subject to PRC withholding income tax at the rate of 10%. The 10% withholding income tax rate may be reduced or exempted pursuant to the provisions of any applicable tax treaties or tax arrangements. See the section entitled "*Risk Factors—Risks Related to Our Business Operations in the PRC—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*."

With respect to gains realized from the sale or other disposition of the shares, there is a possibility that a PRC tax authority may impose an income tax under the indirect transfer rules set out under the Announcement of the State Administration of Taxation on Several Issues Concerning the Enterprise Income Tax on Indirect Property Transfer by Non-Resident Enterprises, or SAT Circular 7, except that such transaction could fall under the safe harbor thereunder. See the section entitled "*Risk Factors—Risks Related to Our Business Operations in the PRC—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*."

Item 1A. RISK FACTORS.

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.

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 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, 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 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 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 98.9% and 96.9% of our total revenue in 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 pirfenidone product and one nintedanib product approved and commercialized, in addition to our product ETUARY. 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.

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.

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;
- 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.

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 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, 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 or the attacks on marine vessels traversing the Red Sea. 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 Agreement with 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, 2023 and 2022 may not be sustainable.

During the years ended December 31, 2023 and 2022, we maintained a high level of gross margin. Our profit margins were 95.9% and 95.3% for the years ended December 31, 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, 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, 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, 2023 and 2022, we had certain concentrations of credit risk of 10%. In addition, 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, 2023 and 2022, our inventories were valued at $4.3 million and $6.1 million, respectively. During the years ended December 31, 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.

If our intangible assets are impaired, our results of operations and financial condition may be adversely affected.

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, 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, 2023 and 2022, our trade receivables amounted to $15.2 million and $15.6 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, 2023 and 2022, our trade receivables turnover days were 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, 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 $1.0 million and $0.9 million for the years ended December 31, 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, 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

There is a risk that our marketed product in the PRC, ETUARY, along with any other products that 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 commercial success of our existing 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.

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.

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, ETUARY for the treatment of IPF in the PRC, that we have developed, and it is possible that none of our existing product candidates 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 the last patient out in 2024 and submit an NMPA application for F351 in the PRC in the first quarter of 2025.

In addition, we are actively preparing an IND application that we expect to file by the end of 2024 for a Phase 2 clinical trial to evaluate F351 for the treatment of advanced liver fibrosis associated with NASH. Following IND clearance, we plan to initiate a Phase 2a, PoC clinical trial in 2025 in the United States to evaluate the safety, tolerability, PK, and PD of F351 for patients with advanced liver fibrosis associated with noncirrhotic NASH. The FDA has provided pre-IND advice on the design of the planned Phase 2a trial of F351 and provided guidance on the contents of the IND filing. If we observe positive trends in the Phase 2a trial of F351, we expect to initiate a Phase 2 trial of F351 in the United States.

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 patients, which can currently only be definitively diagnosed through a liver biopsy. Specifically, identifying patients most likely to meet NASH enrollment criteria on biopsy is an on-going challenge, with existing clinical indicators lacking both sensitivity and specificity. As a result, NASH 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 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, 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 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.

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.

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 83,002 patients in 2017 to 131,654 patients in 2022, and is expected to increase to 214,664 patients by 2027 and 320,677 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, 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, 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, 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, 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, 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, and any other future products, if approved. Further, we may fail to find an appropriate group of distributors suitable for our commercialized product, ETUARY, 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, 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 between Russia and Ukraine and the 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 inflation and rising interest rates, public health crises, the conflict between Russia and Ukraine and the 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. 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 SSc-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 date, there is no effective clinical therapy for 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 SSc-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 the end of 2024 for a Phase 2 clinical trial to evaluate F351 for the treatment of advanced liver fibrosis associated with noncirrhotic NASH. Following IND clearance, we plan to initiate a Phase 2a, PoC clinical trial in 2025 in the United States to evaluate the safety, tolerability, PK, and PD of F351 for patients with advanced liver fibrosis associated with noncirrhotic NASH. The FDA has reviewed the planned Phase 2a 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 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 trial in NASH-associated liver fibrosis. Furthermore, if the NMPA or FDA believes that additional data is necessary to supplement our clinical study data and Phase 2a 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 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 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 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—F351 Overview*."

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, 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, 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 clinical trial in the U.S. Foreign CMOs may be subject to U.S. legislation, including the proposed BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory 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, 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, 2023 and 2022.

We may not be able to meet the increasing demand for our commercialized product, ETUARY, which is approved in the PRC, and any other future products, if approved, maintain adequate manufacturing capacity or successfully manage our anticipated growth.

To produce ETUARY 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, 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, 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, generic drugs and any other future products, if approved. Further, demand for our commercialized product, ETUARY, 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.

Risks Related to Our Reliance on Third Parties

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.

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, ETUARY, which is 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.

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.

During the years ended December 31, 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.

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.

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, ETUARY, 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. 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 falls within the patent scope, 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 shall not exceed 14 years. However, 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. 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 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.

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 successfully commercialized product, ETUARY, which is approved in the PRC for the treatment of IPF. ETUARY is currently in its Phase 3 clinical trials in the PRC for the treatment of SSc-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, 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, and, on March 13, 2024, we submitted an IND application for F230 in the PRC.

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 contracts 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. 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 NASH. Although there are guidelines issued by the FDA for the development of drugs for the treatment of NASH, 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 therapies, we expect that the path for regulatory approval for NASH 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 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 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 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.

United States

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.

PRC

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, 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, 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.

United States

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 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 to the ACA and new legislative proposals have resulted in uncertainty regarding the ACA's future viability and destabilization of the health insurance market. The resulting impact on our business is uncertain and could be material.

Efforts to control prescription drug prices could also have a material adverse effect on our 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 generic drug and biosimilar competition, enable the Medicare program to negotiate drug prices more directly and improve transparency regarding drug prices and ways to lower our consumers' out-of-pocket costs. The Trump administration also proposed to establish an "international pricing index" that would be used as a benchmark to determine the costs and potentially limit the reimbursement of drugs under Medicare Part B. Among other pharmaceutical manufacturer industry-related proposals, Congress has proposed bills to 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 under Medicare Parts B and D that lack generic or biosimilar competition. Price negotiations for Part D begin in 2023. Taking effect in 2023, 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 the federal deficit, and the IRA's impact on competition and commercialization is uncertain but could be material.

In addition, many states have proposed or enacted legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing, such as by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. For example, in 2017, California's governor signed a prescription drug price transparency 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 effect on our business. Proposals that could impact coverage and reimbursement of our future products, 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 of operations may be adversely affected.

PRC

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, 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 to the national data protection authorities and or data subjects (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, 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, 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.

Risks Related to Our Business Operations in the PRC

Modifications to laws, regulations, and rules by the PRC government could lead to alterations in our operational processes and business approaches.

The PRC government has some oversight and discretion over the conduct of our business in the PRC and may intervene or influence 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 or policies regarding our industry that could require us to seek permission from the PRC authorities to continue to operate our business in the PRC that could potentially affect our business, financial condition and results of operations. Furthermore, recent statements made by the PRC government, including the Opinions on Strictly Cracking Down Illegal Securities Activities in Accordance with the Law, and new rules published for comments by the PRC government, including the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Enterprises to become effective on March 31, 2023, establish a new filing-based regime to regulate overseas offerings and listings by domestic companies. If we were to become subject to the direct intervention or influence of the PRC government at any time due to changes in laws or other unforeseeable reasons, it may 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, 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.

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

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.

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.

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 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, 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 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 world-wide 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, immoveable 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 immoveable 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.

Risks Related to Commercialization of Our Product and Product Candidates

We may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, to date, no anti-fibrosis product for the treatment of pneumoconiosis has been approved in the PRC, and 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 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. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy and safety profile of our product candidates, including ETUARY and F351, compared with other competitor anti-fibrosis treatments;
- our ability to offer our product, ETUARY, and future products, if approved, for sale at competitive prices;
- the convenience of TID dosing compared with alternative treatments;
- patient understanding of NASH and associated fibrosis and its progressive nature and need for treatment;
- improvement of confirmatory-diagnosis and monitoring of NASH and associated fibrosis;

- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product, ETUARY, which is approved in the PRC, and future products, if approved, together with other medications.

For details related to risks regarding market acceptance of our commercialized product, ETUARY, which is approved in the PRC , see "*—There is a risk that our marketed product in the PRC, ETUARY, along with any other products that 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.*"

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, and while there are guidelines issued by the NMPA and FDA for the development of drugs for the treatment of NASH 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. 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 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 are no currently approved therapeutic drug treatments for liver fibrosis, 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, SSc-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, 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.

United States

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.

PRC

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, 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 is expected to be volatile.

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 18,280,548 shares of common stock at a weighted average exercise price of $1.49 as of December 31, 2023. 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 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 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 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.

We may be unable to integrate successfully and realize the anticipated benefits of the Contributions.

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, we had approximately $193.5 million of federal and $10.5 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 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, 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, 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. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate use, disclosure of or access to confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product, ETUARY, and product candidates could be hindered or delayed.

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.

Item 1B. UNRESOLVED STAFF COMMENTS.

None.

Item 1C. CYBERSECURITY.

We strive to safeguard our important data, hardware, and internal network from digital attacks, theft and damage. In the ordinary course of our business, we collect, use, store, and digitally transmit confidential, sensitive, proprietary, and personal information. The secure maintenance of this information and our information technology systems is important to our operations and business strategy. To this end, we have implemented processes designed to assess, identify, and manage risks from potential unauthorized occurrences on or through our information technology systems that may result in adverse effects on the confidentiality, integrity, and availability of these systems and the data residing therein. At Gyre Therapeutics, these processes are managed and monitored by a third-party information technology ("IT") consulting company (the "Managed Service Provider") and are overseen by our Chief Financial Officer. At Gyre Pharmaceuticals, these processes are managed and monitored by a dedicated IT team, which is led by the General Manager. Gyre Therapeutics' and Gyre Pharmaceuticals' processes include mechanisms, controls, technologies, systems, and other processes designed to prevent or mitigate data loss, theft, misuse, or other security incidents or vulnerabilities affecting the data. For example, Gyre Therapeutics and Gyre Pharmaceuticals maintain software and hardware inventories, perform security monitoring and alerting, and complete ongoing risk assessments. Gyre Therapeutics and Gyre Pharmaceuticals also conduct regular employee trainings on cyber and information security, among other topics. In addition, both companies consult with outside advisors and experts on a regular basis to assist with assessing, identifying, and managing cybersecurity risks, including to anticipate future threats and trends, and their impact on the Company's risk environment.

Our Chief Financial Officer, who reports directly to our Chief Executive Officer, is responsible for assessing and managing Gyre Therapeutics' cybersecurity risks with support from the Managed Service Provider, which employs IT consultants with over 20 years of experience managing information technology and cybersecurity matters and are certified as Microsoft Certified Systems Engineers. Our Gyre Pharmaceuticals IT department senior supervisor, who reports directly to our General Manager at Gyre Pharmaceuticals and has over 20 years of experience managing information technology and cyber security matters, is responsible for assessing and managing Gyre Pharmaceuticals' cybersecurity risks. Our General Manager at Gyre Pharmaceuticals reports the Board of Directors. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework. In the last fiscal year, we have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, that have materially affected us, but we face certain ongoing cybersecurity risks that, if realized, are reasonably likely to materially affect us. Additional information on cybersecurity risks we face is discussed in Part I, Item 1A, "Risk Factors," under the heading "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."

The Board of Directors, as a whole and at the committee level, has oversight for the most significant risks facing us and for our processes to identify, prioritize, assess, manage, and mitigate those risks. The Audit Committee, which is comprised solely of independent directors, has been designated by our Board to oversee cybersecurity risks. The Audit Committee receives regular updates on cybersecurity and information technology matters and related risk exposures from our management team. The Board also receives updates from management and the Audit Committee on cybersecurity risks on at least an annual basis.

Item 2. PROPERTIES.

Gyre Therapeutics' Properties

Our corporate headquarters are in San Diego, California, where we lease approximately 1,643 rentable square feet of office space. The lease commenced on November 11, 2023 and expires on the last day of the 38th full calendar month beginning on or after November 11, 2023. Gyre expects to be able to renew this lease or obtain alternative facilities on commercially reasonable terms.

Gyre Pharmaceuticals' Properties

Owned Properties

Gyre Pharmaceuticals has land use right certificates for two parcels of land in Shunyi District, Beijing, PRC and Cangzhou, Hebei province, PRC with an aggregate site area of 66,559 square meters and building ownership certificates for six properties with an aggregate gross floor area of 12,206 square meters. Gyre Pharmaceuticals' two production centers are in Beijing, PRC and Cangzhou, PRC.

Leased Properties

Gyre Pharmaceuticals leases 21 properties in the PRC. Among Gyre Pharmaceuticals' 21 leased properties, eight are used as offices, 12 are used as employee dormitories and one is operated as a laboratory.

Item 3. LEGAL PROCEEDINGS.

We are currently not a party to any material legal proceedings. From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information for Common Stock

Gyre Therapeutics, Inc. is listed on the Nasdaq Capital Market under the symbol "GYRE."

Holders of Common Stock

As of March 19, 2024, there were approximately 46 stockholders of record of our common stock. Since many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

On September 20, 2022, we paid a special, one-time cash dividend of approximately $45.0 million (or $1.43 per share) to our common stockholders of record as of the close of business on September 6, 2022. On January 12, 2023, we paid a special, one-time cash dividend of approximately $7.6 million (or $0.24 per share) to our common stockholders of record as of the close of business on January 5, 2023. In June 2023, we distributed $3.5 million, which reflected, in connection with the Vertex Transaction, the hold-back amount received from Vertex less expenses and a reserve for potential tax liabilities, to the holders of Catalyst Common Stock as of January 5, 2023 (the "CVR Holders"). We currently intend to retain all future earnings, if any, for use in our business and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors our board of directors may deem relevant.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [RESERVED].

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with our audited financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section of this report entitled "Risk Factors." You should carefully read the "Cautionary Note About Forward-Looking Statements" and "Risk Factors" sections of this Annual Report on Form 10-K to gain an understanding of the important factors that could cause actual results to differ materially from the results described below.

Overview

We are a financially-sustainable pharmaceutical company with a record of financial success that develops and commercializes small-molecule anti-inflammatory and anti-fibrotic drugs targeting organ diseases, focusing specifically on organ fibrosis. Fibrotic diseases represent a large patient population with significant unmet medical needs. Fibrosis involves a complex, multi-stage process with multiple pathways. While there are numerous potential targets for anti-fibrotic therapy, both established and emerging, addressing a single molecular pathway may not be sufficient to prevent, halt, or reverse fibrosis.

Our strategy is to use our experience in the successful development and commercialization of ETUARY® (Pirfenidone) to expand into new indications and develop similar drug candidates. Pirfenidone, the first anti-fibrotic drug approved for IPF in Japan, the EU, the U.S., and the PRC, is a small molecule drug that inhibits the synthesis of TGF-ß1, TNF-α, and other fibrosis and inflammation modulators. We have obtained approval for ETUARY (pirfenidone) in the PRC for IPF.

Gyre Pharmaceuticals successfully advanced Pirfenidone from R&D to commercialization in the PRC for the treatment of IPF. ETUARY's annual sales have consistently grown each year, reaching $112.1 million in 2023. In addition to IPF, Pirfenidone is undergoing three additional Phase 3 studies for CTD-ILD to broaden its indications and market: SSc-ILD, DM-ILD and PD.

F351, our lead development candidate, is a structural derivative of ETUARY (Pirfenidone). It is a new oral chemical entity with an anti-fibrotic, TGF-ß1-targeting mechanism of action, for which we hold patents in major markets. Studies suggest that F351 and its major metabolites have minimal drug-drug interaction risks. Despite potential efficacy in IPF, we are prioritizing F351 for the treatment of liver fibrosis due to the large potential addressable market and significant unmet need.

Gyre Pharmaceuticals has completed a Phase 2 trial of F351 in the PRC for CHB-associated liver fibrosis. The Phase 2 trial showed that F351 was well-tolerated without notable toxicity and patients treated showed statistically-significant improvement of liver fibrosis, with the best efficacy results achieved at 270 mg/day dosing. Based on these results, a confirmatory Phase 3 trial is ongoing in the PRC. The enrollment of 248 patients for the confirmatory Phase 3 trial has been completed, with last patient out expected in 2024 and clinical results expected by early 2025.

In the U.S., we have completed a Phase 1 clinical trial of F351 in healthy volunteers. We are preparing an IND application and expect to submit it in late 2024. Following results from the PRC Phase 3 trial in CHB-associated liver fibrosis and pending approval of our IND, we expect to initiate a Phase 2a trial to evaluate F351 for the treatment of NASH-associated liver fibrosis in 2025.

F351 Asset Acquisition

On December 26, 2022, Catalyst, purchased the F351 Assets from GNI Japan and GNI Hong Kong, other than such assets and intellectual property rights located in the PRC, pursuant to the F351 Agreement.

Business Combination Agreement

On December 26, 2022, Catalyst entered into a Business Combination Agreement, as amended on March 29, 2023 and August 30, 2023 (the "Business Combination Agreement") with GNI USA, GNI Japan, GNI Hong Kong, SG (collectively with GNI USA, GNI Japan and GNI Hong Kong, the "Contributors," and each a "Contributor"), certain individuals and CPI. On October 30, 2023 (the "Effective Time"), the Contributions (as defined below) became effective and Catalyst acquired an indirect controlling interest in Beijing Continent Pharmaceuticals Co., Ltd. (doing business as Gyre Pharmaceuticals Co., Ltd.). In connection with the Contributions, and immediately prior to the Effective Time of the Contributions, Catalyst amended its certificate of incorporation, increased the number of authorized shares of its common stock, par value $0.001 per share (the "Catalyst Common Stock") from 100,000,000 shares to 400,000,000 shares, effected the Reverse Stock Split and changed its name to Gyre Therapeutics, Inc.

Shares of Catalyst Common Stock were previously listed on The Nasdaq Capital Market under the symbol "CBIO." Catalyst filed a listing application for the combined company with the Nasdaq Stock Market Inc. ("Nasdaq"). On October 31, 2023, Gyre's common stock commenced trading on the Nasdaq Capital Market under the symbol "GYRE", on a post-reverse stock split adjusted basis.

Pursuant to the Business Combination Agreement, at the Effective Time of the Contributions, and after giving effect to the 1-for-15 reverse stock split:

a) GNI USA contributed all of its ordinary shares in the capital of CPI to Catalyst in exchange for 45,923,340 shares of Gyre Common Stock (the "CPI Contribution"),

b) GNI USA contributed its interest in Further Challenger International Limited ("Further Challenger") for 17,664,779 shares of Gyre Common Stock (the "FC Contribution" and together with the CPI Contribution, the "GNI USA Contributions"), and

c) each Minority Holder contributed 100% of the interest he or she held in his or her respective entity in exchange for an aggregate of 10,463,627 shares of Gyre Common Stock (the "Minority Holder Contributions" and together with the GNI USA Contributions, the "Contributions").

As a result of the GNI USA Contributions, Gyre directly and indirectly holds 100% of CPI's shares. Through Gyre's ownership of CPI, prior to the Minority Holder Contributions, Gyre held a 56.0% indirect interest in Gyre Pharmaceuticals. Upon completion of the Minority Holder Contributions, Gyre obtained additional indirect interests in Gyre Pharmaceuticals and holds, in aggregate, a 65.2% indirect interest in Gyre Pharmaceuticals.

Immediately after the closing of the Contributions, excluding potentially dilutive securities, GNI USA owned approximately 83.6% of the outstanding shares of Gyre Common Stock, Catalyst's existing stockholders, excluding GNI USA, owned approximately 2.8% of the outstanding Gyre Common Stock, and the Minority Holders owned approximately 13.7% of the outstanding shares of Gyre Common Stock. The Convertible Preferred Stock remained outstanding after the closing of the Contributions and is not included in the above ownership percentages.

At the Effective Time, Gyre Pharmaceuticals terminated its 2021 Stock Incentive Plan (the "2021 Plan") and the options (the "Gyre Pharmaceuticals Options") outstanding under the 2021 Plan were terminated and replaced with options granted under a subplan for Chinese participants under the Gyre 2023 Omnibus Incentive Plan (the "2023 Omnibus Incentive Plan") that are substantially similar in all material respects to the Gyre Pharmaceuticals Options previously outstanding under the 2021 Plan.

Each share of Catalyst Common Stock and option to purchase Catalyst Common Stock that was issued and outstanding at the Effective Time remained issued and outstanding, and such shares and options were unaffected by the Contributions.

Gyre Pharmaceuticals is a commercial-stage biopharmaceutical company registered and established in the PRC in 2002. Gyre Pharmaceuticals is committed to the research and development of new drugs as well as manufacturing and commercialization of ETUARY (pirfenidone capsule) for the treatment of idiopathic pulmonary fibrosis and other pharmaceutical products. The registered office of Gyre Pharmaceuticals is located at 60 Shunkang Road, Shunyi District, Beijing, PRC.

The immediate holding company of Gyre Pharmaceuticals is BJContinent Pharmaceuticals Limited ("BJC"). The intermediate holding company of Gyre Pharmaceuticals is CPI. Immediately following the GNI USA Contributions, the immediate holding company of CPI is Gyre. The majority stockholder of Gyre is GNI USA and the majority stockholder of GNI USA is GNI Japan.

The GNI USA Contributions were treated as an asset acquisition under U.S. generally accepted accounting principles ("U.S. GAAP"), with CPI treated as the accounting acquirer and presented as the predecessor for post-acquisition reporting purposes. Since Catalyst is the legal acquirer, the GNI USA Contributions were accounted for as a reverse asset acquisition. This determination was based upon the terms of the Business Combination Agreement and other factors including that, immediately following the GNI USA Contributions: (i) GNI USA (as the parent company of CPI immediately prior to the GNI USA Contributions) owns a substantial majority of the voting power of the combined company; (ii) GNI USA has the ability to control the board of directors of the combined company; and (iii) senior management of Gyre Pharmaceuticals and GNI USA hold a majority of the key positions in senior management of the combined company. Immediately prior to the closing of the GNI USA Contributions, Catalyst did not meet the definition of a business because Catalyst did not have an organized workforce that significantly contributed to its ability to create output, and substantially all of its fair value was concentrated in in-process research and development ("IPR&D").

As of the closing date of the GNI USA Contributions, the net assets of Catalyst were recorded at their acquisition-date relative fair values in the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K and the reported operating results prior to the GNI USA Contributions are those of CPI.

The Minority Holder Contributions were treated as an equity transaction, where we obtained additional indirect interests in and maintained our control over Gyre Pharmaceuticals.

Contingent Value Rights Agreement

Concurrent with the signing of the Business Combination Agreement on December 26, 2022, Catalyst and the Rights Agent (as defined in the CVR Agreement) executed a contingent value rights agreement (the "CVR Agreement"), as amended on March 29, 2023, pursuant to which each CVR Holder, excluding the Sellers, received one contractual contingent value right (a "CVR") issued by the Company for each share of Catalyst common stock held by such holders. Each CVR entitles the CVR Holder thereof to receive certain cash payments in the future. For additional information, see Note 13 — *Commitments and Contingencies* to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Reverse Stock Split

We effected a 1-for-15 reverse stock split immediately prior to the Effective Time of the Contributions. The par value of the Catalyst Common Stock following the Reverse Stock Split was not adjusted and remains at $0.001 per share. All of the Catalyst's issued and outstanding common stock and options have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. Proportionate adjustments were made to the per share exercise price and the number of shares issuable upon the exercise or vesting of all stock options and warrants outstanding, which resulted in a proportional decrease in the number of shares of our common stock reserved for issuance upon exercise or vesting of such stock options, warrants, and in the case of stock options and warrants, a proportional decrease in the exercise price of such stock options and warrants.

No fractional shares were issued in connection with the Reverse Stock Split and stockholders who would otherwise be entitled to a fraction of one share received a proportional cash payment.

Private Placement and Securities Purchase Agreement

On October 27, 2023, we entered into the Securities Purchase Agreement for a private placement with GNI USA. Pursuant to the Securities Purchase Agreement, GNI USA agreed to purchase (i) 811 shares of Gyre's Convertible

Preferred Stock and (ii) warrants to purchase up to 811 shares of Convertible Preferred Stock (the "Preferred Stock Warrants") for an aggregate purchase price of $5.0 million. The Private Placement closed immediately after the closing of the Contributions.

The Preferred Stock Warrants are exercisable at an exercise price of $4,915.00 per share of Convertible Preferred Stock and expire on October 30, 2033. Each share of Convertible Preferred Stock is convertible into approximately 666.67 shares of the Gyre Common Stock, as adjusted for the Reverse Stock Split. The Preferred Stock Warrants issued are considered freestanding financial instruments and classified as a liability.

Financial Operations Overview

During the year ended December 31, 2023, we had a net loss of $85.5 million and a net loss attributable to common stockholders of $92.9 million. For the year ended December 31, 2022, our net income was $4.3 million and net income attributable to common stockholders was $2.3 million. As of December 31, 2023, we had accumulated deficit of $85.5 million and cash and cash equivalents of $33.5 million. As of December 31, 2022, we had retained earnings of $7.4 million and cash of $25.2 million.

Components of Results of Operations

Revenues

Sales of Pharmaceutical Products

We generate revenue primarily through sales of ETUARY and certain generic drugs in the PRC. Distributors are our direct customers, and sales to distributors accounted for 100% of the revenue from ETUARY. Such distributors sell ETUARY to certain outlets, including hospitals and other medical institutions, as well as pharmacies.

License of Intellectual Property

Revenue from licensing intellectual property is recognized when the control of the right to use the license is transferred to the customer.

Operating Expenses

Cost of Revenue

Cost of revenue mainly consists of cost of sales representing direct and indirect costs incurred to bring the product to saleable condition. Cost of sales primarily consists of (i) raw material costs; (ii) staff costs for production employees; (iii) depreciation and amortization related to property and equipment and intangible assets used in production; (iv) taxes and surcharges; (v) transportation costs; and (vi) miscellaneous other costs.

Selling and Marketing Expenses

Selling and marketing expenses primarily relate to selling and marketing our product ETUARY in the PRC and consist of expenses incurred from hosting academic conferences, seminars and symposia; promotional expenses associated with market education on ETUARY for its use in hospitals; and staff costs primarily consisting of salaries and benefits for in-house marketing and promotion staff.

Research and Development Expenses

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services used in research and development are initially deferred and capitalized in prepaid and other current assets. The capitalized amounts are then expensed as the related goods are delivered or services are performed, or until it is no longer expected that the goods or services will be delivered.

Research and development costs consist primarily of costs related to the pre-clinical and clinical development of our product candidates, which include payroll and other personnel-related expenses, laboratory supplies and reagents, contract research and development services for pre-clinical research and clinical trials, materials, and consulting costs, as well as allocations of facilities, depreciation and other overhead costs.

General and Administrative Expenses

General and administrative expenses consist of (i) accounting, IT, legal, administrative, and other internal service staff costs; (ii) stock-based compensation representing share options granted to our functional employees; (iii) professional service fees, primarily for legal and accounting services; and (iv) other miscellaneous expenses.

Acquired IPR&D

Acquired IPR&D expenses represent costs incurred for acquisitions of IPR&D with no alternative future use, which are expensed immediately upon acquisition.

Divestiture Losses

Prior to the GNI USA Contributions, we recorded a loss from the divestiture of almost all our assets other than our 56.0% indirect ownership interest in Gyre Pharmaceuticals. This expense was reflected in our consolidated statements of operations and comprehensive (loss) income. The loss is presented net of the direct costs incurred with the transaction.

Loss on Disposal of Property and Equipment

Prior to the GNI USA Contributions, we recorded a loss on disposal of property and equipment. This expense was reflected in our consolidated statements of operations and comprehensive (loss) income. The loss is presented net of loses incurred in connection with the sale of property and equipment.

Other Income (Expense), Net

Interest Income, Net

Interest income consists primarily of interest earned on our long-term certificates of deposit. Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Other Income

Other income consists mostly of government grants. Government grants are recognized at their fair value where there is reasonable assurance that the grant will be received, and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed. Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual installments or deducted from the carrying amount of the asset and released to profit or loss by way of a reduced depreciation charge.

Change in Fair Value of Warrant Liability

In connection with the Private Placement, we issued the Preferred Stock Warrants, which are freestanding financial instruments classified as warrant liability since the underlying securities are contingently redeemable upon the occurrence of events which are outside of our control. The Preferred Stock Warrants are recorded at fair value upon issuance and are subject to remeasurement at the end of each reporting period, with any change in fair value recognized in our statements of operations as other (income) expense.

Other Expenses

Other expense consists of any non-operating costs, such as loss from equity method investments.

Provision for Income Taxes

Provision for income taxes are comprised primarily of current income tax provision, mainly attributable to the profitable Gyre Pharmaceuticals operations in the PRC, and deferred income tax provision, mainly including deferred tax recognized for temporary differences in relation to research and development tax credit and net operating loss carry forwards for U.S. tax purposes, deemed income inclusions from controlled foreign corporations for U.S. tax purposes, and fixed and intangible assets, net of valuation allowances.

Results of Operations

The following tables summarize our results of operations for the years ended December 31, 2023 and 2022 (in thousands, except percentage change):

	Year Ended December 31,			
	2023	2022	Change ($)	Change (%)
Revenues	$ 113,450	$ 102,290	$ 11,160	10.9 %
Cost of revenues	4,636	4,793	(157)	(3.3)%
Gross Profit	108,814	97,497	11,317	11.6 %
Operating expenses excluding cost of revenues:				
Selling and marketing	61,159	54,238	6,921	12.8 %
Research and development	13,780	16,686	(2,906)	(17.4)%
General and administrative	14,662	17,370	(2,708)	(15.6)%
Acquired in-process research and development	83,104	—	83,104	**
Divestiture losses	2,711	—	2,711	**
Loss on disposal of property and equipment	628	—	628	**
Total operating expenses excluding cost of revenues	176,044	88,294	87,750	99.4 %
(Loss) income from operations	(67,230)	9,203	(76,433)	**
Other income (expense), net:				
Interest income, net	1,044	726	318	43.8 %
Other income	1,076	857	219	25.6 %
Change in fair value of warrant liability	(9,261)	—	(9,261)	**
Other expenses	(2,594)	(1,374)	(1,220)	88.8 %
(Loss) income before income taxes	(76,965)	9,412	(86,377)	**
Provision for income taxes	(8,515)	(5,098)	(3,417)	67.0 %
Net (loss) income from operations	(85,480)	4,314	(89,794)	**
Net income attributable to noncontrolling interest	7,453	2,012	5,441	270.4 %
Net (loss) income attributable to common stockholders	$ (92,933)	$ 2,302	$ (95,235)	**

** Not meaningful.

Comparison of the Years Ended December 31, 2023 and 2022

Revenues

Revenues for the years ended December 31, 2023 and 2022 were $113.5 million and $102.3 million, respectively. The increase was primarily due to a $12.6 million increase in pharmaceutical product sales, driven by enhanced marketing and sales initiatives in regions of the PRC where sales were previously lower in 2022, partially offset by a $1.4 million decrease in revenue related to a one-time licensing fee recognized in 2022 from our license agreement with Fu Fang Chuan Gui Tincture entered into in 2021.

Cost of Revenues

Cost of revenues for the years ended December 31, 2023 and 2022 was $4.6 million and $4.8 million, respectively. The decrease of $0.2 million was primarily driven by a $0.3 million reduction attributed to favorable foreign exchange rate fluctuations and a $0.2 million decrease in stock-based compensation expenses. These reductions were partially offset by a $0.3 million increase in cost of revenues due to increased sales. The change in stock-based compensation is related to options being fully vested in 2022 and the modification of option terms in 2023.

Selling and Marketing Expenses

Selling and marketing expenses increased by $6.9 million, or 12.8%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase was primarily driven by a $3.8 million increase in selling and marketing payroll costs due to an increase in staff headcount, a $3.5 million increase in promotional expenses, and a $0.7 million increase in traveling expenses of our sales staff, partially offset by a $1.3 million decrease in stock-based compensation. The change in stock-based compensation is related to options being fully vested in 2022 and the modification of option terms in 2023.

Research and Development Expenses

The table below details our costs for research and development for the years ended December 31, 2023 and 2022 (in thousands, except percentage change):

	Year Ended December 31,			
	2023	2022	Change ($)	Change (%)
Direct program expenses:				
Clinical trials	$ 4,228	$ 4,132	$ 96	2.3 %
Materials and utilities	2,607	2,877	(270)	(9.4)%
Pre-clinical research	2,038	3,236	(1,198)	(37.0)%
Indirect expenses:				
Personnel-related costs including stock-based compensation	4,092	5,716	(1,624)	(28.4)%
Facilities, depreciation and other	815	725	90	12.4 %
Total research and development expenses	$ 13,780	$ 16,686	$ (2,906)	(17.4)%

Research and development expenses decreased by $2.9 million, or 17.4%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The decrease was primarily driven by a $1.8 million decrease in stock-based compensation, related to options being fully vested in 2022 and the modification of option terms in 2023, as well as by a $1.2 million decrease in pre-clinical research expenses. The latter is a result of several research and development projects advancing to the clinical trials stage or reaching the application phase in 2023. This overall decrease was partially offset by a $0.2 million increase in research and development payroll costs due to increased headcount.

General and Administrative Expenses

General and administrative expenses decreased by $2.7 million, or 15.6%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The decrease was primarily driven by a $2.8 million decrease in stock-based compensation. The change in stock-based compensation is related to options being fully vested in 2022, the modification of option terms in 2023 and the new option grants offered after the GNI USA Contributions.

Acquired IPR&D

Acquired IPR&D expenses of $83.1 million for the year ended December 31, 2023 represent costs of incurred for acquisitions of IPR&D with no alternative future use, which were expensed immediately upon the closing of GNI USA Contributions.

Divestiture Losses

During the year ended December 31, 2023, we recorded a loss of $2.7 million from the divestiture of almost all our assets other than our 56.0% indirect ownership interest in Gyre Pharmaceuticals. The loss is presented net of the direct costs incurred with the transaction.

Loss on Disposal of Property and Equipment

We recorded a loss on disposal of property and equipment of $0.6 million during the year ended December 31, 2023. The loss is presented net of loses incurred in connection with the sale of property and equipment.

Other Income (Expense), Net

Interest income increased by $0.3 million, or 43.8%, for the year ended December 31, 2023 compared to the year ended December 31, 2022, primarily due to additional investments in long-term certificates of deposit.

Other income increased by $0.2 million, or 25.6%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase in other income was mainly attributed to $1.0 million of PRC government grants income recognized during the year ended December 31, 2023 in comparison to $0.9 million of PRC government grants income recognized during the year ended December 31, 2022.

Change in fair value of warrant liability was a $9.3 million expense for the year ended December 31, 2023 and was related to the remeasurement of the Preferred Stock Warrants liability. There were no warrants outstanding during the year ended December 31, 2022.

Other expenses increased by $1.2 million, or 88.8%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. This increase was primarily driven by a $0.7 million increase in loss from equity method investments and $0.5 million in sponsorships for local charity events.

Provision for Income Taxes

Provision for income taxes was $8.5 million and $5.1 million for the years ended December 31, 2023 and 2022, respectively. The increase was primarily attributable to a higher profit from Gyre Pharmaceuticals operations and an increase in deferred tax asset.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2023, we had cash and cash equivalents of $33.5 million and long-term certificates of deposit of $23.4 million, which are available to fund operations, and an accumulated deficit of $85.5 million. Our net loss during the year ended December 31, 2023 was $85.5 million, while cash provided by operating activities was $25.9 million. We believe that our existing cash and cash equivalents, cash flows from operations, and access to capital markets will be sufficient to fund our operating activities and obligations for at least 12 months following the filing date of this Annual Report.

Future Funding Requirements

We expect to use cash flows from operations to meet our current and future financial obligations, including funding our operations, and capital expenditures. Our ability to make these payments depends on our future performance, which will be affected by financial, business, economic, regulatory, and other factors, many of which we cannot control. Factors that may affect financing requirements include, but are not limited to:

- the timing, progress, cost and results of our clinical trials, preclinical studies and other discovery and research and development activities;

- the timing and outcome of, and costs involved in, seeking and obtaining marketing approvals for our products, and in maintaining quality systems standards for our products;
- the timing of, and costs involved in, commercial activities, including product marketing, sales and distribution;
- our ability to successfully commercialize and to obtain regulatory approval for, and successfully commercialize our other or future product candidates;
- increases or decreases in revenue from our marketed products, including decreases in revenue resulting from generic entrants or health epidemics or pandemics;
- the number and development requirements of other product candidates that we pursue;
- our ability to manufacture sufficient quantities of our products to meet expected demand;
- the costs of preparing, filing, prosecuting, maintaining and enforcing any patent claims and other intellectual property rights, litigation costs and the results of litigation;
- our ability to enter into collaboration, licensing or distribution arrangements and the terms and timing of these arrangements;
- the potential need to expand our business, resulting in additional payroll and other overhead expenses;
- the potential in-licensing of other products or technologies;
- the emergence of competing technologies or other adverse market or technological developments; and
- the impacts of inflation and resulting cost increases.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies.

The following table summarizes our cash flows for the periods presented (in thousands):

	Year Ended December 31,	
	2023	2022
Cash Flow Data:		
Net cash provided by operating activities	$ 25,892	$ 10,677
Net cash used in investing activities	(19,760)	(13,814)
Net cash provided by financing activities	2,500	—
Effect of exchange rate changes on cash and cash equivalents	(298)	(1,891)
Net change in cash and cash equivalents	$ 8,334	$ (5,028)

Cash Flows from Operating Activities

Cash provided by operating activities for the year ended December 31, 2023 was $25.9 million, reflecting our net loss of $85.5 million, offset by non-cash items of $103.9 million primarily related to the acquired IPR&D of $83.1 million in connection with the GNI USA Contributions, $9.3 million related to the change in fair value of warrant liability, stock-based compensation of $7.3 million, divestiture losses of $2.7 million, and equity loss of unconsolidated affiliates of $1.3 million. Additionally, cash provided by operating activities reflected changes in net operating assets and liabilities of $7.5 million.

Cash provided by operating activities for the year ended December 31, 2022 was $10.7 million, reflecting our net income of $4.3 million and non-cash items of $14.2 million primarily related to stock-based compensation of $13.4 million, partially offset by net cash outflow of $7.8 million from the changes in net operating assets and liabilities.

Cash Flows from Investing Activities

Cash used in investing activities for the year ended December 31, 2023 was $19.8 million, which consisted of $15.7 million in purchases of certificates of deposit, $8.5 million in purchases of property and equipment and $1.0 million paid for equity method investment, partially offset by $5.6 million of cash acquired in connection with the GNI USA Contributions.

Cash used in investing activities for the year ended December 31, 2022 was $13.8 million, which consisted of $7.5 million in purchases of certificates of deposit, $5.0 million in purchases of property and equipment and $1.3 million in cash paid for equity method investments.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2023 was $2.5 million due to the portion of proceeds from the issuance of Convertible Preferred Stock and Preferred Stock Warrants in the Private Placement received after the GNI USA Contributions.

There was no cash provided by or used in financing activities for the year ended December 31, 2022.

Contractual Obligations and Other Commitments

Leases

We have entered into lease arrangements in (1) San Diego, California for our headquarters, which expires on the last day of the 38th full calendar month beginning on or after November 11, 2023, and (2) the PRC, for office and laboratory spaces through August 2024. As of December 31, 2023, our fixed lease payment obligations were $0.4 million, with $0.2 million payable within 12 months.

Other Contractual Obligations and Commitments

In June 2021, we entered into a transfer agreement with Nanjing Healthnice Pharmaceutical Technology Co., Ltd. ("Nanjing Healthnice"), an independent third party, pursuant to which Nanjing Healthnice agreed to transfer to us the avatrombopag maleate tablets for the treatment of CLD-associated thrombocytopenia and all relevant technologies, complete any research or trials and transfer to us all materials necessary for the application of marketing approval by CDE. Upon the completion of the transfer, we expect that we will be approved by NMPA as the marketing authorization holder of the avatrombopag maleate tablets. In exchange, we will pay a total of approximately $2.3 million upon certain milestones (*e.g.*, the completion of bioequivalence study, or the registration application to CDE) being met. We have completed the bioequivalence study and received CDE acceptance on August 1, 2022, and as of December 15, 2023, we have made total payments of approximately $1.8 million.

In September 2022, we entered into a transfer agreement with New Jiyuan (Beijing) Pharmaceutical Technology Co., Ltd. ("New Jiyuan"), an independent third party, pursuant to which New Jiyuan agreed to transfer to us the minocycline hydrochloride foam for the treatment of moderate to severe acne and all relevant technologies, complete product development and transfer to us all materials necessary for the application of marketing approval of CDE. Upon the completion of the transfer, we expect that we will be approved by NMPA as the marketing authorization holder of the minocycline hydrochloride foam. In exchange, we will pay a total amount of $1.0 million and the payments will be made by installments conditioned upon certain milestones (*e.g.*, the completion of bioequivalence study, or the registration application to CDE) being met. Process verification has been completed. As of December 31, 2023, we have made total payments of approximately $0.7 million.

In December 2022, we entered into a transfer agreement with Hangzhou Baicheng Pharmaceutical Technology Co., Ltd. and Zhejiang CDMO Pharmaceutical Co., Ltd., an independent third party, pursuant to which Baicheng agreed to transfer to us the acetylcysteine injection for the treatment of respiratory diseases with excessive thick mucus discharge and all relevant technologies, assist us in completing any research, trial and other required procedures and transfer to us all materials necessary for the application of marketing approval of CDE. Upon the completion of this transfer agreement, we expect that we will be approved by NMPA as the marketing authorization holder of the acetylcysteine injection. We have received CDE acceptance on January 8, 2024. As of December 31, 2023, we have made payments totaling approximately $0.5 million under this agreement. Upon receiving the CDE's final approval, we will make an additional $40,000 in payments.

Research and Development Programs

As of December 31, 2023, we have committed to allocate $12.7 million toward future research and development activities for various programs.

Property and Equipment

Our commitments related to the purchase of property and equipment contracted but not yet reflected in the consolidated financial statements were $2.8 million as of December 31, 2023 and are expected to be incurred within one year.

Critical Accounting Policies and Estimates

The preparation of the consolidated financial statements and related disclosures in conformity with U.S. GAAP and our discussion and analysis of our financial condition and operating results require our management to make judgments, assumptions and estimates that affect the amounts reported in our consolidated financial statements and accompanying notes. Our significant accounting policies and methods used in preparation of the consolidated financial statements are described in Note 2 — *Summary of Significant Accounting Policies* to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates, and such differences may be material.

Management believes our critical accounting policies and estimates discussed below are critical to understanding its historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

We record revenue in accordance with ASC Topic 606 ("ASC 606"), Revenue from Contracts with Customers, whereby revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration expected to be received in exchange for those goods or services. A five-step model is used to achieve the core principle: (1) identify the customer contract, (2) identify the contract's performance obligations, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations and (5) recognize revenue when or as a performance obligation is satisfied. We apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

(a) Sale of Pharmaceutical Products

Revenue from the sale of pharmaceutical products is recognized at the point in time when control of the asset is transferred to the customer, generally on completion of delivery of the pharmaceutical products and quality inspection by the customer. For the sales of pharmaceutical products, most of our customers are distributors.

Revenue from product sales is recognized net of estimated sales discounts. These discounts are estimated based on sales volumes from the preceding months and applying the discount percentages specified in each contract.

Certain contracts for the sale of pharmaceutical products include certain sales rebates which are incurred after the control and rights of products have been passed to customers that give rise to consideration payable to a customer. As the specific amount of the rebates is not finalized at the point of revenue recognition, we make deductions from revenue based on historical experience. In estimating consideration payable to a customer, we are required to use either the expected value method or the most likely amount method depending on which method better predicts the amount of consideration to which the customer will be entitled. We regularly review the information related to these estimates and adjusts the amounts accordingly.

To estimate the variable consideration for the expected future rebates, the most likely amount method is used for contracts with a single-volume threshold while the expected value method is used for contracts with more than one volume threshold. The selected method that best predicts the amount of variable consideration is primarily driven by the number of volume thresholds contained in the contract. The requirements on constraining estimates of variable consideration are applied and the expected future rebates are deducted from the trade receivables from the customers.

(b) License of intellectual property

Revenue from a license agreement is recognized when the control of the right to use the license is transferred to the customer. Milestone payments, which are included in the transaction price to the extent that it is highly probable that a significant reversal of accumulative revenue recognized will not occur, represent a form of variable consideration when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered highly probable of being achieved and estimate the amount to be included in the transaction price using the most likely amount method. Milestone payments, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received.

Research and Development Expenses and Accruals

Research and development expenses are expensed as incurred when these expenditures relate to our research and development services and have no alternative future uses.

Pre-clinical and clinical trial costs are a significant component of our research and development expenses. We have a history of contracting with third parties that perform various pre-clinical and clinical trial activities on our behalf in the ongoing development of our product candidates. Expenses related to pre-clinical and clinical trials are accrued based on our estimates of the actual services performed by the third parties for the respective period.

We estimate the amount of work completed through discussions with internal personnel and external service providers in conjunction with reporting information obtained directly from the external service providers as to the progress or stage of completion of the services and the agreed-upon fee to be paid for such services. We record the costs of research and development activities based upon the estimated services provided but not yet invoiced and include these costs in accrued expenses and other current liabilities in our consolidated balance sheets and in research and development expense in our consolidated statements of operations and comprehensive income (loss). We make significant judgments and estimates in determining the accrued balance in each reporting period. As actual costs become known, we adjust our accrued estimates.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting expenses that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of research and development expenses.

Income Taxes

We record income taxes using the liability method, under which deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are recorded against deferred tax assets, including net operating losses and tax credits, when it is determined it is more-likely-than-not that some or all of the tax benefits will not be realized.

We account for uncertain tax positions in accordance with the provisions of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 740, *Income Taxes*. When uncertain tax positions exist, we recognize the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Interest and penalties related to unrecognized tax benefits are recorded as a component of income tax expense, if any.

Stock-Based Compensation

We measure the cost of employee, non-employee and director services received in exchange for an award of equity instruments based on the fair value-based measurement of the award on the date of grant and recognize the related expense over the period during which an employee, non-employee or director is required to provide services in exchange for the award on a straight-line basis. The estimated fair value of equity awards that contain performance conditions is expensed over the term of the award once we have determined that it is probable that performance conditions will be satisfied.

Determining the fair value of stock-based awards at the grant date requires judgment. We use the Black-Scholes option-pricing model to determine the fair value of stock options. The determination of the grant date fair value of options using an option-pricing model is affected by our assumptions regarding a number of variables including the fair value of our common stock, its expected common stock price volatility over the expected life of the options, expected term of the stock option, risk-free interest rates and expected dividends. We record stock-based compensation as a compensation expense, net of the forfeited awards. We elected to account for forfeitures when they occur. As such, we recognize stock-based compensation expense over their requisite service period based on the vesting provisions of the individual grants. Such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different. We will continue to use judgment in evaluating the assumptions utilized for our stock-based compensation expense calculations on a prospective basis. See Note 12 — *Stock Based Compensation* to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for more information.

Warrant Liability

In connection with the Private Placement, we issued the Preferred Stock Warrants (see Note 3 — *Fair Value Measurements and Financial Instruments* to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K) which are freestanding financial instruments classified as warrant liability since the underlying securities are contingently redeemable upon the occurrence of events which are outside of our control. The Preferred Stock Warrants are recorded at fair value upon issuance and are subject to remeasurement at the end of each reporting period. We use the Black-Scholes option-pricing model to determine the fair value of the Preferred Stock Warrants which is affected by our assumptions regarding a number of variables, including the fair value of our Convertible Preferred Stock, the expected share price volatility over the expected life of the options, expected term of the warrant, risk-free interest rates and expected dividends. Such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our estimated fair value of warrant liability could be materially different. We will continue to use judgment in evaluating the assumptions utilized for our warrant liability fair value calculations on a prospective basis.

Smaller Reporting Company Status

We are a “smaller reporting company” as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our ordinary shares held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our ordinary shares held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recent Accounting Pronouncements

Refer to Note 2 — *Summary of Significant Accounting Policies* to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for a discussion of recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Quantitative and Qualitative Disclosures About Market Risk

Market risk represents the risk of loss that may impact on our financial position because of adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of exposure resulting from potential changes in exchange rates, interest rates, or inflation.

Foreign Currency Exchange Risk

Our expenses are generally denominated in the currencies of the jurisdictions in which we conduct our operations, which are primarily in the United States and the PRC. Our results of current and future operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. A hypothetical 10% increase or decrease in the relative value of the U.S. dollar to other currencies would not have a material effect on our operating results. As the impact of foreign currency exchange rates has not been material to our historical operating results, we have not entered into derivative or hedging transactions, but we may do so in the future if our exposure to foreign currency becomes more significant.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition, or results of operations, other than its impact on the general economy. Nonetheless, if our costs were to become subject to inflationary pressures, we might not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition, and results of operations.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See Index to Consolidated Financial Statements and Schedules on page F-1 of this Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES.

None.

Item 9A. CONTROLS AND PROCEDURES.

Evaluation of disclosure controls and procedures

As of December 31, 2023, our management, with the participation and supervision of our principal executive officer and our principal financial officer, evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2023 to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States.

As of December 31, 2023, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Item 9B. OTHER INFORMATION.

Trading Arrangements

On December 12, 2023, Nassim Usman, Ph.D., a director of the Company, entered into a Rule 10b5-1 trading arrangement (as defined in Item 408 of Regulation S-K). Dr. Usman's plan provides for the potential exercise of vested stock options and the associated sale of up to 240,000 shares of common stock. The trading arrangement terminates

upon the sale of all shares pursuant to the trading arrangement. During the three months ended December 31, 2023, no other director or officer (as defined in Rule 16a-1(f) promulgated under the Exchange Act) of the Company adopted or terminated any "Rule 10b5-1 trading arrangement" or any "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 9C. DISCLOSURES REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this Item 10 is incorporated herein by reference to the information in our proxy statement for our 2024 Annual Meeting of Stockholders (the "2024 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2023, including under the heading "Corporate Governance," and, as applicable, "Delinquent Section 16(a) Reports" per Item 405 of Regulation S-K.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is available on our website located at www.gyretx.com, under "Corporate Governance." We intend to disclose on our website any amendments to, or waivers from, the code of business conduct and ethics that are required to be disclosed within four business days following the date of the amendment or waiver.

Item 11. EXECUTIVE COMPENSATION.

The information required by this Item 11 is incorporated herein by reference to the information in our 2024 Proxy Statement, including under headings "Executive Compensation" and "Corporate Governance".

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this Item 12 is incorporated herein by reference to information in our 2024 Proxy Statement, including under headings "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans."

Item 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE.

The information required by this Item 13 is incorporated herein by reference to information in our 2024 Proxy Statement, including under headings "Corporate Governance" and "Certain Relationships and Related Party Transactions."

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this Item 14 is incorporated herein by reference to information in our 2024 Proxy Statement, including under the heading "Ratification of Independent Auditor Appointment."

PART IV

Item 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements

   See Index to Consolidated Financial Statements at Part II, Item 8 Financial Statements and Supplementary Data, herein.

2. Consolidated Financial Statement Schedules

   All schedules are omitted because they are not applicable or the required information is shown under Item 8. “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

3. See LIST OF EXHIBITS

(b) See LIST OF EXHIBITS

Item 16.

FORM 10-K SUMMARY.

None.

LIST OF EXHIBITS

Exhibit No.	Exhibit title	Incorporated by reference			
		Form	File No.	Exhibit No.	Filing Date
2.1(a)†#	Asset Purchase Agreement, dated as of December 26, 2022, by and among Catalyst Biosciences, Inc., GNI Group Ltd., and GNI Hong Kong Limited.	8-K	000-51173	2.1	Dec. 27, 2022
2.1(b)	Agreement and Amendment to Asset Purchase Agreement, dated as of March 29, 2023, by and among Catalyst Biosciences, Inc., GNI Group Ltd., and GNI Hong Kong Limited.	8-K	000-51173	2.2	Mar. 30, 2023
2.2(a)#	Business Combination Agreement, dated as of December 26, 2022, by and among Catalyst Biosciences, Inc., GNI USA, Inc., GNI Group Ltd., GNI Hong Kong Limited, Shanghai Genomics, Inc., the individuals listed on Annex A thereto and Continent Pharmaceuticals Inc.	8-K	000-51173	2.2	Dec. 27, 2022
2.2(b)	Amendment to Business Combination Agreement, dated as of March 29, 2023, by and among Catalyst Biosciences, Inc., GNI USA, Inc., GNI Group Ltd., GNI Hong Kong Limited, Shanghai Genomics, Inc., the Minority Holders and Continent Pharmaceuticals Inc.	8-K	000-51173	2.1	Mar. 30, 2023
2.2(c)	Second Amendment to Business Combination Agreement, dated as of August 30, 2023, by and among Catalyst Biosciences, Inc., GNI USA, Inc., GNI Group Ltd., GNI Hong Kong Limited, Shanghai Genomics, Inc. and Continent Pharmaceuticals Inc.	8-K	000-51173	2.1	Aug. 31, 2023
3.1	Fourth Amended and Restated Certificate of Incorporation of the Company.	S-8	333-133881	4.1	May 8, 2006
3.2	Certificate of Amendment to Fourth the Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Aug. 20, 2015
3.3	Second Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Feb. 10, 2017
3.4	Third Certificate of Amendment to the Fourth Amended and Restated Certificate of Incorporation of the Company.	8-K	000-51173	3.1	Oct. 30, 2023
3.5	Amended and Restated Bylaws of the Company.	8-K	000-51173	3.3	Oct. 30, 2023
3.6(a)	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, filed with the Delaware Secretary of State on April 10, 2017.	8-K	000-51173	3.1	Apr. 13, 2017

Exhibit No.	Exhibit title	Incorporated by reference			
		Form	File No.	Exhibit No.	Filing Date
3.6(b)*	Certificate of Elimination of Series A Preferred Stock, filed with the Delaware Secretary of State on March 25, 2024.				
3.7(a)	Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, filed with the Delaware Secretary of State on December 27, 2022.	8-K	000-51173	3.1	Dec. 27, 2022
3.7(b)	Amendment to Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, filed with the Delaware Secretary of State on October 30, 2023.	8-K	000-51173	3.2	Oct. 30, 2023
3.8(a)	Certificate of Designation of Preferences, Rights and Limitations of Series Y Preferred Stock, filed with the Delaware Secretary of State on June 20, 2023, with respect to the Series Y Preferred Stock.	8-K	000-51173	3.1	June 20, 2023
3.8(b)	Certificate of Elimination of Series Y Preferred Stock, filed with the Delaware Secretary of State on August 31, 2023.	8-K	000-51173	3.1	Aug. 31, 2023
4.1	Description of Securities.				
4.2	Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to Silicon Valley Bank on March 3, 2005.	10-K	000-51173	4.3	Mar. 9, 2016
4.3	Form of Warrant to Purchase Stock of Catalyst Biosciences, Inc., issued to purchasers of convertible promissory notes.	10-K	000-51173	4.5	Mar. 9, 2016
4.4	Form of Warrant to Purchase Series X Convertible Preferred Stock.	8-K	000-51173	4.1	Oct. 30, 2023
10.1(a)#	Contingent Value Rights Agreement, dated as of December 26, 2022, by and between Catalyst Biosciences, Inc. and American Stock Transfer & Trust Company, LLC.	S-3	333-273395	2.5	July 24, 2023
10.2(b)	Amendment to Contingent Value Rights Agreement, dated as of March 29, 2023, by and between Catalyst Biosciences, Inc. and American Stock Transfer & Trust Company, LLC.	8-K	000-51173	2.3	Mar. 30, 2023
10.3#	Asset Purchase Agreement, dated as of February 27, 2023, by and between Catalyst Biosciences, Inc. and GC Biopharma Corp.	8-K	000-51173	10.1	Mar. 2, 2023
10.4	Securities Purchase Agreement, dated as of October 27, 2023, by and between Catalyst Biosciences, Inc. and GNI USA, Inc.	8-K	000-51173	10.1	Oct. 30, 2023
10.5+	Amended and Restated Employment Agreement, dated as of August 28, 2018, by and between Catalyst Biosciences, Inc. and Dr Nassim Usman.	8-K	000-51173	10.1	Aug. 31, 2018

Exhibit No.	Exhibit title	Incorporated by reference			
		Form	File No.	Exhibit No.	Filing Date
10.6+	Waiver Agreement between Catalyst Biosciences, Inc. and Dr. Nassim Usman, dated January 17, 2023.	10-Q	000-51173	10.2	May 15, 2023
10.7+	Waiver Agreement between Catalyst Biosciences, Inc. and Dr. Grant Blouse, dated January 14, 2023.	10-Q	000-51173	10.3	May 15, 2023
10.8+	Waiver Agreement between Catalyst Biosciences, Inc. and Ms. Seline Miller, dated January 17, 2023.	10-Q	000-51173	10.4	May 15, 2023
10.9+	Catalyst Biosciences, Inc. (formerly Targacept, Inc.) 2015 Stock Incentive Plan (as Amended and Restated Effective June 9, 2016).	DEF 14A	000-51173	Appendix A	Apr. 25, 2016
10.10+	Form of Incentive Stock Option Award Notice.	8-K	000-51173	10.1	July 14, 2017
10.11+	Form of Non-qualified Stock Option Award Notice.	8-K	000-51173	10.2	July 14, 2017
10.12+	Catalyst Biosciences, Inc. 2018 Omnibus Incentive Plan.	DEF 14A	000-51173	Appendix A	May 1, 2020
10.13+	Catalyst Biosciences, Inc. 2018 Employee Stock Purchase Plan.	DEF 14A	000-51173	Appendix B	May 11, 2018
10.14+	Form of Stock Option Award Agreement.	10-K	000-51173	10.8	Mar. 31, 2022
10.15+	Gyre Therapeutics, Inc. 2023 Omnibus Incentive Plan	8-K	000-51173	10.2	Oct. 30, 2023
10.16+	Form of Indemnification Agreement	8-K	000-51173	10.3	Oct. 30, 2023
10.17+	Employment Agreement, dated as of October 30, 2023, by and between the Company and Charles Wu.	8-K	000-51173	10.4	Oct. 30, 2023
10.18+	Employment Agreement, dated as of October 30, 2023, by and between the Company and Ruoyu Chen.	8-K	000-51173	10.5	Oct. 30, 2023
10.19+	Separation Agreement, dated October 30, 2023, by and between the Company and Dr. Nassim Usman.	8-K	000-51173	10.1	Nov. 2, 2023
10.20+	Separation Agreement, dated October 30, 2023, by and between the Company and Seline Miller.	8-K	000-51173	10.2	Nov. 2, 2023
10.21+	Employment Agreement, dated as of January 15, 2024, by and between the Company and Dr. Han Ying.	8-K	000-51173	10.1	Jan. 19, 2024
16.1	Letter to the SEC from EisnerAmper LLC, dated November 2, 2023.	8-K	000-51173	16.1	Nov. 2, 2023
21.1*	List of subsidiaries of the Company.				
23.1*	Consent of Grant Thornton Zhitong Certified Public Accountants LLP, Independent Registered Public Accounting Firm.				
24.1*	Power of Attorney (included as part of the signature page hereto).				

Exhibit No.	Exhibit title	Incorporated by reference			
		Form	File No.	Exhibit No.	Filing Date
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1**	Certification of the Chief Executive Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2**	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) of the Exchange Act and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
97.1*	Clawback Policy of the Company				
101.INS*	Inline XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

* Filed herewith.
** Furnished.
† The annexes, schedules, and certain exhibits to this Exhibit have been omitted pursuant to Item 601(a)(5).
# Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit were omitted by means of marking such portions with an asterisk because the identified confidential portions (i) the Company customarily and actually treats that information as private or confidential and (ii) the information was not material.
+ Denotes management contract, compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GYRE THERAPEUTICS, INC.

Date: March 27, 2024

By: /s/ Han Ying, Ph.D.
Han Ying, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Date: March 27, 2024

By: /s/ Ruoyu Chen
Ruoyu Chen
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Han Ying, Ph.D. and Ruoyu Chen, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Han Ying, Ph.D. **Han Ying, Ph.D.**	Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2024
/s/ Ruoyu Chen **Ruoyu Chen**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2024
/s/ Ying Luo, Ph.D. **Ying Luo, Ph.D.**	Chairman of the Board of Directors	March 27, 2024
/s/ Thomas Eastling **Thomas Eastling**	Director	March 27, 2024
/s/ Gordon Carmichael, Ph.D. **Gordon Carmichael, Ph.D.**	Director	March 27, 2024
/s/ Songjiang Ma **Songjiang Ma**	President and Director	March 27, 2024
/s/ Rodney L. Nussbaum **Rodney L. Nussbaum**	Director	March 27, 2024
/s/ Renate Parry, Ph.D. **Renate Parry, Ph.D.**	Director	March 27, 2024

/s/ Nassim Usman, Ph.D. **Nassim Usman, Ph.D.**	Director	March 27, 2024

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Gyre Therapeutics, Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Gyre Therapeutics, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of comprehensive (loss) income, changes in convertible preferred stock and equity, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes and the financial statement schedule included under Item 15(a) (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical audit matters

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

Reverse asset acquisition

As described further in Notes 1 and 7 to the financial statements, the Company completed the GNI USA Contribution on October 30, 2023. The GNI USA Contribution was treated as a reverse asset acquisition for accounting purposes, with Continent Pharmaceuticals Inc. ("CPI") treated as the accounting acquirer. We identified the reverse asset acquisition to be a critical audit matter.

The principal considerations for our determination that the reverse asset acquisition, including (1) the determination that the transaction was an asset acquisition, (2) the determination that CPI was the accounting acquirer, and (3) the

determination of the fair value of the associated consideration, specifically the expected volatility and expected term assumptions used in the Black-Scholes option pricing model to calculate the fair value of the outstanding stock options assumed in the Merger, is a critical audit matter, is the complexity of the transaction and the significant judgments by management, which in turn led to a high degree of auditor judgment and effort in performing procedures and evaluating audit evidence. The audit effort also involved the use of professionals with specialized skill and knowledge.

Our related audit procedures included the following, among others:

- Reading and evaluating the underlying agreements in consideration of the relevant accounting guidance
- Evaluating management's assessment and conclusion on the asset acquisition and accounting acquirer
- Evaluating the disclosures related to the reverse asset acquisition made in the financial statements
- Evaluating, with the assistance of specialists, management's assessment of the fair value of stock options assumed by CPI, specifically the reasonableness of the expected volatility and expected term assumptions used by management in determining the fair value of the stock options assumed
- Evaluating the competence, capability and objectivity of the independent valuation firm engaged by the Company

Preferred stock warrants

As described in Note 3 and 11 to the financial statements, in October 2023, the Company completed a private placement whereby the Company issued shares of convertible preferred stock and warrants to purchase shares of convertible preferred stock. The warrants were classified as a liability instrument and are subject to fair value remeasurement at the end of each reporting period.

The fair value of warrant liabilities was estimated by management using the Black-Scholes option pricing model. As the Company's warrant liabilities are not traded in an active market with readily observable prices, the use of this model includes significant unobservable inputs to measure the fair value of the warrant liabilities. We identified the warrant liabilities to be a critical audit matter.

The principal considerations for our determination that warrant liabilities is a critical audit matter is the significant judgment by management when assessing the volatility and expected term assumptions, which in turn led to a high degree of auditor judgment and effort in performing procedures and evaluating audit evidence relating to those assumptions. The audit effort also involved the use of professionals with specialized skill and knowledge.

Our related audit procedures included the following, among others:

- Reading and evaluating the convertible preferred shares and warrants agreement
- Evaluating, with the assistance of specialists, management's assessment of the fair value of the warrant liabilities, specifically the reasonableness of the expected volatility and expected term assumptions used by management in determining the fair value
- Evaluating the competence, capability and objectivity of the independent valuation firm engaged by the Company

/s/ Grant Thornton Zhitong Certified Public Accountants LLP

We have served as the Company's auditor since 2023.

Grant Thornton Zhitong Certified Public Accountants LLP
Beijing, China
March 27, 2024

Gyre Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 33,509	$ 25,175
Accounts and note receivables, net	15,552	17,136
Other receivables from GNI	1,287	—
Inventories, net	4,281	6,122
Prepaid assets	1,547	377
Other current assets	1,045	843
Total current assets:	57,221	49,653
Property and equipment, net	23,288	17,709
Long-term receivable from GCBP	4,722	—
Intangible assets, net	205	297
Right-of-use assets	489	666
Land use rights, net	1,493	1,559
Deferred tax assets	4,695	4,081
Long-term certificates of deposit	23,431	7,394
Other assets, noncurrent	995	3,394
Total assets	$ 116,539	$ 84,753
Liabilities, convertible preferred stock, and equity		
Current liabilities:		
Accounts payable	$ 355	$ 122
Deferred revenue	39	145
Due to related parties	1,369	118
CVR excess closing cash payable	1,085	—
Accrued expenses and other current liabilities	11,935	9,264
Income tax payable	5,054	2,101
Operating lease liabilities, current	210	492
Total current liabilities:	20,047	12,242
Operating lease liabilities, noncurrent	199	121
Deferred government grants	213	118
CVR derivative liability, noncurrent	4,722	—
Warrant liability, noncurrent	12,835	—
Other noncurrent liabilities	49	55
Total liabilities	$ 38,065	$ 12,536
Commitments and contingencies (Note 13)		
Convertible Preferred Stock, $0.001 par value, 5,000,000 shares authorized; 13,151 shares and nil shares issued and outstanding at December 31, 2023 and 2022, respectively	64,525	—
Equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized; 76,595,616 shares and 63,588,119 shares issued and outstanding at December 31, 2023 and 2022, respectively	77	64
Additional paid-in capital	68,179	32,795
Statutory reserve	3,098	2,660
(Accumulated deficit) retained earnings	(85,538)	7,395
Accumulated other comprehensive loss	(1,644)	(392)
Total Gyre stockholders' (deficit) equity	(15,828)	42,522
Noncontrolling interest	29,777	29,695
Total equity	13,949	72,217
Total liabilities, convertible preferred stock, and equity	$ 116,539	$ 84,753

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

Gyre Therapeutics, Inc.
Consolidated Statements of Operations and Comprehensive (Loss) Income
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	2022
Revenues	$ 113,450	$ 102,290
Operating expenses:		
Cost of revenues	4,636	4,793
Selling and marketing	61,159	54,238
Research and development	13,780	16,686
General and administrative	14,662	17,370
Acquired in-process research and development	83,104	—
Divestiture losses	2,711	—
Loss on disposal of property and equipment	628	—
Total operating expenses	180,680	93,087
(Loss) income from operations	(67,230)	9,203
Other income (expense), net:		
Interest income, net	1,044	726
Other income	1,076	857
Change in fair value of warrant liability	(9,261)	—
Other expenses	(2,594)	(1,374)
(Loss) income before income taxes	(76,965)	9,412
Provision for income taxes	(8,515)	(5,098)
Net (loss) income from operations	(85,480)	4,314
Net income attributable to noncontrolling interest	7,453	2,012
Net (loss) income attributable to common stockholders	$ (92,933)	$ 2,302
Net (loss) income per share attributable to common stockholders:		
Basic	$ (1.41)	$ 0.04
Diluted	$ (1.41)	$ 0.03
Weighted average shares used in calculating net (loss) income per share attributable to common stockholders:		
Basic	65,831,675	63,588,119
Diluted	65,831,675	75,686,406
Other comprehensive (loss) income:		
Net (loss) income from operations	$ (85,480)	$ 4,314
Foreign currency translation adjustments	(1,484)	(4,928)
Comprehensive loss from operations	(86,964)	(614)
Net income attributable to noncontrolling interest	7,453	2,012
Foreign currency translation adjustments attributable to noncontrolling interest	(647)	(2,170)
Comprehensive income (loss) attributable to noncontrolling interest	6,806	(158)
Comprehensive loss attributable to common stockholders	$ (93,770)	$ (456)

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

Gyre Therapeutics, Inc.
Consolidated Statements of Convertible Preferred Stock and Equity
(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Statutory Reserve	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)	Total Gyre Stockholders' Equity (Deficit)	Non-controlling Interest	Total Equity
	Shares	Amount	Shares	Amount							
Balances as of December 31, 2021	—	$ —	63,588,119	$ 64	25,315	$ 1,413	$ 6,340	$ 2,366	$ 35,498	$ 23,967	59,465
Appropriation of statutory reserve	—	—	—	—	—	1,247	(1,247)	—	—	—	—
Stock-based compensation expense	—	—	—	—	7,480	—	—	—	7,480	5,886	13,366
Foreign currency translation adjustment	—	—	—	—	—	—	—	(2,758)	(2,758)	(2,170)	(4,928)
Net income	—	—	—	—	—	—	2,302	—	2,302	2,012	4,314
Balances as of December 31, 2022	—	—	63,588,119	64	32,795	2,660	7,395	(392)	42,522	29,695	72,217
Deemed issuance of common stock and Convertible Preferred Stock to former stockholders of Catalyst upon the GNI USA Contributions	12,340	63,099	2,531,851	3	21,246	—	—	—	21,249	—	21,249
Acquisition of minority interest	—	—	10,463,627	10	7,845	438	—	(415)	7,878	(7,878)	—
Issuance of Preferred Stock upon Private Placement	811	1,426	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	6,127	—	—	—	6,127	1,154	7,281
Stock options exercised	—	—	12,019	—	166	—	—	—	166	—	166
Foreign currency translation adjustment	—	—	—	—	—	—	—	(837)	(837)	(647)	(1,484)
Net (loss) income	—	—	—	—	—	—	(92,933)	—	(92,933)	7,453	(85,480)
Balances as of December 31, 2023	13,151	$ 64,525	76,595,616	$ 77	68,179	$ 3,098	$ (85,538)	$ (1,644)	$ (15,828)	$ 29,777	13,949

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

Gyre Therapeutics, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2023	2022
Operating Activities		
Net (loss) income from operations	$ (85,480)	$ 4,314
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Acquired in-process research and development	83,104	—
Stock-based compensation	7,281	13,366
Depreciation and amortization	1,074	1,087
Noncash lease expense	355	404
Amortization of land use rights	40	42
Deferred income taxes, net	(1,160)	(838)
Bad debt expense and other non-cash items	(61)	22
Accrued interest on long-term certificates of deposit	(633)	(178)
Change in fair value of long-term receivable	(39)	—
Change in fair value of derivative liabilities	39	—
Change in fair value of warrant liability	9,261	—
Equity loss of unconsolidated affiliates	1,314	251
Divestiture losses	2,711	—
Loss on disposal of property and equipment	628	4
Changes in operating assets and liabilities:		
Accounts and note receivables	1,398	(7,920)
Other receivables from GNI	(96)	—
Inventories	1,747	(879)
Prepaid and other assets	(82)	973
Income tax payable	3,003	(1,344)
Accounts payable	192	(112)
Other noncurrent liabilities	(102)	—
Due to related parties	425	—
Accrued expenses and other liabilities	1,446	1,914
Operating lease liabilities	(473)	(429)
Net cash provided by operating activities	25,892	10,677
Investing Activities		
Acquisition of intangible assets	(69)	(13)
Purchase of certificates of deposit	(15,735)	(7,484)
Purchase of property and equipment	(8,517)	(4,985)
Proceeds from sale of equipment	664	—
Purchase of equity method investment	(1,000)	(1,332)
Cash and cash equivalents acquired in connection with the GNI USA Contributions	5,587	—
Payments made for acquisition costs	(124)	—
Cash balance in a disposed subsidiary	(566)	—
Net cash used in investing activities	(19,760)	(13,814)
Financing Activities		
Proceeds from issuance of Convertible Preferred Stock and Preferred Stock Warrants under the Private Placement	2,500	—
Net cash provided by financing activities	2,500	—
Effect of exchange rate changes on cash and cash equivalents	(298)	(1,891)
Net increase (decrease) in cash and cash equivalents	8,334	(5,028)
Cash and cash equivalents at beginning of the period	25,175	30,203
Cash and cash equivalents at end of period	$ 33,509	$ 25,175
Supplemental Disclosure of Non-Cash Financing and Investing Activities:		
Deemed issuance of common stock and Convertible Preferred Stock to former stockholders of Catalyst upon the GNI USA Contributions	$ 84,348	$ —
Advance payment for Convertible Preferred Stock and Preferred Stock Warrants acquired upon the GNI USA Contributions	$ 2,500	$ —
Disposal consideration in other receivables from GNI	$ 768	$ —
Acquisition costs in due to related parties	$ 535	$ —
Right-of-use asset obtained in exchange for operating lease liabilities	$ 277	$ 57
Proceeds from the exercise of stock options included in other receivable	$ 166	$ —
Purchase of property and equipment included in accounts payable	$ —	$ 727
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	$ 6,346	$ 6,306

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

1. Organization and Nature of Operations

Description of Business

Gyre Therapeutics, Inc. (the "Company," "Gyre," or the "combined company"), formerly known as Catalyst Biosciences, Inc. ("Catalyst"), is a biopharmaceutical company originally incorporated in Delaware on March 7, 1997 under the name Targacept, Inc. Catalyst was a biopharmaceutical company with expertise in protease engineering. Prior to ceasing research and development activities in March 2022, Catalyst had several protease assets that were designed to address unmet medical needs in disorders of the complement or coagulation systems.

After completion of the transactions under the Business Combination Agreement as described below, Gyre became a financially-sustainable pharmaceutical company with a record of financial success that develops and commercializes small-molecule anti-inflammatory and anti-fibrotic drugs targeting organ diseases, focusing specifically on organ fibrosis. Fibrotic diseases represent a large patient population with significant unmet medical needs.

F351 Asset Acquisition

On December 26, 2022, Catalyst executed and closed an Asset Purchase Agreement, which was amended on March 29, 2023 (the "F351 Agreement"), with GNI Group Ltd. ("GNI Japan") and GNI Hong Kong Limited ("GNI HK") to purchase all of the assets and intellectual property rights primarily related to a clinical-stage proprietary Hydronidone compound for the treatment of nonalcoholic steatohepatitis ("NASH"), a severe form of nonalcoholic fatty liver disease (collectively, the "F351 Assets"), other than such assets and intellectual property rights located in the People's Republic of China ("PRC").

Business Combination Agreement

On December 26, 2022, Catalyst entered into a Business Combination Agreement, as amended on March 29, 2023 and August 30, 2023 (the "Business Combination Agreement") with GNI USA, Inc. ("GNI USA"), GNI Japan, GNI HK, Shanghai Genomics, Inc. ("SG" and collectively with GNI USA, GNI Japan and GNI HK, the "Contributors," and each a "Contributor"), certain individuals (each, a "Minority Holder" and collectively, the "Minority Holders") and Continent Pharmaceuticals Inc. ("CPI"). On October 30, 2023 (the "Effective Time"), the Contributions (as defined below) became effective and Catalyst acquired an indirect controlling interest in Beijing Continent Pharmaceuticals Co., Ltd. ("BC"). In connection with the Contributions, and immediately prior to the Effective Time of the Contributions, Catalyst amended its certificate of incorporation, increased the number of authorized shares of its common stock, par value $0.001 per share (the "Common Stock") from 100,000,000 shares to 400,000,000 shares, effected a 1-for-15 reverse stock split (the "Reverse Stock Split") and changed its name to Gyre Therapeutics, Inc.

Shares of Catalyst Common Stock were previously listed on The Nasdaq Capital Market under the symbol "CBIO." Catalyst had filed a listing application for the combined company with the Nasdaq Stock Market Inc. ("Nasdaq"). On October 31, 2023, Gyre's Common Stock commenced trading on the Nasdaq Capital Market under the symbol "GYRE", on a post-reverse stock split adjusted basis.

Pursuant to the Business Combination Agreement, at the Effective Time of the Contributions, and after giving effect to the 1-for-15 reverse stock split,

a) GNI USA contributed all of its ordinary shares in the capital of CPI to Catalyst in exchange for 45,923,340 shares of Gyre Common Stock (the "CPI Contribution"),

b) GNI USA contributed its interest in Further Challenger International Limited ("Further Challenger") for 17,664,779 shares of Gyre Common Stock (the "FC Contribution" and together with the CPI Contribution, the "GNI USA Contributions"), and

c) each Minority Holder contributed 100% of the interest he or she held in his or her respective entity in exchange for an aggregate of 10,463,627 shares of Gyre Common Stock (the "Minority Holder Contributions" and together with the GNI USA Contributions, the "Contributions").

As a result of the GNI USA Contributions, Gyre directly and indirectly holds 100% of CPI's shares. Through Gyre's ownership of CPI, prior to the Minority Holder Contributions, Gyre held a 56.0% indirect interest in BC. Upon completion of the Minority Holder Contributions, Gyre obtained additional indirect interests in BC and holds, in aggregate, a 65.2% indirect interest in BC.

Immediately after the closing of the Contributions, excluding potentially dilutive securities, GNI USA owned approximately 83.6% of the outstanding shares of Gyre Common Stock, Catalyst's existing stockholders, excluding GNI USA, owned approximately 2.8% of the outstanding Gyre Common Stock, and the Minority Holders owned approximately 13.7% of the outstanding shares of Gyre Common Stock. The Convertible Preferred Stock remained outstanding after the closing of the Contributions and is not included in the above ownership percentages.

At the Effective Time, BC terminated its 2021 Stock Incentive Plan (the "2021 Plan") and the options (the "BC Options") outstanding under the 2021 Plan were terminated and replaced with options granted under a subplan for Chinese participants under the Gyre 2023 Omnibus Incentive Plan (the "2023 Omnibus Incentive Plan") that are substantially similar in all material respects to the BC Options previously outstanding under the 2021 Plan.

Each share of Catalyst Common Stock and option to purchase Catalyst Common Stock that was issued and outstanding at the Effective Time remained issued and outstanding, and such shares and options were unaffected by the Contributions.

BC is a commercial-stage biopharmaceutical company registered and established in the PRC in 2002. BC is committed to the research and development of new drugs as well as manufacturing and commercialization of ETUARY (pirfenidone capsule) for the treatment of idiopathic pulmonary fibrosis and other pharmaceutical products. The registered office of BC is located at 60 Shunkang Road, Shunyi District, Beijing, PRC.

The immediate holding company of BC is BJContinent Pharmaceuticals Limited ("BJC"). The intermediate holding company of BC is CPI. Immediately following the Contributions, the immediate holding company of CPI is Gyre. The immediate holding Company of Gyre is GNI USA and the ultimate holding company of Gyre is GNI Japan.

The GNI USA Contributions were treated as an asset acquisition under U.S. generally accepted accounting principles ("U.S. GAAP"), with CPI treated as the accounting acquirer and presented as the predecessor for the post-acquisition SEC reporting purposes. Since Catalyst is the legal acquirer, the GNI USA Contributions were accounted for as a reverse asset acquisition. This determination was based upon the terms of the Business Combination Agreement and other factors including that, immediately following the GNI USA Contributions: (i) GNI USA (as the parent company of CPI immediately prior to the GNI USA Contributions) owns a substantial majority of the voting power of the combined company; (ii) CPI, through GNI USA, has the ability to control the board of directors of the combined company; and (iii) senior management of BC and GNI USA holds a majority of the key positions in senior management of the combined company. Immediately prior to the closing of the Contributions, Catalyst did not meet the definition of a business because Catalyst did not have an organized workforce that significantly contributed to its ability to create output, and substantially all of its fair value was concentrated in in-process research and development ("IPR&D").

As of the closing date of the GNI USA Contributions, the net assets of Catalyst were recorded at their acquisition-date relative fair values in the accompanying consolidated financial statements of the Company and the reported operating results prior to the GNI USA Contributions are those of CPI.

The Minority Holder Contributions were treated as an equity transaction, where the Company obtained additional indirect interest and maintained its control in BC.

Contingent Value Rights Agreement

Concurrent with the signing of the Business Combination Agreement on December 26, 2022, Catalyst and the Rights Agent (as defined in the CVR Agreement) executed a contingent value rights agreement (the "CVR Agreement"), as amended on March 29, 2023, pursuant to which each holder of Catalyst Common Stock as of January 5, 2023 (the "CVR Holder"), excluding GNI, received one contractual contingent value right (a "CVR") for each share of Catalyst Common Stock held by such holder. Each CVR entitles the holder thereof to receive certain cash payments in the future. For additional information, see Note 13 — *Commitments and Contingencies*.

Reverse Stock Split

The Company effected a 1-for-15 reverse stock split immediately prior to the Effective Time of the Contributions. The par value of the Catalyst Common Stock following the Reverse Stock Split was not adjusted and remains at $0.001 per share. All of the Catalyst's issued and outstanding common stock and options have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

All share and per share information has been retroactively adjusted to give effect to the Reverse Stock Split for all periods presented, unless otherwise indicated. Proportionate adjustments were made to the per share exercise price and the number of shares issuable upon the exercise or vesting of all stock options and warrants outstanding, which resulted in a proportional decrease in the number of shares of the Company's common stock reserved for issuance upon exercise or vesting of such stock options, warrants, and in the case of stock options and warrants, a proportional decrease in the exercise price of such stock options and warrants.

No fractional shares were issued in connection with the Reverse Stock Split and stockholders who would otherwise be entitled to a fraction of one share received a proportional cash payment.

Liquidity

For the year ended December 31, 2023, the Company had a net loss of $85.5 million, while net cash provided by operating activities was $25.9 million. As of December 31, 2023, the Company had an accumulated deficit of $85.5 million and cash and cash equivalents of $33.5 million. Based on the Company's current operating plan, management believes that existing cash and cash equivalents, cash flows from operations, and access to capital markets will be sufficient to fund the Company's operating activities and obligations for at least 12 months following the issuance of these consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements include the accounts of the Company and its controlled subsidiaries have been prepared in accordance with U.S. GAAP. Intercompany accounts and transactions, if applicable, have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, management evaluates its estimates, including those related to revenue recognition, allowance of doubtful accounts, long-term receivable, CVR derivative liability, warrant liability, allowance for credit losses, reserves for excess or obsolete inventory, operating lease right-of-use assets and liabilities, recognition of research and development expenses to the appropriate financial reporting period based on the progress of the research and development projects, income taxes, stock-based compensation and useful lives of property and equipment and intangibles with definite lives. The Company bases its estimates on various assumptions that the Company believes to be reasonable under the circumstances. Actual results could differ from those estimates.

Noncontrolling Interest

The Company reports noncontrolling interest ("NCI") in a subsidiary as a separate component of equity in the consolidated balance sheets. Additionally, the Company reports the portion of net income (loss) and comprehensive income (loss) attributed to the Company and NCI separately in the consolidated statements of operations and comprehensive income (loss).

Segments

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker ("CODM") in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM, as a group, includes Gyre's Chief of Executive Officer ("CEO"), BC's General Manager, and the Chairman of Gyre's Board of Directors ("Gyre's Board"). The Company has determined that it operates in two distinct operating segments and has two reportable segments.

Risks and Uncertainties

The Company is subject to a number of risks associated with companies at a similar stage, including dependence on key individuals, competition from larger and established companies, uncertainty of clinical results, ability to obtain adequate financing to support growth, the ability to attract and retain additional qualified personnel to manage the anticipated growth of the Company, and general economic conditions.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash, accounts and note receivable, and long-term certificates of deposits.

As of December 31, 2023 and 2022, the Company had cash of $33.5 million and $25.2 million, respectively, and long-term certificates of deposit of $23.4 million and $7.4 million, respectively.

The Company is exposed to United States credit risk in the event of default by the United States institutions holding cash to the extent beyond the amount insured by the United States federal depository insurance corporation.

In May 2015, a new Deposit Insurance System ("DIS") managed by the People's Bank of China was implemented by the Chinese government. Deposits in the licensed banks in mainland China are protected by DIS, up to a limit of Chinese Renminbi ("RMB") 500,000. The Company maintains cash and deposits in excess of the amount protected by DIS and in the event of bankruptcy of one of these financial institutions, the Company may be unable to claim its deposits back in full. Management believes that these financial institutions are of high credit quality and continually monitors the creditworthiness of these financial institutions.

Accounts receivable are typically unsecured and are derived from product sales. The Company manages credit risk related to the accounts receivable through ongoing monitoring of outstanding balances and limiting the amount of credit extended based upon payment history and creditworthiness. Historically, the Company has collected receivables from customers within the credit terms with no significant credit losses incurred.

Concentration of Customer Risk

For the years ended December 31, 2023 and 2022, one customer, Sinopharm Group Co., Ltd., accounted for approximately 50.5% and 45.1%, of accounts receivable, respectively. For the year ended December 31, 2023, three customers known as Sinopharm Group Co., Ltd., China Resources Pharmaceutical Group Ltd, and Shanghai Pharmaceuticals Holding Co., Ltd accounted for approximately 50.1%, 13.7%, and 11.2% of total revenue respectively. For the year ended December 31, 2022, three customers known as Sinopharm Group Co., Ltd., Shanghai Pharmaceuticals Holding Co., Ltd, and China Resources Pharmaceutical Group Ltd accounted for approximately 47.7%, 11.6%, and 10.8% of total revenue respectively. All customers are located in the PRC.

Cash and Cash Equivalents

The Company invests portion of its excess cash in bank deposits, consisting primarily of money market mutual funds. The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be cash equivalents.

Fair Value Measurements

The Company applies fair value accounting for all financial assets and liabilities and non-financial assets and liabilities that are recognized or disclosed at fair value in the consolidated financial statements on a recurring basis.

Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

The fair value hierarchy requires that an entity maximize the use of observable inputs when estimating fair value. The fair value hierarchy includes the following three-level classification which is based on the market observability of the inputs used for estimating the fair value of the assets or liabilities being measured:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than quoted prices in active markets for identical assets and liabilities, quoted prices for identical or similar assets or liabilities in inactive markets, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Inputs that are generally unobservable and typically reflect management's estimate of assumptions that market participants would use in pricing the asset or liability.

For assets and liabilities that are recognized in the financial statements at fair value on a recurring basis, the Company determines whether transfers have occurred between levels in the hierarchy by reassessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

Derivative Financial Instruments

The Company evaluates its contracts to determine if those contracts qualify as derivatives under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815, *Derivatives and Hedging*. For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date. Any changes in fair value are recorded as non-operating, non-cash other income or expense for each reporting period. Derivative instrument liabilities are classified in the balance sheet as current or non-current based on whether or not net-cash settlement of the derivative instrument is probable within the next 12 months from the balance sheet date.

The Company determined that certain contingent payments under the CVR Agreement qualified as derivatives under ASC 815, and as such, were recorded as a liability. Refer to Note 3 — *Fair Value Measurements and Financial Instruments* and Note 13 — *Commitments and Contingencies* for additional information regarding the CVR derivative liability.

Preferred Stock Warrants

Warrants to purchase shares of the Convertible Preferred Stock ("Preferred Stock Warrants") are freestanding financial instruments classified as warrant liability on the Company's consolidated balance sheets since the underlying securities are contingently redeemable upon the occurrence of events which are outside of the Company's control. The Preferred Stock Warrants are recorded at fair value upon issuance and are subject to remeasurement at the end of each reporting period. Any change in the fair value of the Preferred Stock Warrants is recorded as changes in fair value of warrant liability in other income (expense), net on the consolidated statement of operations and comprehensive income (loss). The Company adjusts the liability for changes in fair value of the Preferred Stock Warrants until the warrants are exercised or expired.

Convertible Preferred Stock

The Company records shares of non-voting Convertible Preferred Stock at its relative fair value on the date of issuance. The Company applied the guidance in ASC 480-10-S99-3A, *SEC Staff Announcement: Classification and Measurement of Redeemable Securities*, to account for the Convertible Preferred Stock. The Convertible Preferred Stock could become redeemable upon the occurrence of an event that is not solely within the control of the issuer and therefore, is classified within mezzanine equity in the accompanying consolidated balance sheets.

Long-term Certificates of Deposit

The long-term certificates of deposit will mature between February 2025 and July 2026. Certificates of deposit are accounted for at amortized cost with no adjustments for changes in fair value. Premiums and discounts, if any, are amortized or accreted over the lives of the related fixed maturities as an adjustment to the yield using the effective interest method. The Company recorded no allowance for credit losses associated with the certificates of deposit as of December 31, 2023 and 2022.

Long-Term Receivable

Catalyst sold its legacy rare bleeding disorder program to GC Biopharma Corp. ("GCBP") in February 2023. The Company determined that the hold-back from the GCBP asset sale qualified as a long-term receivable. The receivable is considered a loan held for investment since the Company has the intent and ability to hold to maturity. The Company has elected to account for the receivable under the fair value option method of accounting and any changes in fair value are recorded in interest and other income, net on the consolidated statement of operations and comprehensive income (loss). Refer to Note 3 — *Fair Value Measurements and Financial Instruments* for additional information regarding the long-term receivable.

Accounts and Note Receivables, Net

The Company recognizes a receivable when it has an unconditional right to payment, which represents the amount the Company expects to collect in a transaction. The Company's trading terms with its customers are mainly on credit, and the credit period is usually within three months. Accounts and note receivables are recorded at net realizable value. The allowance for credit losses is determined by management's best estimate of expected credit losses of the receivables based on historical data, current information, and future economic forecasts. Receivables are grouped into asset pools based on delinquency status and customer type, with fixed reserve percentages set for each pool. The reserve percentages are determined by considering factors such as historical experience with customers, regulatory and legal environments, and other relevant current and future macroeconomic factors.

Accounts and note receivables, net, consisted of the following at the dates indicated (in thousands):

	December 31,	
	2023	2022
Accounts receivable	$ 15,204	$ 15,738
Note receivable	389	1,522
Allowance for credit losses	(41)	(124)
Accounts and note receivables, net	$ 15,552	$ 17,136

Changes in the allowance for credit losses as of December 31, 2023 and 2022 consisted of the following (in thousands):

	2023	2022
Balance, beginning of year	$ (124)	$ (70)
Provision for allowance for credit losses	—	(88)
Recoveries collected and write-off	82	26
Foreign currency translation adjustments	1	8
Balance, end of year	$ (41)	$ (124)

Inventories, Net

Inventories, consisting of raw materials, work in progress, and finished goods, are valued at the lower of cost or net realizable value with cost being determined on the first-in, first-out method. The Company will record a write-down to its net realizable value in cost of sales in the periods that the decline in value is first identified. The average cost of work in progress and finished goods consists primarily of material, labor and manufacturing overhead expenses (including fixed production-overhead costs) and includes the services and products of third-party suppliers. Net realizable value is based on estimated selling prices less any estimated costs to be incurred to completion and disposal. The Company also regularly monitors inventory quantities on hand and in transit, and reserves for excess and obsolete inventories using estimates based on historical experience, historical and projected sales trends, specific categories of inventory, and expiration and age of on-hand inventory. Inventories presented in the consolidated balance sheets are net of reserves for excess and obsolete inventory. If actual conditions or product demands are less favorable than assumptions, additional inventory reserves may be required.

Property and Equipment, Net

Property and equipment, except for construction-in-progress, are stated at cost less accumulated depreciation and any impairment losses. The cost of an item of property and equipment comprises its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use.

Expenditure incurred after items of property and equipment that have been put into operation, such as repairs and maintenance, is normally charged to profit or loss in the period in which it is incurred. In situations where the recognition criteria are satisfied, the expenditure for a major inspection is capitalized in the carrying amount of the asset as a replacement. Where significant parts of property and equipment are required to be replaced at intervals, the Company recognizes such parts as individual assets with specific useful lives and depreciates them accordingly.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

Buildings	20 to 30 years
Leasehold improvement	Shorter of the estimated useful life or the term of the lease
Machinery and electronic devices	3 to 10 years
Furniture and fixtures	3 to 5 years
Motor vehicles	3 to 5 years

Where parts of an item of property and equipment have different useful lives, the cost of that item is allocated on a reasonable basis among the parts and each part is depreciated separately.

An item of property and equipment including any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. The difference between the net sales proceeds and the carrying amount of the asset is recorded as gain or loss in profit or loss in the reporting period the relevant asset is derecognized.

Construction in progress represents a building under construction or machinery not yet put into operation, which is stated at cost less any impairment losses, if applicable, and is not depreciated. Cost comprises the direct costs of construction and machinery, and capitalized borrowing costs on related funds borrowed during the period of construction. Construction in progress is reclassified to the appropriate category of property and equipment when completed and ready for use.

Property and equipment is reviewed for impairment when events or circumstances exist which suggest that the carrying amount of the asset group may not be recoverable.

Intangible Assets, Net

Intangible assets acquired separately are measured upon initial recognition at cost. The useful lives of intangible assets are assessed to be either finite or indefinite. Intangible assets with finite lives, consisting primarily of patents,

technological know-how and computer software, are subsequently amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired.

Patents and Technological Know-How

Patents and technological know-how that have finite useful lives are stated at cost less any impairment losses and are amortized on a basis that best reflects how their economic benefits are utilized or on the straight-line basis, if not materially different from actual utilization, over their estimated useful life of 10 to 20 years.

Computer Software

Purchased computer software is stated at cost less any impairment losses and is amortized on the straight-line basis over its estimated useful life of two to three years.

Leases

The Company assesses at contract inception whether a contract is, or contains, a lease based on the unique facts and circumstances present. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. Operating lease right-of-use ("ROU") assets represent the Company's right to use an underlying asset during the lease term, and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating leases are included in ROU assets, current operating lease liabilities, and long-term operating lease liabilities on the accompanying consolidated balance sheets. Operating lease liabilities are recognized based on the present value of the future minimum lease payments over the expected lease term at commencement date or the lease modification date, if applicable. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the ROU assets may be required for items such as initial direct costs paid or incentives received.

The Company determines the expected lease term as the noncancelable period of the lease and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the consolidated balance sheets. The Company recognizes lease expense for these short-term leases on a straight-line basis over the lease term. The Company's leases do not contain any residual value guarantees.

The Company has elected to combine lease and non-lease components as a single component. The lease expense for minimum lease payments is recognized over the expected term on a straight-line basis. Variable lease payments, which are primarily comprised of property maintenance, taxes, and other payments based on usage, are recognized when the expense is incurred.

Land Use Rights, Net

All land in mainland China is subject to government or collective ownership, and land use rights can be purchased for a specified period of time. The purchase price of land use rights represents the operating lease prepayments under ASC Topic 842, *Leases* and is recorded as land use rights, net asset on the consolidated balance sheets, which is amortized over the remaining lease term.

Impairment of Long-Lived Assets

Long-lived assets, including property and equipment, finite-lived intangible assets, ROU assets and land use rights, are reviewed for possible impairment whenever events or circumstances indicate that the carrying amount of such assets may not be recoverable. The evaluation is performed at the asset group level, i.e., the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities. Recoverability of these assets is measured by a comparison of the carrying amounts of an asset group to the future undiscounted cash flows the assets are expected to generate from the use and eventual disposition. If such a review indicates the carrying amount of the asset group is not recoverable, an impairment loss shall be measured as the amount by which the carrying

amount of an asset group exceeds its fair value. Any impairment loss is allocated to the long-lived assets of the group on a pro rata basis using the relative carrying amounts of those assets, except that the carrying amount of an individual asset shall not be reduced below its fair value. Calculating the fair value of the assets involves significant estimates and assumptions. These estimates and assumptions include, among others, projected future cash flows, risk-adjusted discount rates, future economic and market conditions, and the determination of appropriate market comparables. Changes in these factors and assumptions used can materially affect the amount of impairment loss recognized in the period the asset was considered impaired. The Company did not record any impairment of long-lived assets as of December 31, 2023 and 2022.

Income Tax Expense

Income taxes are recorded using the liability method, under which deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Valuation allowances are recorded against deferred tax assets, including net operating losses and tax credits, when it is determined it is more-likely-than-not that some or all of the tax benefits will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC Topic 740, *Income Taxes*. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

Interest and penalties related to unrecognized tax benefits, if any, are recorded as a component of income tax expense.

Revenue Recognition

The Company records revenue in accordance with ASC Topic 606 (“ASC 606”), Revenue from Contracts with Customers, whereby revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration expected to be received in exchange for those goods or services. A five-step model is used to achieve the core principle: (1) identify the customer contract, (2) identify the contract’s performance obligations, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations and (5) recognize revenue when or as a performance obligation is satisfied. The Company applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer.

(a) Sale of Pharmaceutical Products

The Company mainly sells its pharmaceutical products to distributors in the PRC, who ultimately sell the products to hospitals, other medical institutions and pharmacies. Revenue from the sale of pharmaceutical products is recognized at the point in time when control of the product is transferred to the customer, generally upon completion of quality inspection by the distributor after delivery of the pharmaceutical products.

The Company records revenue for product sales, net of estimated product returns. Customers have limited return rights related only to the product damage or defect identified upon delivery of the product. The Company estimates the amount of product sales that may be returned and records the estimate as a reduction of revenue and a refund liability in the period the related product revenue is recognized. To date, actual returns have not differed materially from the Company’s estimates.

Rebates are offered to distributors, consistent with pharmaceutical industry practices. The estimated amounts of unpaid or unbilled rebates are recorded as a reduction of revenue, if any. Estimated rebates are determined based on contracted rates and sales volumes and, to a lesser extent, distributor inventories. The Company regularly reviews the information related to these estimates and adjusts the amounts accordingly. The Company uses the expected value method to estimate the amount of consideration to which it will be entitled.

The requirements on constraining estimates of variable consideration, i.e., when it is probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with the variable consideration is subsequently resolved, are applied and the expected future rebates are deducted from the trade receivables from the customers.

The Company has applied the practical expedients under ASC 606 with regard to assessment of financing component and concluded that there is no significant financing component given that the period between delivery of goods and payment is generally one year or less.

(b) License of Intellectual Property

Revenue from a license agreement is recognized at a point in time when the control of the right to use the license is transferred to the customer. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

Development or regulatory milestone payments, which are included in the transaction price to the extent that it is probable that a significant reversal of accumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of any milestones, and if necessary, adjusts its estimated transaction price on a cumulative catch-up basis.

The Company did not recognize any contract assets as of December 31, 2023 and 2022.

Deferred Revenue

Deferred revenue is recognized when a payment is received from a customer before the Company transfers the related goods or services. Deferred revenue is recognized as revenue when the Company performs under the contract (i.e., transfers control of the related goods or services to the customer). As of December 31, 2023, the Company's deferred revenue balance was $39,000. Deferred revenue was $145,000 as of December 31, 2022 which has been recognized as revenue during the year ended December 31, 2023.

Cost of Revenue

Cost of revenue mainly consists of cost of sales representing direct and indirect costs incurred to bring the product to saleable condition. Cost of sales primarily consists of (i) raw material costs; (ii) staff costs for production employees; (iii) depreciation and amortization related to property and equipment and intangible assets used in production; (iv) taxes and surcharges; (v) transportation costs; and (vi) miscellaneous other costs.

Stock-Based Compensation

The Company measures the cost of employee, non-employee and director services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant. For equity awards that only contain service conditions, the Company recognizes the related expense over the period during which the employee, non-employee or director is required to provide service in exchange for the award on a straight-line basis. The estimated fair value of equity awards that contain performance conditions is expensed over the term of the award once the Company has determined that it is probable that performance conditions will be satisfied. The cost is recognized with a corresponding increase in equity.

Determining the fair value of stock-based awards at the grant date requires judgment. The Company uses the Black-Scholes option-pricing model to determine the fair value of stock options. The determination of the grant date fair value of options using an option-pricing model is affected by the Company's assumptions regarding a number of variables including the fair value of its common stock, its expected common stock price volatility over the expected

life of the options, expected term of the stock option, risk-free interest rates and expected dividends. The Company elected to account for forfeitures when they occur.

For awards that do not ultimately vest because non-market performance or service conditions have not been met, no expense is recognized. Where awards include a market or non-vesting condition, the transactions are treated as vesting irrespective of whether the market or non-vesting condition is satisfied, provided that all other performance and service conditions are satisfied.

Where the terms of an equity award are modified, a minimum expense is recognized as if the terms had not been modified if the original terms of the award are met. In addition, an expense is recognized for any modification that increases the total fair value of the stock-based payments or is otherwise beneficial to the employee as measured at the date of modification.

Where an equity-settled award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. This includes any award where non-vesting conditions within the control of either the Company or the employee are not met. However, if a new award is substituted for the cancelled award and is designated as a replacement award on the date that it is granted, the cancelled and new awards are treated as if they were a modification of the original award, as described in the previous paragraph.

Acquired IPR&D

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquired IPR&D with no alternative future use is charged to expense at the acquisition date. Refer to Note 7 — *GNI USA Contributions under the Business Combination Agreement* for a more detailed description.

Research and Development Expenses

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services used in research and development are initially deferred and capitalized in prepaid and other current assets. The capitalized amounts are then expensed as the related goods are delivered or services are performed, or until it is no longer expected that the goods or services will be delivered. Research and development costs consist of payroll and other personnel-related expenses, laboratory supplies and reagents, contract research and development services, materials, and consulting costs, as well as allocations of facilities and other overhead costs.

Selling and Marketing Expenses

Selling and marketing expenses primarily relate to sales of ETUARY and consist of conference expenses incurred from hosting academic conferences, seminars and symposia; promotional expenses associated with market education on ETUARY for its use in hospitals; and staff costs primarily consisting of salaries and benefits for in-house marketing and promotion staff.

General and Administrative Expenses

General and administrative expenses consist of (i) accounting, IT, legal, administrative, and other internal service staff costs; (ii) stock-based compensation representing share options granted to its functional employees; (iii) professional service fees, primarily for legal and accounting services; and (iv) other miscellaneous expenses.

Government Grants

Government grants are recognized at their fair value where there is reasonable assurance that the grant will be received, and all attaching conditions will be complied with. When the grant relates to an expense item, it is recognized as income on a systematic basis over the periods that the costs, for which it is intended to compensate, are expensed. Where the grant relates to an asset, the fair value is credited to a deferred income account and is released to profit or loss over the expected useful life of the relevant asset by equal annual installments or deducted from the carrying

amount of the asset and released to profit or loss by way of a reduced depreciation charge. Grant income is included within other income in the consolidated statements of operations and comprehensive (loss) income.

Interest Income

Interest income is recognized on an accrual basis using the effective interest method by applying the rate that exactly discounts the estimated future cash receipts over the expected life of the financial instrument or a shorter period, when appropriate, to the net carrying amount of the financial asset.

Comprehensive Income (Loss)

The Company is required to report all components of comprehensive income (loss), including net income (loss), in the accompanying consolidated financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including net income, unrealized gains and losses on investments and foreign currency translation adjustments.

Net Income (Loss) Per Share ("EPS") Attributable to Common Stockholders

The Company calculates basic and diluted EPS attributable to common stockholders in accordance with ASC Topic 260, *Earnings per Share* ("ASC 260"), which requires EPS for each class of stock (common stock and participating securities) to be calculated using the two-class method. The two-class method determines EPS for each class of common stock and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings attributable to stockholders. The two-class method requires earnings available to common stockholders for the period to be allocated between common stock and participating securities based upon their respective rights to receive dividends as if all earnings for the period had been distributed. The Company's Convertible Preferred Stock is classified as a participating security in accordance with ASC 260. The Convertible Preferred Stock contractually entitled the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in the Company's losses. As such, net losses attributable to stockholders for the periods presented were not allocated to these securities.

Basic EPS is calculated by dividing net income or loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted EPS is computed by giving effect to all potentially dilutive securities outstanding for each period presented. For periods in which the Company reports net loss attributable to common stockholders, diluted EPS attributable to common stockholders is the same as basic EPS attributable to common stockholders since the effects of potentially dilutive securities are antidilutive. See Note 16 — *EPS* for more information.

Foreign Currency Translation and Remeasurement

The functional currency of the Company is the US Dollar. The local currency of foreign operations, except for those in highly inflationary economies, generally are considered to be their functional currency. The functional currency of BC is RMB. The determination of the respective functional currency is based on the criteria stated in ASC Topic 830, *Foreign Currency Matters*. The Company uses the U.S. Dollar as its reporting currency.

Assets and liabilities are translated at foreign exchange rates on the balance sheet date. Equity amounts are translated at historical exchange rates. Revenue and expenses are translated at the average foreign exchange rates. The effects of these translation adjustments are reported within accumulated other comprehensive income in the consolidated balance sheets and consolidated statements of convertible preferred stock and equity, with the translation gain (loss) shown as a separate component of other comprehensive income (loss) in the accompanying consolidated statements of operations and comprehensive (loss) income. During the year ended December 31, 2023, the Company had translation loss of $1.5 million. During the year ended December 31, 2022, the Company had translation loss of $4.9 million.

Foreign currency gains and losses arising from transactions denominated in a currency other than the functional currency of the entity involved are included within other income (expense), net in the consolidated statements of

operations and comprehensive (loss) income. The foreign currency transaction gains or losses for the years ended December 31, 2023 and 2022 were immaterial.

Foreign Currency Risk

The RMB is not a freely convertible currency. The State Administration for Foreign Exchange, under the authority of the People's Bank of China, controls the conversion of RMB into other currencies. The value of the RMB is subject to changes in central government policies and to international economic and political developments affecting supply and demand in the China Foreign Exchange Trading System market. 99.5% of the Company's cash and long-term certificates of deposit as of December 31, 2023 of $26.5 million and $23.4 million, respectively, were denominated in RMB.

Accounting Pronouncements Recently Adopted

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*: Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. The amendments in ASU 2021-04 provide guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The amendments in this ASU 2021-04 are effective for all entities for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. The Company adopted ASU 2021-04 and related updates on January 1, 2022, and the adoption did not have a material impact on its consolidated financial statements.

In August 2020, FASB issued ASU 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40)* to simplify accounting for certain financial instruments. ASU 2020-06 eliminates the previous models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The amendments in this ASU are effective for public business entities for fiscal years beginning after December 15, 2021. The Company adopted ASU 2020-06 on January 1, 2022, and the adoption did not have a material impact on its consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, *Business Combinations – Accounting for Contract Assets and Contact Liabilities from Contracts with Customers*. The guidance is intended to improve the accounting for acquired revenue contracts with customers in a business combination by addressing diversity in practice. The guidance requires an acquirer to recognize and measure contract assets and liabilities acquired in a business combination in accordance with ASC 606 as if they had originated the contracts, as opposed to at fair value on the acquisition date. The Company adopted ASU 2021-08 and related updates on January 1, 2023. The adoption of ASU 2021-08 had no impact on the consolidated financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832) — Disclosures by Business Entities about Government Assistance*. The amendments in this ASU require disclosures about transactions with a government that have been accounted for by analogizing to a grant or contribution accounting model to increase transparency about (1) the types of transactions, (2) the accounting for the transactions, and (3) the effect of the transactions on an entity's financial statements. The amendments in this ASU are effective for all entities within their scope for financial statements issued for annual periods beginning after December 15, 2021. The Company adopted this standard as of January 1, 2022. The adoption of this ASU did not have any material impact on the Company's consolidated financial statements.

New Accounting Pronouncements – Issued But Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, *Improvements to Reportable Segment Disclosures (Topic 280)*. This ASU updates reportable segment disclosure requirements by requiring disclosures of significant reportable segment expenses that are regularly provided to the CODM and included within each reported measure of a segment's profit or loss. This ASU also requires disclosure of the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment

performance and deciding how to allocate resources. The ASU is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Adoption of the ASU should be applied retrospectively to all prior periods presented in the financial statements. Early adoption is permitted. The Company plans to adopt annual requirements and related updates under ASU 2023-07 on January 1, 2024 and interim requirements under ASU 2023-07 on January 1, 2025. The Company is currently assessing the impact of adoption of this standard on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures (Topic 740)*. The ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is permitted. This ASU will result in the required additional disclosures being included in the Company's consolidated financial statements, once adopted. The Company plans to adopt ASU 2023-09 and related updates as of January 1, 2025. The Company will assess the impact of adoption of this standard on its consolidated financial statements.

3. Fair Value Measurements and Financial Instruments

For a description of the fair value hierarchy and fair value methodology, see Note 2 — *Summary of Significant Accounting Policies*. As of December 31, 2023, the Company's highly liquid money market funds are included within cash equivalents.

The following tables present the fair value hierarchy for financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2023 (in thousands*)*:

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets				
Money market funds[(1)]	$ 5,860	$ —	$ —	$ 5,860
Long-term receivable from GCBP	—	—	4,722	4,722
Total financial assets	$ 5,860	$ —	$ 4,722	$ 10,582
Financial liabilities				
CVR derivative liability	$ —	$ —	$ 4,722	$ 4,722
Warrant liability, noncurrent	—	—	12,835	12,835
Total financial liabilities	$ —	$ —	$ 17,557	$ 17,557

(1) Included in cash and cash equivalents on accompanying consolidated balance sheet.

The carrying amounts of cash, accounts and note receivables, net, other receivables, accounts payable, due to related parties, CVR excess closing cash payable, and accrued liabilities approximate their fair values due to their short maturities.

During the year ended December 31, 2023, there were no transfers of fair value measurement between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and liabilities.

There were no financial assets and liabilities measured at fair value as of December 31, 2022.

Long-term Receivables and CVR Derivative Liability

The long-term receivable and the corresponding CVR derivative liability, noncurrent relate to the asset purchase agreement with GCBP. The fair value of this long-term receivable and derivative liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The estimated fair value of the long-term receivable and CVR derivative liability, noncurrent was determined based on the anticipated amount and timing of projected cash flows to be received from GCBP pursuant to the GCBP asset purchase agreement discounted to their present values using an estimated discount rate of 5.05%. As of December 31, 2023, the Company expects to receive a $5.0 million hold-back payment from GCBP in the first quarter of 2025, which will be distributed, net of expenses, to the CVR Holders. The change in fair value of the long-term receivable from GCBP and the

corresponding CVR derivative liability, noncurrent was recorded in interest and other income, net on the consolidated statement of operations and comprehensive income (loss).

Warrant Liability

In October 2023, Catalyst entered into a Securities Purchase Agreement for a private placement with GNI USA (the "Private Placement"). The Private Placement closed immediately following the closing of the Contributions on October 30, 2023. Upon closing of the Private Placement, the Company issued 811 shares of Convertible Preferred Stock and 811 Preferred Stock Warrants to purchase shares of Convertible Preferred Stock to GNI for an aggregate purchase price of approximately $5.0 million. The Preferred Stock Warrants are immediately exercisable at an exercise price of $4,915.00 per share of Convertible Preferred Stock and expire on October 30, 2033. The number of shares of Common Stock issuable upon exercise and conversion of the Preferred Stock Warrants is 540,666. The Company accounted for the Private Placement as a non-arm's length transaction. The Preferred Stock Warrants were initially recognized at fair value upon issuance and the remaining proceeds from the Private Placement were allocated to the Convertible Preferred Stock.

The Preferred Stock Warrants are freestanding financial instruments classified as a warrant liability on the Company's consolidated balance sheet. The Preferred Stock Warrants are revalued each reporting period with the change in fair value recorded as change in fair value of warrant liability in other income (expense), net on the consolidated statement of operations and comprehensive income (loss).

The fair value of the warrant liability is estimated based on the Black-Scholes option pricing model using the following weighted-average assumptions:

Share price	$ 25.7
Exercise price	$ 4,915.00
Dividend yield	—
Risk-free interest	3.88%
Term (years)	9.83
Expected volatility	84.00%

The following table sets forth the changes in the estimated fair value of the Company's Level 3 financial assets and liabilities (in thousands):

	Long-term receivable from GCBP	CVR derivative liability	Warrant liability
Balance at December 31, 2022	$ —	$ —	$ —
Additions in the period	4,683	4,683	3,574
Changes in fair value	39	39	9,261
Balance at December 31, 2023	$ 4,722	$ 4,722	$ 12,835

Financial Instruments

Cash equivalents consisted of the following (in thousands):

December 31, 2023	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 5,860	$ —	$ —	$ 5,860
Total financial assets	$ 5,860	$ —	$ —	$ 5,860
Classified as:				
Cash and cash equivalents				$ 5,860
Total financial assets				$ 5,860

4. Balance Sheet Components

Inventories, net

Inventories, net of reserves of $46,000 and $9,000 as of December 31, 2023 and 2022, respectively, consisted of the following components (in thousands):

	December 31,	
	2023	2022
Raw materials	$ 919	$ 1,056
Work in progress	1,997	3,667
Finished goods	1,365	1,399
Inventories, net	$ 4,281	$ 6,122

The provision for inventory and write-downs for the years ended December 31, 2023 and 2022 were immaterial.

Accrued expenses and other current liabilities

Accrued expenses and other liabilities consist of the following (in thousands):

	December 31,	
	2023	2022
Accrued payroll and welfare	$ 5,790	$ 5,038
Supplier reimbursement	2,247	2,474
Accrued expenses - general and administrative	1,190	—
Accrued sales discount	903	748
Accrued professional services	837	—
Employee reimbursement	648	646
Accrued expenses - research and development	161	158
Accrued expenses - selling expenses	44	13
Deferred government grants	40	22
Other accrued liabilities	75	165
Accrued expenses and other current liabilities	$ 11,935	$ 9,264

Deferred government grants

Deferred government grants represent funds provided by the government for research and development, construction of new facilities, or improvement of existing production facilities. The amount of deferred government grants as of December 31, 2023 and 2022, is net of the amount recognized as government grant income. During the years ended December 31, 2023 and 2022, the Company received $1.1 million and $0.8 million government grants, respectively. During the years ended December 31, 2023 and 2022, the Company recognized $1.0 million and $0.9 million of government grant income within other income in the consolidated statements of operations and comprehensive (loss) income, respectively.

Summarized below are deferred government grants as of December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Government grants for property and equipment, included in accrued expenses and other current liabilities	$ 40	$ 22
Current deferred government grants	40	22
Government grants for property and equipment	213	118
Non-current deferred government grants	213	118
Total deferred government grants	$ 253	$ 140

Property and equipment, net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2023	2022
Buildings	$ 12,289	$ 10,837
Construction in progress	7,875	4,851
Machinery and electronic devices	6,598	4,880
Furniture and fixtures	606	631
Leasehold improvement	—	334
Motor vehicles	185	174
Property and equipment, gross	27,553	21,707
Less: Accumulated depreciation	(4,265)	(3,998)
Property and equipment, net	$ 23,288	$ 17,709

Depreciation expense was $1.0 million and $0.9 million for each of the years ended December 31, 2023 and 2022, respectively.

5. Intangible Assets

The gross carrying amounts and accumulated amortization of the Company's intangible assets with determinable lives as of December 31, 2023 and 2022 were as follows (in thousands):

	December 31, 2023		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	$ 430	$ (290)	$ 140
Computer software	171	(106)	65
Total intangible assets	$ 601	$ (396)	$ 205

	December 31, 2022		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Patents	$ 1,496	$ (1,372)	$ 124
Technological know-how	438	(277)	161
Computer software	104	(92)	12
Total intangible assets	$ 2,038	$ (1,741)	$ 297

Intangible assets are carried at cost less accumulated amortization and impairment, if applicable, and the amortization expense is recorded in operating expenses. The weighted average amortization period for the intangible assets as of December 31, 2023 is 5.05 years.

Amortization expense was $0.1 million and $0.2 million for each of the years ended December 31, 2023, and 2022, respectively. Based on finite-lived intangible assets recorded as of December 31, 2023, the estimated future amortization expense is as follows (in thousands):

	Estimated Amortization Expense
2024	$ 34
2025	34
2026	34
2027	33
2028	18
Thereafter	52
Total	$ 205

6. Revenue

The Company's product revenues were mainly generated from the sale of ETUARY. Sales of ETUARY accounted for 98.9% and 96.9% of total revenue for the years ended on December 31, 2023 and 2022, respectively.

Sales of Pharmaceutical Products

The Company generates revenue mostly through sales of ETUARY and certain generic drugs. The distributors were the Company's direct customers, and sales to distributors accounted for 100% of revenue from ETUARY. The distributors sell ETUARY to outlets, including hospitals and other medical institutions, as well as pharmacies.

Product returns to date have not been significant and the Company has not considered it necessary to record a reserve for product returns. The Company's product revenues were recognized at a point in time when the underlying product was delivered to the customer, which was when the customer obtained control of the product. Revenue from sales of pharmaceutical products was $113.5 million and $100.9 million for the years ended December 31, 2023 and 2022, respectively. All sales are generated in the PRC.

License of Intellectual Property

Revenue from licensing intellectual property is recognized when the control of the right to use the license is transferred to the customer. Milestone payments, which are included in the transaction price to the extent that it is highly probable that a significant reversal of accumulative revenue recognized will not occur, represent a form of variable consideration, which is recognized as revenue when the uncertainty associated with the variable consideration is subsequently resolved. At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered highly probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered highly probable of being achieved until those approvals are received.

The Company's sales by product categories for the years ended December 31, 2023 and 2022 are as follows (in thousands):

	Year ended December 31,	
	2023	2022
Sales of Pharmaceutical Products	$ 113,450	$ 100,876
License of Intellectual Property	—	1,414
Total	$ 113,450	$ 102,290

7. GNI USA Contributions under the Business Combination Agreement

The GNI USA Contributions under the Business Combination Agreement (see Note 1) was treated as a reverse asset acquisition, with CPI as the accounting acquirer and Catalyst as the legal acquirer. Under U.S. GAAP, a company must evaluate if an integrated set of assets and activities qualifies as a business acquisition or an asset acquisition by

assessing if the gross assets' fair value is primarily concentrated in a single asset or a group of similar assets. If this criterion is met, the acquired operations are not considered a business. Catalyst did not meet the business definition as its fair value was concentrated in one IPR&D asset, it lacked an organized workforce contributing significantly to output creation, and no substantive processes were acquired. As such, the GNI USA Contributions was treated as an asset acquisition. In an asset acquisition, goodwill is not recognized, and the cost allocated to the acquired IPR&D with no alternative future use is expensed.

The following summarizes the purchase price paid in the GNI USA Contributions (in thousands, except per share amounts):

Catalyst Common Stock outstanding		2,532
Multiplied by the fair value per share of Catalyst stock (1)	$	7.67
Fair value of common shares to be owned by Catalyst's stockholders	$	19,420
Fair value of preferred shares to be owned by Catalyst's stockholders (2)	$	63,099
Fair value of Catalyst	$	82,519
Pre-GNI USA Contributions Catalyst stock options assumed by CPI (3)	$	1,829
Fair value of consideration issued	$	84,348
Acquisition costs	$	659
Purchase price	$	85,007

(1) The purchase price was based on the closing price of Catalyst Common Stock on October 30, 2023.

(2) This amount is calculated based on 12,340 shares of Convertible Preferred Stock outstanding as of October 30, 2023. Each share of preferred stock converts into approximately 666.67 shares of common stock. The fair value was calculated using the closing price of Catalyst Common Stock on October 30, 2023 and the number of underlying common shares.

(3) Any option to purchase Catalyst Common Stock that was issued and outstanding at the Effective Time remains issued and outstanding and unaffected by the GNI USA Contributions. In a reverse acquisition, however, from an accounting perspective, the Catalyst employee stock option awards have been exchanged for share-based payment awards of the accounting acquirer. Accordingly, this balance represents the pre-Contributions service portion of the estimated fair value of the employee stock option awards issued to Catalyst option holders. In calculating the estimated fair value of the option awards based on the Black-Scholes model, management used the following weighted-average assumptions:

Expected term (in years)	5.00
Volatility	84.30%
Risk free interest rate	3.65%
Dividend yield	—%

The total purchase price paid in the GNI USA Contributions has been allocated to the net assets acquired and liabilities assumed based on their fair values at the Effective Time. The allocation of the purchase price, as shown above, is as follows (in thousands):

Cash and cash equivalents	$	5,587
Other receivables from GNI		423
Prepaid assets		1,097
Other current assets		41
Long-term receivable from GCBP		4,683
Other assets, noncurrent		168
IPR&D		83,104
Accounts payable		(44)
Advance payment received from GNI		(2,500)
Accrued expenses and other current liabilities		(1,784)
CVR excess closing cash payable		(1,085)
CVR derivative liability, noncurrent		(4,683)
Net assets acquired	$	85,007

The Minority Holder Contributions were treated as an equity transaction, where the Company obtained additional indirect interest and maintained its control in BC.

8. Restructuring

Prior to the Contributions, CPI entered into a CP U.S. Share Purchase Agreement with GNI USA and divested almost all of its assets other than its 56.0% indirect ownership interest in BC. GNI USA is the parent company of Gyre. In connection with the transaction, the Company recorded a receivable in the amount of $0.8 million included in other receivables from GNI on the consolidated balance sheet as of December 31, 2023 and recognized a loss of $2.7 million during the year ended December 31, 2023, included in divestiture losses of the consolidated statements of operations and comprehensive (loss) income.

9. Leases

Operating leases

BC's corporate headquarters, a 968 square meter office space, is situated in Beijing, PRC, with the lease expiring in June 2024. Additionally, a laboratory center spanning approximately 640 square meters was leased in Shanghai, China, which expired in November 2023. In 2022, the Company secured a new lease for an office space of approximately 180 square meters in Zhengzhou, China, with the lease set to expire in August 2024. In November 2023, the Company also secured a new lease for its U.S. headquarters in San Diego, United States, with the lease set to expire in December 2026.

The Company also has multiple short-term leased properties used as offices and employee dormitories. The Company recorded a total of $89,000 and $52,000 short-term rent expenses during the years ended December 31, 2023 and 2022, respectively. The short-term rent expense amounts are recorded in operating expenses in the accompanying consolidated statements of operations and comprehensive (loss) income.

As of December 31, 2023, the Company recorded an aggregate ROU asset of $0.5 million and an aggregate lease liability of $0.4 million in the accompanying consolidated balance sheets.

Rent expense related to operating leases was $0.5 million for each of the years ended December 31, 2023 and 2022, respectively. Variable lease payments for the years ended December 31, 2023 and 2022 were immaterial.

Supplemental cash flow information related to operating leases was as follows (in thousands*)*:

	Year Ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating lease	$ 573	$ 517

The present value assumptions used in calculating the present value of the lease payments were as follows:

	Year Ended December 31,	
	2023	2022
Weighted-average remaining lease term	2.2 years	1.5 years
Weighted-average discount rate	4.78%	4.75%

As of December 31, 2023, undiscounted future minimum payments under the Company's operating leases were as follows (in thousands):

	Amount
2024	$ 226
2025	103
2026	106
Total undiscounted lease payments	435
Less: imputed interest	(26)
Total lease liabilities	409
Less: current portion of lease liabilities	(210)
Lease liabilities, net of current portion	$ 199

The Company is required to maintain security deposits of $0.1 million in connection with various leases, which amounts are included in other assets, noncurrent on the Company's consolidated balance sheets.

Land use rights

As of December 31, 2023, the Company held land use rights for two land parcels in Beijing's Shunyi District, expiring in 2053, and in Cangzhou, Hebei Province, expiring from 2067 to 2071. These parcels, with a combined area of approximately 66,559 square meters, are utilized as manufacturing facilities. As of December 31, 2023, the aggregate recorded land use rights, net assets for these parcels was $1.5 million.

10. Stockholders' Equity

Common Stock

Under the Company's amended and restated certificate of incorporation, the Company has 400,000,000 shares of Common Stock authorized for issuance with a $0.001 par value per share. The number of authorized shares of Common Stock may be increased or decreased by the affirmative vote of the holders of a majority of the Company's stock who are entitled to vote. The holders of Common Stock have voting rights equal to one vote per share of Common Stock held. The holders of Common Stock are entitled to receive dividends when and as declared or paid by the Company's board of directors.

Common stock reserved for future issuance is as follows:

	December 31,	
	2023	2022
Convertible Preferred Stock issued and outstanding	8,767,332	—
Preferred Stock Warrants issued and outstanding	540,666	—
Options issued and outstanding	18,280,548	17,036,941
Total common stock reserved	27,588,546	17,036,941

2021 ATM Program

On October 15, 2021, Catalyst entered into an Equity Distribution Agreement (the "ATM Agreement") with Piper Sandler & Co. ("Piper Sandler") as sales agent, pursuant to which the Company may offer and sell, from time to time,

through Piper Sandler, shares of the Company's Common Stock, par value of $0.001 per share, with aggregate gross sales proceeds of up to $50.0 million through an at-the-market offering program (the "ATM Program"). The Company will pay Piper Sandler a commission of 3% of the gross proceeds of any shares sold. The Company also agreed to reimburse Piper Sandler for certain expenses incurred in connection with its services under the ATM Agreement, including up to $50,000 for legal expenses in connection with the establishment of the ATM Program. The Company does not currently intend to use this or any other ATM Program prior to April 1, 2024.

Sales of shares of common stock under the ATM Program may be made pursuant to the registration statement on Form S-3 (File No. 333-253874), which was declared effective by the SEC on May 3, 2021, and a related prospectus supplement filed with the SEC on October 15, 2021. For the years ended December 31, 2023 and 2022, no shares of common stock were sold under the ATM Program.

Restricted Net Assets

Under PRC laws and regulations, BC is subject to restrictions on foreign exchange and cross-border cash transfers, including to parent companies and U.S. stockholders. The ability to distribute earnings to the parent companies and U.S. stockholders is also limited. Current PRC regulations permit BC to pay dividends to BJC only out of its accumulated profits as determined in accordance with PRC accounting standards and regulations. Amounts restricted include paid-in capital and the statutory reserves of BC. The aggregate amounts of restricted capital and statutory reserves, which represented the amount of net assets of the relevant subsidiaries not available for distribution were $64.3 million and $61.5 million as of December 31, 2023 and 2022, respectively.

As a result of the above restrictions, parent-only financial statements are presented in Schedule I.

Statutory Reserve

BC is required to set aside at least 10% of its after-tax profits as the statutory reserve fund until the cumulative amount of the statutory reserve fund reaches 50% or more of its registered capital, if any, to fund its statutory reserves, which are not available for distribution as cash dividends. At the Company's discretion, the Company may allocate a portion of after-tax profits based on PRC accounting standards to a discretionary reserve fund.

Appropriations to these reserves by BC were $2.2 million for the year ended December 31, 2022. There were no appropriations to these reserves during the year ended December 31, 2023.

11. Convertible Preferred Stock

The Company is authorized to issue 5,000,000 shares of preferred stock with par value $0.001 per share under its restated certificate of incorporation, of which 125,040 shares are designated as Convertible Preferred Stock as of December 31, 2023.

In December 2022, Catalyst issued 12,340 shares of Convertible Preferred Stock to GNI in connection with the F351 Asset Acquisition (see Note 1 — *Organization and Nature of Operations*).

In October 2023, immediately following the closing of the Contributions, the Company issued 811 shares of Convertible Preferred Stock and 811 Preferred Stock Warrants to GNI under the Private Placement. For additional information, see Note 3 — *Fair Value Measurements and Financial Instruments.*

In November 2023, GNI provided notice to the Company to convert its 13,151 shares of Convertible Preferred Stock. The conversion became effective on January 22, 2024.

As of December 31, 2023, the Convertible Preferred Stock is classified outside of stockholders' equity because the shares contain certain redemption features that are not solely within the Company's control. The Company does not adjust the carrying value of the Convertible Preferred Stock to its redemption value since the Convertible Preferred Stock is not currently redeemable, and it is not probable that it will become redeemable in the future at any of the balance sheet dates. Subsequent adjustments to the carrying value will be made only when it becomes probable that such redemption will occur.

Holders of Convertible Preferred Stock are entitled to receive dividends equal to, on an as-if-converted-to-common-stock basis, and in the same form as dividends actually paid on shares of the Company's common stock. Except as otherwise required by law, the Convertible Preferred Stock does not have voting rights. However, as long as any shares of Convertible Preferred Stock are outstanding, the Company may not, without the affirmative vote of the holders of a majority of the then outstanding shares of Convertible Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to Convertible Preferred Stock or alter or amend the Certificate of Designation that authorized the Convertible Preferred Stock, amend or repeal any provision of, or add any provision to, the Certificate of Incorporation or Bylaws of the Company, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Convertible Preferred Stock, (ii) issue further shares of Convertible Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Convertible Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing. Convertible Preferred Stock does not have a preference upon any liquidation, dissolution or winding-up of the Company.

As of December 31, 2023 the Company had 13,151 shares of Convertible Preferred Stock issued and outstanding. Each share of Convertible Preferred Stock is convertible into approximately 666.67 shares of Common Stock. As of December 31, 2023, the number of shares of common stock issuable upon conversion of the outstanding shares of Convertible Preferred Stock is 8,767,332.

12. Stock Based Compensation

BC 2021 Stock Incentive Plan

In February 2021, the board of directors of BC approved the 2021 Plan to grant options to certain employees and consultants of BC.

The 2021 Plan had a contractual term of seven years. Options granted under the 2021 Plan were accounted for as equity awards and subject to a service condition. Upon the Contributions, BC terminated the 2021 Plan and the BC Options under the 2021 Plan were terminated and replaced with options to purchase Gyre Common Stock granted under the 2023 Omnibus Incentive Plan that are substantially similar in all material respects to the BC Options previously outstanding under the 2021 Plan.

In October 2023, prior to the Contributions, the Board of Directors of BC modified the expiration term of the fully vested BC Options to be extended to February 3, 2028. Following this modification, the total incremental stock-based compensation of $2.0 million was immediately recognized.

2018 Omnibus Incentive Plan

In June 2018, stockholders of Catalyst approved a 2018 Omnibus Incentive Plan, as amended in June 2021 (the "2018 Omnibus Incentive Plan"). Each option to purchase shares of Catalyst common stock that was issued and outstanding under the 2018 Omnibus Incentive Plan immediately prior to the Effective Time remains outstanding and unaffected after the Contributions in accordance with its terms.

2023 Omnibus Incentive Plan

The 2023 Omnibus Incentive Plan was approved by Catalyst's stockholders in August 2023 and ratified by Gyre's Board in October 2023. The 2023 Omnibus Incentive Plan became effective on October 30, 2023. The 2023 Omnibus Incentive Plan permits the Company to deliver up to 17,845,496 shares of Common Stock and will automatically increase by the lesser of (i) 5% of the total number of outstanding shares of Common Stock on December 31st of the preceding calendar year and (ii) such smaller number of shares of Common Stock as determined by the Board on the first day of each fiscal year beginning on January 1, 2024.

After the Contributions, the Company modified the expiration term of the fully vested options originally granted as the BC options to be extended to October 30, 2030. As a result of this modification, the total incremental stock-based compensation of $0.8 million was immediately recognized.

On October 30, 2023, upon closing of the Contributions, the Gyre Board approved grants to five individuals, to be made on October 31, 2023, of an aggregate of 820,824 fully vested stock options in consideration for services rendered in connection with the Contributions transactions. Although the awards were granted for the services in connection with the Contributions, which were direct and incremental costs incurred to complete the reverse asset acquisition, they were issued to Gyre's employees and consultants who worked on the Contributions instead of third-parties and therefore, do not qualify as transactions costs of the reverse asset acquisition.

The following table summarizes stock option activity considering the conversion of BC Options to Gyre options to purchase shares of Gyre Common Stock upon completion of the GNI USA Contributions:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at December 31, 2022	17,036,941	$ 0.75	5.1	$ 12,667
Forfeited	(18,936)	$ 0.75		
Deemed issuance of options to former stockholders of Catalyst upon the GNI USA Contributions	435,916	$ 20.10		
Granted	838,686	$ 6.93		
Exercised	(12,059)	$ 13.86		
Outstanding at December 31, 2023	18,280,548	$ 1.49	6.9	$ 444,197
Exercisable at December 31, 2023	18,262,686	$ 1.48	6.9	$ 19,433

The weighted-average grant date fair value of options granted during the year ended December 31, 2023 was $5.45 per share. No options were granted during the year ended December 31, 2022.

The aggregate intrinsic value of options exercised during the year ended December 31, 2023 was $0.1 million. No options were exercised during the year ended December 31, 2022.

Valuation Assumptions

The Company estimated the fair value of stock options granted using the Black-Scholes option-pricing formula and a single option award approach. Due to its limited relevant historical data, the Company estimated its volatility considering a number of factors, including the use of the volatility of comparable public companies. The expected term of options granted under the 2023 Omnibus Incentive Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to the Company's limited relevant history. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. This fair value is being amortized ratably over the requisite service periods of the awards, which is generally the vesting period.

The fair value of employee stock options granted was estimated using the following weighted-average assumptions:

	Year Ended December 31, 2023
Expected volatility (%)	84.30-84.30
Risk-free interest rate (%)	3.82-4.77
Expected option life (in years)	5.0-5.8
Expected dividend yield (%)	—
Weighted average share price of the Company (USD per share)	$ 6.93

Total stock-based compensation recognized was as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Cost of revenues	$ 52	$ 249
Selling and marketing	344	1,643
Research and development	481	2,301
General and administrative	6,404	9,173
Total	$ 7,281	$ 13,366

As of December 31, 2023, the Company had an unrecognized stock-based compensation expense of $0.1 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 1.87 years.

13. Commitments and Contingencies

Contingent Value Rights Agreement

Each CVR under the CVR Agreement (see Note 1 — *Organization and Nature of Operations*) entitles the holder to receive (i) certain cash payments from the net proceeds related to the disposition of Catalyst's legacy assets, (ii) 100% of the excess cash (net of all current or contingent liabilities, including transaction-related expenses) retained by the Company in excess of $1.0 million as of the closing date of the transactions under the Business Combination Agreement, (iii) 100% of the amount actually received by the Company, net of expenses, pursuant to an asset purchase agreement Catalyst entered into with Vertex Pharmaceuticals Inc. ("Vertex") in May 2022 and (iv) 100% of the excess amount, by which the preapproved costs to manage, negotiate, settle and finalize certain third party claims exceed the costs actually incurred with respect to such claims. The CVRs are not transferable, except in certain limited circumstances as provided for in the CVR Agreement, will not be certificated or evidenced by any instrument, and will not be registered with the SEC or listed for trading on any exchange.

In August, 2023, Catalyst fully settled the CVR payments related to the Vertex asset purchase agreement.

In February 2023, Catalyst sold its legacy rare bleeding disorder program to GCBP. As a result, the Company distributed the net cash proceeds received from the GCBP asset sale of $0.2 million to the CVR Holders as well as recorded a $4.5 million long-term CVR derivative liability for the future distribution of the hold-back amount to be received in May 2025. As of December 31, 2023, the carrying value of the CVR derivative liability was $4.7 million on the consolidated balance sheet. Refer to Note 3 — *Fair Value Measurements and Financial Instruments* for additional information regarding the CVR derivative liability and GCBP asset sale.

On October 30, 2023, pursuant to the CVR Agreement, the Company recorded a $1.1 million CVR excess closing cash payable upon closing of the Contributions, which is anticipated to be distributed among the CVR Holders and remained outstanding as of December 31, 2023.

Litigation and Legal Matters

The Company is subject to claims and legal proceedings that arise in the ordinary course of business. Such matters are inherently uncertain, and there can be no guarantee that the outcome of any such matter will be decided favorably to the Company or that the resolution of any such matter will not have a material adverse effect upon the Company's consolidated financial statements.

In April 2023, separate stockholders of Catalyst filed lawsuits in the Delaware Chancery Court, captioned *Bushansky v. Catalyst Biosciences, Inc., et al* and *Scott v. Catalyst Biosciences, Inc., et al.,* alleging Catalyst violated its fiduciary duties under Delaware Law by failing to disclose purportedly material information regarding the proposed Business Combination Agreement. In February 2024, both lawsuits were dismissed with prejudice and the Company reimbursed the stockholders for their legal and other expenses related to the litigation in the aggregate amount of $0.4 million.

The Company recorded a litigation settlement liability in the amount of $0.4 million in October 2023 when it became probable and estimable, which was included in accrued expenses and other current liabilities on the consolidated balance sheet.

Purchasing Commitments

Property and Equipment

The Company's commitments related to purchase of property and equipment contracted but not yet reflected in the consolidated financial statements were $2.8 million as of December 31, 2023 and were expected to be incurred within one year.

F351

In September 2020, BC entered into an intellectual property ("IP") transfer agreement (the "F351 Transfer Agreement") with GNI Japan and certain of its wholly owned subsidiaries (the "GNI Group"). According to the F351 Transfer Agreement, BC acquired the exclusive right to use Hydronidone IP rights in mainland China and the right of first offer for the global IP rights (the "F351 IP Rights").

Under the F351 Transfer Agreement, in exchange for the F351 IP Rights, BC is obligated to pay GNI Group $4.8 million upon submission of the F351 New Drug Application (the "NDA") to Center for Drug Evaluation of the National Medical Products Administration (the "NMPA") of the PRC, $1.2 million after the NDA passes the NMPA's Center for Food and Drug Review and Inspection's on-site registration inspection for the F351 product, and $7.2 million upon NMPA's approval of the NDA.

Research and Development Programs

In addition to the F351 program, as of December 31, 2023, the Company has committed to allocate $12.7 million toward future research and development activities for various programs.

Indemnifications

In the normal course of business, the Company enters into agreements that indemnify others for certain liabilities that may arise in connection with a transaction or certain events and activities. If the indemnified party were to make a successful claim pursuant to the terms of the indemnification, the Company may be required to reimburse the loss. These indemnifications are generally subject to various restrictions and limitations. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations.

14. Income Taxes

In October 2023, the Company completed its acquisition of the controlling interest in BC. As a result of the Contributions, the Company directly or indirectly owned multiple controlled foreign corporations ("CFCs") for US tax purposes.

The components of the Company's provision for income taxes for the years ended December 31, 2023 and 2022 consist of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Current income tax provision:		
Federal	$ —	$ —
State	6	1
Foreign - PRC	9,343	5,987
Total current income tax provision	$ 9,349	$ 5,988
Deferred income tax provision:		
Federal	$ —	$ (91)
State	—	—
Foreign - PRC	(834)	(799)
Total deferred income tax provision	$ (834)	$ (890)
Total income tax provision	$ 8,515	$ 5,098

The reconciliation of the federal statutory income tax rate to the Company's effective tax rate for the years ended December 31, 2023 and 2022 are as follows:

	Year Ended December 31,	
	2023	2022
Tax computed at federal statutory rate	21.00%	21.00%
Rate difference due to different jurisdiction	-2.43%	4.31%
Preferential income tax rate for HNTE	3.19%	-10.37%
Non-deductible expense – Operating	-6.28%	33.06%
Non-deductible expense – One-time expense related to the Contributions	-22.16%	0.00%
R&D Super-deduction	1.45%	-12.42%
Valuation allowance change	-4.37%	0.00%
ESOP	-0.55%	21.81%
Other	-0.76%	-2.52%
Effective tax rate	-10.91%	54.87%

Significant components of the Company's deferred tax assets as of December 31, 2023 and 2022 consist of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Accruals and reserves	$ 2,811	$ 183
Deferred revenue	39	—
Net operating loss carry forwards	40,669	—
Other equity investments	—	150
Tax credit carry forwards	4,463	—
Fixed and intangible assets	15,332	3,428
Impact from foreign corporations	4,590	—
Capitalized transaction costs	658	414
Lease liabilities	98	—
Deferred income tax assets before valuation allowance	68,660	4,175
Deferred tax liability – ROU assets	(108)	—
Deferred tax liability – Fixed assets	(84)	(94)
Less: valuation allowance	(63,773)	—
Deferred tax assets, net	$ 4,695	$ 4,081

The movements of the valuation allowance are as follows (in thousands):

	2023	2022
Balance at the beginning of the year	$ —	$ —
Changes of valuation allowances	(63,773)	—
Balance at the end of the year	$ (63,773)	$ —

Based on the available objective evidence on December 31, 2023, the Company does not believe it is more likely than not that its net deferred tax assets will be realizable for US tax purposes. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets on December 31, 2023 for US tax purposes.

As of December 31, 2023, after consideration of certain limitations (see below), the Company had approximately $193.5 million federal and $10.5 million state net operating loss carryforwards ("NOL") available to reduce future taxable income which, if unused, will begin to expire in 2037 for federal and 2034 for state tax purposes. The federal net operating loss carryforward includes $191.9 million that have an indefinite life.

As of December 31, 2023, the Company also had tax credit carry forwards available to offset future tax liabilities of approximately $8,000 for federal and $7.5 million for state. If unused, the federal credit will begin to expire in 2042 and the state tax credit does not expire.

If the Company experiences a greater than 50 percentage point aggregate change in ownership over a three-year period (a Section 382 ownership change), utilization of its pre-change NOL carryforwards are subject to annual limitation under Section 382 of the Internal Revenue Code (California has similar provisions). The annual limitation is determined by multiplying the value of the Company's stock immediately before such ownership change by the applicable long-term tax-exempt rate. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. The Company determined that ownership changes under Section 382 occurred on December 31, 2007, August 20, 2015, April 13, 2017, February 15, 2018, February 18, 2020, and December 26, 2022. Approximately $156.5 million and $75.2 million of the NOLs will expire unutilized for federal and California state income tax purposes, respectively. The Company has derecognized NOL related deferred tax assets in the tax affected amounts of $32.9 million and $0 for federal and California state income tax purposes, respectively, through the year ended December 31, 2023.

All of the federal R&D credits could expire unutilized, whereas none of the California R&D credits are subject to expiration. Approximately $6.0 million of gross federal R&D credit-related deferred tax assets were derecognized due to the Section 383 limitation. The ability of the Company to use its remaining NOL and credit carryforwards may be further limited if the Company experiences a Section 382 ownership change as a result of future changes in its stock ownership.

On June 29, 2020, the California Governor signed Assembly Bill 85 ("A.B. 85"), which now becomes California law. A.B. 85, which includes several tax measures, provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than $5 million of tax per year. Generally, A.B. 85 suspends the use of California NOLs for taxable years 2021, 2022, and 2023 for taxpayers with taxable income of $1 million or more. Since the Company is not expected to generate California source taxable income of more than $1 million, no material impact is anticipated at this time.

Accounting for Uncertainty in Income Taxes

The Company only recognizes tax benefits if it is more likely than not that they will be sustained upon audit by the relevant tax authority based upon their technical merits. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained.

The Company had approximately $1.8 million of unrecognized tax benefits as of December 31, 2023. As the Company has a full valuation allowance on its deferred tax assets, the unrecognized tax benefits have reduced the deferred tax assets and the valuation allowance in the same amount. The Company does not expect the amount of unrecognized tax benefits to materially change in the next twelve months.

A reconciliation of the beginning and ending balance of the unrecognized tax benefits is as follows (in thousands):

Beginning Balance on January 1, 2022	$	—
Increase/(Decrease) of unrecognized tax benefits taken in prior years		—
Increase/(Decrease) of unrecognized tax benefits related to current year		—
Ending Balance on December 31, 2022		—
Increase as a result of the GNI USA Contributions on October 30, 2023		1,833
Increase/(Decrease) of unrecognized tax benefits taken in prior years		—
Increase/(Decrease) of unrecognized tax benefits related to current year		—
Ending Balance on December 31, 2023	$	1,833

Interest and penalties related to unrecognized tax benefits would be included as income tax expense in the Company's consolidated statements of operations. As of December 31, 2023 and 2022, the Company had not recognized any tax-related penalties or interest in its consolidated financial statements.

The Company files income tax returns in the United States federal, California, and Florida for tax year 2023. The Company filed an initial return in 2022 in Florida and final returns in 2021 in Kansas, Missouri and New Jersey state jurisdictions. The Company is not currently under examination by income tax authorities in federal, state or other jurisdictions. As of December 31, 2023 and 2022, the Company had no uncertain tax positions which affected its financial position as its results of operations or its cash flow, and will continue to evaluate for uncertain tax positions in the future. The Company is subject to United States federal and state income tax examinations by authorities for all tax years due to accumulated net operating losses that are being carried forward for tax purposes.

APB 23

Generally, a taxable outside basis difference associated with a foreign subsidiary may not be recognized if the indefinite reversal criterion of ASC paragraph 740-30-25-17 (APB Opinion No. 23, Accounting for Income Taxes – Special Areas ("APB 23")) is met. A deferred tax liability is recognized when an entity no longer meets the indefinite reversal criterion. ASC paragraph 740-30-25-17 provides a presumption that all undistributed earnings will be transferred to the parent entity may be overcome, and no income taxes shall be accrued by the parent entity, if sufficient evidence shows that the subsidiary has invested or will invest the undistributed earnings indefinitely or that the earnings will be remitted in a tax-free liquidation.

The Company does not have a plan of repatriation of earnings from non-US subsidiaries to the Company. However, to the extent the Company will not permanently reinvest in its PRC business, a DTL of approximately $2.5 million as of December 31, 2023 related to PRC withholding taxes on repatriation of BC's earnings (i.e., the Company's primary operating subsidiary in the PRC) would need to be recorded.

15. Related Party Transactions

F351 Transfer Agreement

Pursuant to the F351 Transfer Agreement (see Note 13), as part of the consideration, BC paid $2.6 million and $8.9 million to GNI during the years ended December 31, 2021 and December 31, 2020, respectively.

Research and development with GNI

No research and development fees were paid to GNI during the year ended December 31, 2023. During the year ended December 31, 2022, the Company paid $0.2 million as research and development fees to GNI.

As of December 31, 2023 and 2022, the Company had a $1.4 million and $0.1 million related parties payable due to GNI, respectively.

Other receivables from GNI

As of December 31, 2023, the Company had recorded $1.3 million in other receivables from GNI, of which $0.8 million was from CPI's restructuring transaction (see Note 8) and $0.5 million was from Gyre's cost sharing with GNI. No amounts were due from GNI as of December 31, 2022.

16. EPS

The dilutive effect of outstanding stock options and warrants is calculated using the treasury stock method. Stock options and warrants are anti-dilutive and excluded from the diluted net income per share attributable to common stock calculation if the exercise price exceeds the average market price of the common shares.

The following table sets forth the computation of EPS attributable to common stockholders, basic and diluted (in thousands, except share and per share data):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net (loss) income from operations	$ (85,480)	$ 4,314
Less: Allocation of undistributed earnings to noncontrolling interest	7,453	2,012
Net (loss) income attributable to common stockholders - basic and diluted	$ (92,933)	$ 2,302
Denominator:		
Basic common shares outstanding:		
Weighted average common shares outstanding	65,831,675	63,588,119
Weighted average shares used in calculating net (loss) income per share attributable to common stockholders, basic	65,831,675	63,588,119
Dilutive potential common shares:		
Weighted average of common stock options	—	12,098,287
Weighted average shares used in calculating net (loss) income per share attributable to common stockholders, diluted	65,831,675	75,686,406
Net (loss) income per share attributable to common stockholders:		
Basic	$ (1.41)	$ 0.04
Diluted	$ (1.41)	$ 0.03

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	December 31, 2023
Options to purchase common stock	18,280,548
Convertible Preferred stock (as converted)	8,767,332
Preferred Stock Warrants (as converted)	540,666
Total	27,588,546

17. Employee Benefit Plans

Mainland China Contribution Plan

Pursuant to relevant PRC regulations, the Company is required to make contributions to various defined contribution plans organized by municipal and provincial PRC governments. The contribution for each employee is based on a percentage of the employee's current compensation as required by the local government. The contributions are charged to profit or loss as they become payable in accordance with the rules of the central pension scheme. The total

contributions for such employee benefits were $4.3 million and $3.6 million for the years ended December 31, 2023, and 2022, respectively.

Defined-Contribution Savings Plan

In the U.S., the Company maintains a defined-contribution savings plan pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan is available to employees who meet the minimum age and length of service requirements. The contributions made during the year ended December 31, 2023 were immaterial.

18. Segment Information

The Company is a consolidated entity comprised of two distinct operating segments: BC and Gyre after the Contributions. The Company's reportable segments are based upon internal organizational structure, the manner in which operations are managed, the criteria used by CODM to evaluate segment performance the availability of separate financial information, and overall materiality considerations. All Gyre's operations are within the U.S., while all of BC's operations are in mainland China.

BC

BC has one major commercial drug product, ETUARY, and several product candidates in pre-clinical and clinical development. BC's product revenues are mainly generated from the sale of ETUARY and certain generic drugs. BC primarily sells its pharmaceutical products to distributors in the PRC, who ultimately sell the products to hospitals, other medical institutions and pharmacies. BC also generates revenue from license agreements. However, the license agreements did not generate any revenue for the year ended December 31, 2023 and an immaterial amount for the year ended December 31, 2022.

Gyre

Gyre is a biopharmaceutical company focused on the development and commercialization of F351 for the treatment of NASH-associated liver fibrosis in the United States. Other than the IP associated with F351 in the U.S., Gyre has no other product candidates since the Company sold all of its legacy IP assets prior to the closing of the Contributions. Subsequent to the closing of the Contributions, Gyre has not generated any revenue.

Segment information for the years ended December 31, 2023 and 2022 is as follows (in thousands):

	Year Ended December 31, 2023			
	BC	Gyre	Other	Consolidated
Revenues	$ 113,450	$ —	$ —	$ 113,450
Cost of revenues	4,636	—	—	4,636
Gross profit	108,814	—	—	108,814
Operating expenses excluding cost of revenues:				
Selling and marketing	61,159	—	—	61,159
Research and development	13,698	82	—	13,780
General and administrative	8,872	5,214	576 (1)	14,662
Acquired in-process research and development	—	83,104	—	83,104
Divestiture losses	—	—	2,711 (2)	2,711
Loss on disposal of property and equipment	628	—	—	628
Total operating expenses excluding cost of revenues	84,357	88,400	3,287	176,044
Income (Loss) from operations	$ 24,457	$ (88,400)	$ (3,287)	$ (67,230)
Supplemental Disclosure of stock-based compensation expense				
Cost of revenues	$ 52	$ —	$ —	$ 52
Selling and marketing	344	—	—	344
Research and development	481	—	—	481
General and administrative	1,916	4,488	—	6,404
Stock-based compensation total	$ 2,793	$ 4,488	$ —	$ 7,281

(1) $0.6 million represents legal expense recorded in CPI during the year ended December 31, 2023.
(2) $2.7 million represents divestiture losses. See Note 8 for details.

	December 31, 2023			
	BC	Gyre	Other	Consolidated
Total assets	$ 101,761	$ 13,865	$ 913	$ 116,539

	Year Ended December 31, 2022			
	BC	Gyre	Other	Consolidated
Purchase of property and equipment	$ (8,517)	$ —	$ —	$ (8,517)

	Year Ended December 31, 2022			
	BC	Gyre	Other	Consolidated
Revenues	$ 102,290	$ —	$ —	$ 102,290
Cost of revenues	4,793	—	—	4,793
Gross profit	97,497	—	—	97,497
Operating expenses excluding cost of revenues:				
Selling and marketing	54,238	—	—	54,238
Research and development	16,686	—	—	16,686
General and administrative	17,240	—	130 (3)	17,370
Total operating expenses excluding cost of revenues	88,164	—	130	88,294
(Loss) income from operations	9,333	—	(130)	9,203
Supplemental Disclosure of stock-based compensation expense				
Cost of revenues	$ 249	$ —	$ —	$ 249
Selling and marketing	1,643	—	—	1,643
Research and development	2,301	—	—	2,301
General and administrative	9,173	—	—	9,173
Stock-based compensation total	$ 13,366	$ —	$ —	$ 13,366

(3) $0.1 million represents the other subsidiaries, CPI and GNI HK, etc. reported an aggregate $0.1 million general and administrative expense during the year ended December 31, 2022.

	December 31, 2022			
	BC	Gyre	Other	Consolidated
Total assets	$ 79,857	$ —	$ 4,896	$ 84,753

	Year Ended December 31, 2022			
	BC	Gyre	Other	Consolidated
Purchase of property and equipment	$ (4,985)	$ —	$ —	$ (4,985)

19. Subsequent Events

Conversion of Convertible Preferred Stock

On November 22, 2023, GNI provided notice to the Company to convert 13,151 shares of Convertible Preferred Stock into shares of common stock. On January 22, 2024, subject to the terms and conditions of the Convertible Preferred Stock Certificate of Designation, 8,767,332 shares of common stock were issued to GNI upon such conversion.

Additional Financial Information of Parent Company
Financial Statements Schedule I

Gyre Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except shares and per share amounts)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Related party receivables	$ 768	$ 3,159
Total current assets	768	3,159
Investment in subsidiaries	49,709	40,632
Total assets	$ 50,477	$ 43,791
Liabilities, convertible preferred stock, and stockholders' equity		
Current liabilities:		
Due to related parties	$ 538	$ 5
Accrued expenses and other current liabilities	1,242	1,264
Total current liabilities:	1,780	1,269
Convertible Preferred Stock, $0.001 par value, 5,000,000 shares authorized; 13,151 shares and nil shares issued and outstanding at December 31, 2023 and 2022, respectively	64,525	—
Stockholders' (deficit) equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized; 76,595,616 shares and 63,588,119 shares issued and outstanding at December 31, 2023 and 2022, respectively	77	64
Additional paid-in capital	68,179	32,795
Statutory reserve	3,098	2,660
(Accumulated deficit) retained earnings	(85,538)	7,395
Accumulated other comprehensive loss	(1,644)	(392)
Total stockholders' (deficit) equity	(15,828)	42,522
Total liabilities, convertible preferred stock, and stockholders' (deficit) equity	$ 50,477	$ 43,791

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

Gyre Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(In thousands)

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
General and administrative	$ 605	$ 94
Divestiture losses	2,711	—
Loss before equity in (loss) income of subsidiaries	3,316	94
Equity in (loss) income of subsidiaries	(89,617)	2,396
Net (loss) income	$ (92,933)	$ 2,302
Other comprehensive (loss) income, net of tax of nil:		
Foreign currency translation adjustments	(837)	(2,758)
Comprehensive loss	$ (93,770)	$ (456)

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

Gyre Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2023	2022
Operating Activities		
Net (loss) income	$ (92,933)	$ 2,302
Adjustments to reconcile net (loss) income to net cash used for operating activities:		
Equity loss (income) of subsidiaries	89,617	(2,396)
Divestiture losses	2,711	—
Changes in operating assets and liabilities:		
Due to related parties	533	5
Net cash provided by operating activities	(72)	(89)
Effect of exchange rate changes on cash and cash equivalents	72	89
Net change in cash and cash equivalents	—	—
Cash and cash equivalents at beginning of the period	—	—
Cash and cash equivalents at end of period	$ —	$ —

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

Notes

1. Schedule I has been provided pursuant to the requirements of Rule 12-04(a) and 5-04(c) of Regulation S-X, which require condensed financial information as to the financial position, changes in financial position and results of operations of a parent company as of the same dates and for the same periods for which audited consolidated financial statements have been presented when the restricted net assets of consolidated subsidiaries exceed 25 percent of consolidated net assets as of the end of the most recently completed fiscal year.

2. The condensed financial information has been prepared using the same accounting policies as set out in the consolidated financial statements except that the equity method has been used to account for investments in its subsidiaries. CPI, the legal acquiree and accounting acquirer of the Contributions considered the "registrant" and presented as the parent company, Gyre Therapeutics, Inc. ("Gyre") to supplement its condensed financial statement in Schedule I. The parent company records its investments in subsidiaries under the equity method of accounting as prescribed in ASC 323, Investments-Equity Method, and Joint Ventures. Such investments are presented on the Condensed Balance Sheets as "Investment in subsidiaries". Ordinarily under the equity method, an investor in an equity method investee would cease to recognize its share of the losses of an investee once the carrying value of the investment has been reduced to nil absent an undertaking by the investor to provide continuing support and fund losses. For the purpose of this Schedule I, the parent company has continued to reflect its share, based on its proportionate interest, of the losses of subsidiaries regardless of the carrying value of the investment even though the parent company is not obligated to provide continuing support or fund losses.

3. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted.

4. As of December 31, 2023 and 2022, there were no material contingencies, significant provisions of long-term obligations, mandatory dividend or redemption requirements of redeemable stocks or guarantees of the parent company.

GYRE THERAPEUTICS, INC.
CERTIFICATE OF ELIMINATION
OF
SERIES A PREFERRED STOCK

Pursuant to Section 151(g) of the
General Corporation Law of the State of Delaware

Pursuant to the provisions of Section 151(g) of the General Corporation Law of the State of Delaware (the "General Corporation Law"), Gyre Therapeutics, Inc. (the "Company"), a corporation organized and existing under and by virtue of the provisions of the General Corporation Law, hereby certifies as follows:

1. That, at a meeting of the Board of Directors of the Company, resolutions were duly adopted setting forth the proposed elimination of the series of stock as set forth herein:

   NOW, THEREFORE BE IT RESOLVED, that, the officers of the Company be, and each of them hereby is, authorized, personally or by attorney, in the name and on behalf of the Company, to execute, deliver and cause to be filed with the Secretary of State of the State of Delaware a Certificate of Elimination, in substantially the form attached hereto as Exhibit A, pursuant to the provisions of Section 151(g) of the DGCL for the purpose of eliminating from the Company's Fourth Amended and Restated Certificate of Incorporation all matters set forth in the Certificate of Designation with respect to the Series A Preferred Stock.

2. That the Certificate of Designation with respect to the Series A Preferred Stock was filed with the Secretary of State of the State of Delaware on April 10, 2017 (the "Certificate of Designation").

3. That none of the authorized shares of the Series A Preferred Stock are outstanding, and none will be issued.

4. That, in accordance with the provisions of Section 151(g) of the General Corporation Law, the Company's Fourth Amended and Restated Certificate of Incorporation, as amended, is hereby further amended to eliminate all matters set forth in the Certificate of Designation with respect to the Series A Preferred Stock.

IN WITNESS WHEREOF, the Company has caused this Certificate of Elimination to be signed by its Chief Executive Officer this 25th day of March, 2024.

By: /s/ Han Ying, Ph.D.
Han Ying, Ph.D.
Chief Executive Officer

Exhibit 4.1

DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF
THE SECURITIES EXCHANGE ACT OF 1934

Gyre Therapeutics, Inc. ("we," "our," "us," or the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended ("1934 Act"): our common stock. The following summary of the terms of our common stock is based upon our Fourth Amended and Restated Certificate of Incorporation, as amended (our "restated certificate of incorporation") and our bylaws. This summary does not purport to be complete and is subject to, and is qualified in its entirety by express reference to, the applicable provisions of our restated certificate of incorporation and our bylaws, which are filed as exhibits to our Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our restated certificate of incorporation, our bylaws and the applicable provisions of the Delaware General Corporation Law ("DGCL") for more information.

Description of Common Stock

Under our restated certificate of incorporation, we have authority to issue 400,000,000 shares of our common stock, par value $0.001 per share. As of December 31, 2023, 76,595,616 shares of our common stock were issued and outstanding. All shares of our common stock will, when issued, be duly authorized, fully paid and nonassessable.

Dividends. Subject to preferential dividend rights of any other class or series of stock, the holders of shares of our common stock are entitled to receive dividends, including dividends of our stock, as and when declared by our board of directors, subject to any limitations imposed by law and to the rights of the holders, if any, of our preferred stock. On September 20, 2022, we paid a special, one-time cash dividend of approximately $45.0 million (or $1.43 per share) to our common stockholders of record as of the close of business on September 6, 2022. On January 12, 2023, we paid a special, one-time cash dividend of approximately $7.6 million (or $0.24 per share) to our common stockholders of record as of the close of business on January 5, 2023. In June 2023, we distributed $3.5 million, which reflected, in connection with an asset purchase agreement with Vertex Pharmaceuticals Inc. ("Vertex"), the hold-back amount received from Vertex less expenses and a reserve for potential tax liabilities, to holders of the contingent value right issued to our stockholders of record on January 5, 2023. We do not anticipate paying periodic cash dividends on our common stock for the foreseeable future. Any future determination about the payment of dividends will be made at the discretion of our board of directors and will depend upon our earnings, if any, capital requirements, operating and financial conditions and on such other factors as the board of directors deems relevant.

Liquidation. In the event we are liquidated, dissolved or our affairs are wound up, after we pay or make adequate provision for all of our known debts and liabilities, each holder of our common stock will be entitled to share ratably in all assets that remain, subject to any rights that are granted to the holders of any class or series of preferred stock.

Voting Rights. For all matters submitted to a vote of stockholders, each holder of our common stock is entitled to one vote for each share registered in his or her name. Except as may be required by law and in connection with some significant actions, such as mergers, consolidations, or amendments to our restated certificate of incorporation that affect the rights of stockholders, holders of our common stock vote together as a single class. There is no cumulative voting in the election of our directors, which means that, subject to any rights to elect directors that are granted to the holders of any class or series of preferred stock, a plurality of the votes cast at a meeting of stockholders at which a quorum is present is sufficient to elect a director.

Other Rights and Restrictions. Subject to the preferential rights of any other class or series of stock, all shares of our common stock have equal dividend, distribution, liquidation and other rights, and have no preference, appraisal or exchange rights, except for any appraisal rights provided by Delaware law. Furthermore, holders of our common stock have no conversion, sinking fund or redemption rights, or preemptive rights to subscribe for any of our securities. Our restated certificate of incorporation and our bylaws do not restrict the ability of a holder of our common stock to transfer his or her shares of our common stock.

The rights, powers, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of preferred stock which we may designate and issue in the future.

Listing. Our common stock is listed on the Nasdaq Capital Market under the symbol "GYRE."

Transfer Agent and Registrar. The transfer agent for our common stock is Equiniti Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, NY 11219.

Description of Preferred Stock

Under our restated certificate of incorporation, we have authority, subject to any limitations prescribed by law and without further stockholder approval, to issue from time to time up to 5,000,000 shares of preferred stock, par value $0.001 per share, in one or more series. On December 22, 2022, we designated 123,418 shares of our preferred stock as "Series X Convertible Preferred Stock" (hereinafter referred to as, "Convertible Preferred Stock"). As of December 31, 2023, we had 13,151 shares of preferred stock issued and outstanding.

Pursuant to our restated certificate of incorporation, we are authorized to issue "blank check" preferred stock, which may be issued from time to time in one or more series upon authorization by our board of directors. Our board of directors, without further approval of the stockholders, is authorized to fix the designation, powers, preferences, relative, participating optional or other special rights, and any qualifications, limitations and restrictions applicable to each series of the preferred stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes could, among other things, adversely affect the voting power or rights of the holders of our common stock and, under certain circumstances, make it more difficult for a third party to gain control of us, discourage bids for our common stock at a premium or otherwise adversely affect the market price of the common stock.

Series X Convertible Preferred Stock

Conversion. Under our restated certificate of incorporation, (i) effective as of 5:00 p.m. (New York City time) on the second business day after the date on which such stockholder approval is received, each share of Convertible Preferred Stock then outstanding automatically converts into approximately 10,000 of common stock, and (ii) at any time thereafter at the option of the holder thereof, into approximately 10,000 shares of common stock, in the case of each of (i) and (ii) subject to certain beneficial ownership limitations, including that a holder of Convertible Preferred Stock is prohibited from converting shares of Convertible Preferred Stock into shares of common stock if, as a result of such conversion, such holder, together with its affiliates, would beneficially own more than a specified percentage (to be initially set at 9.9% and thereafter adjusted by the holder between to a number between 4.9% and 19.9%) of the total number of shares of common stock issued and outstanding immediately after giving effect to such conversion.

Voting Rights. Except as otherwise provided in the Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, filed with the Secretary of State of the State of Delaware on December 27, 2022, as amended on October 30, 2023 (as amended, "Certificate of Designation") or as otherwise required by the DGCL, Convertible Preferred Stock does not have voting

rights. However, as long as any shares of Convertible Preferred Stock are outstanding, in addition to any other requirement of the DGCL or our restated certificate of incorporation, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of Convertible Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to Convertible Preferred Stock or alter or amend the Certificate of Designation, amend or repeal any provision of or add any provision to, our restated certificate of incorporation or our bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of Convertible Preferred Stock, regardless of whether any of the foregoing actions shall be by means of amendment to our restated certificate of incorporation or by merger, consolidation or otherwise, (ii) issue further shares of Convertible Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Convertible Preferred Stock, (iii) at any time while at least 30% of the originally issued Convertible Preferred Stock remains issued and outstanding, consummate either: (A) any Fundamental Transaction (as defined in the Certificate of Designation) or (B) any merger or consolidation of the combined company with or into another entity or any stock sale to, or other business combination in which the combined company's stockholders immediately before such transaction do not hold at least a majority of the capital stock of the combined company immediately after such transaction, or (iv) enter into any agreement with respect to any of the foregoing.

Dividends. Holders of Convertible Preferred Stock shall be entitled to receive when, as and if dividends are declared and paid on shares of common stock, an equivalent dividend (with the same dividend declaration date and payment date), calculated on an as-converted basis without regard to the Beneficial Ownership Limitation (as defined in the Certificate of Designation), provided, however, in no event shall holders of Convertible Preferred Stock be entitled to receive (a) the "rights" distributed pursuant to the Contingent Value Rights Agreement, dated December 26, 2022, as amended on March 29, 2023 (as amended, the "CVR Agreement") or any amounts paid under the CVR Agreement, or (b) cash distributions declared by the combined company on or prior to the closing of the transactions contemplated by the Business Combination Agreement, dated as of December 26, 2022, as amended on March 29, 2023 and August 30, 2023, by and among us, GNI USA, Inc., a Delaware corporation, GNI Group Ltd., a company incorporated under the laws of Japan with limited liability, GNI Hong Kong Limited, a company incorporated under the laws of Hong Kong with limited liability, Shanghai Genomics, Inc., a company organized under the laws of the People's Republic of China, the Minority Holders (as defined therein) and Continent Pharmaceuticals Inc., a Cayman Islands company limited by shares.

Liquidation. Convertible Preferred Stock ranks (i) senior to any class or series of capital stock of the combined company hereafter created specifically ranking by its terms junior to any Convertible Preferred Stock; (ii) on parity with common stock and any class or series of capital stock of the combined company hereafter created specifically ranking by its terms on parity with Convertible Preferred Stock; and (iii) junior to (A) any class or series of capital stock of the combined company hereafter created specifically ranking by its terms senior to any Convertible Preferred Stock or (B) any "rights" distributed pursuant to the CVR Agreement or any amounts paid under the CVR Agreement, in each case, as to distributions of assets upon liquidation, dissolution or winding up of the combined company, whether voluntarily or involuntarily.

Certain Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval, subject to any limitations imposed by the listing requirements of The Nasdaq Capital Market. We may issue these additional shares for a variety of corporate purposes, including future public or private offerings to raise additional capital or to facilitate corporate acquisitions or for payment as a dividend on our capital stock. The existence of unissued and unreserved preferred stock may enable our board of directors to issue shares of preferred stock with terms that could render more difficult or

discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, if we issue preferred stock, the issuance could adversely affect the voting power of holders of common stock and the likelihood that holders of common stock will receive dividend payments or payments upon liquidation.

Anti-Takeover Effects of Provisions of Our Charter Documents

Our restated certificate of incorporation provides for our board of directors to be divided into three classes serving staggered terms. Approximately one-third of our board of directors will be elected each year. The provision for a classified board could prevent a party who acquires control of a majority of the outstanding voting stock from obtaining control of the board of directors until the second annual stockholders meeting following the date the acquirer obtains the controlling stock interest. The classified board provision could discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of the Company and could increase the likelihood that incumbent directors will retain their positions. Our restated certificate of incorporation provides that directors may be removed with or without cause only by the affirmative vote of the holders of at least 66 2/3% of the voting power of all outstanding stock entitled to vote in the election of directors, voting together as a single class.

Our restated certificate of incorporation requires that certain amendments to the restated certificate of incorporation and amendments by the stockholders of our bylaws require the affirmative vote of holders of at least 66 2/3% of the then outstanding stock entitled to vote generally in the election of directors, voting together as a single class. These provisions could discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of the Company and could delay changes in management.

Our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual stockholders meeting, including proposed nominations of persons for election to our board of directors. At an annual stockholders meeting, stockholders may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors. Stockholders may also consider a proposal or nomination by a person who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given to the Secretary of the Company timely written notice, in proper form, of his or her intention to bring that business before the annual stockholders meeting. Our bylaws do not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting of the stockholders. However, our bylaws may have the effect of precluding the conduct of business at a meeting if the proper procedures are not followed. These provisions may also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of the Company.

Our bylaws provide that only our board of directors, the chairperson of the board, the President or the Chief Executive Officer may call a special meeting of stockholders. Because our stockholders do not have the right to call a special meeting, a stockholder could not force stockholder consideration of a proposal over the opposition of our board of directors by calling a special meeting of stockholders prior to such time as a majority of our board of directors, the chairperson of the board, the President or the Chief Executive Officer believed the matter should be considered or until the next annual meeting provided that the requestor met the notice requirements. The restriction on the ability of stockholders to call a special meeting means that a proposal to replace the board also could be delayed until the next annual stockholders meeting.

Our restated certificate of incorporation does not allow stockholders to act by written consent without a meeting. Without the availability of stockholder's actions by written consent, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a stockholders' meeting.

Anti-Takeover Effects of Provisions of Delaware Law

We are subject to the provisions of Section 203 of the DGCL, or Section 203. Under Section 203, we would generally be prohibited from engaging in any business combination with any interested stockholder for a period of three years following the time that this stockholder became an interested stockholder unless:

- prior to this time, our board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers, and by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- at or subsequent to such time, the business combination is approved by our board of directors and authorized at a special or annual stockholders meeting, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

Under Section 203, a "business combination" includes:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder, subject to limited exceptions;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as an entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by such entity or person.

Limitation of Liability and Indemnification

Our restated certificate of incorporation provides that our directors shall not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duty as a director, except for liability for breach of the director's duty of loyalty to us or our stockholders, for acts or omissions not in good faith or involving intentional misconduct or a knowing violation of law, for payment of dividends or approval of stock purchases or redemptions that are prohibited by the DGCL, or for any transaction from which the director derived an improper personal benefit. Under the DGCL, our directors have a fiduciary duty to us that is not eliminated by this provision of the restated certificate of incorporation and, in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available. This provision also does not affect our directors' responsibilities under any other laws, such as federal securities laws or state or federal environmental laws.

Section 145 of the DGCL empowers a corporation to indemnify its directors and officers against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably

incurred by them in connection with any action, suit or proceeding brought by third parties by reason of the fact that they were or are directors or officers of the corporation, if they acted in good faith, in a manner they reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe that their conduct was unlawful. The DGCL provides further that the indemnification permitted thereunder shall not be deemed exclusive of any other rights to which the directors and officers may be entitled under the corporation's bylaws, any agreement, a vote of stockholders or otherwise. Our restated certificate of incorporation provides that, to the fullest extent permitted by Section 145 of the DGCL, we shall indemnify any person who is or was a director or officer of us, or is or was serving at our request as a director, officer or trustee of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against the expenses, liabilities or other matters referred to in or covered by Section 145 of the DGCL. Our bylaws provide that we will indemnify any person who was or is a party or threatened to be made a party to any proceeding by reason of the fact that such person is or was a director or officer of us or is or was serving at our request as a director, officer or trustee of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise to the fullest extent permitted by the DGCL.

In addition, we have entered into indemnification agreements with each of our directors and with certain of our executive officers. Pursuant to the indemnification agreements, we has agreed to indemnify and hold harmless these directors and officers to the fullest extent permitted by the DGCL. The agreements generally cover expenses that a director or officer incurs or amounts that a director or officer becomes obligated to pay because of any proceeding to which he or she is made or threatened to be made a party or participant by reason of his or her service as a current or former director, officer, employee or agent of the Company. The agreements also provide for the advancement of expenses to the directors and officers subject to specified conditions. There are certain exceptions to our obligation to indemnify the directors and officers, including any intentional malfeasance or act where the director or officer did not in good faith believe he or she was acting in our best interests, with respect to "short-swing" profit claims under Section 16(b) of the 1934 Act and, with certain exceptions, with respect to proceedings that he or she initiates.

Section 145 of the DGCL also empowers a corporation to purchase insurance for its officers and directors for such liabilities. We maintain liability insurance for our officers and directors.

EXHIBIT 21.1

SUBSIDIARIES OF GYRE THERAPEUTICS, INC.

Note: Gyre Therapeutics, Inc. or one of its Subsidiaries has 100% ownership of the Subsidiaries listed below, except for Beijing Continent Pharmaceuticals Co., Ltd. (65.2%) and Beijing Continent Biomedical Technology Co., Ltd (65.2%).

Subsidiaries	Jurisdiction
Further Challenger International Limited	British Virgin Islands
Nepenthe Holdings Limited	Hong Kong
Ratel Holdings Limited	British Virgin Islands
Aaring Limited	Hong Kong
Rosefinch Holdings Limited	British Virgin Islands
Continent Pharmaceuticals Inc.	Cayman Islands
BJContinent Pharmaceuticals Limited	Hong Kong
Beijing Continent Pharmaceuticals Co., Ltd.	People’s Republic of China
Beijing Continent Biomedical Technology Co., Ltd.	People’s Republic of China

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 27, 2024, with respect to the consolidated financial statements included in the Annual Report of Gyre Therapeutics, Inc. on Form 10-K for the years ended December 31, 2023 and 2022. We consent to the incorporation by reference of said report in the Registration Statements of Gyre Therapeutics Inc. on Forms S-8 (Nos. 333-206523, 333-206526, 333-212345, 333-219301, 333-225902, 333-239712, 333-264027 and 333-275222), and Form S-3 (No. 333-273395).

/s/ Grant Thornton Zhitong Certified Public Accountants LLP

Beijing, China
March 27, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Han Ying, certify that:

1. I have reviewed this Annual Report on Form 10-K of Gyre Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2024

/s/ Han Ying, Ph.D.

Han Ying, Ph.D.
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a) AND 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ruoyu Chen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Gyre Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2024

/s/ Ruoyu Chen

Ruoyu Chen
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Catalyst Biosciences, Inc. (the "Company") for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Han Ying, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2024

/s/ Han Ying, Ph.D.

Han Ying, Ph.D.
Chief Executive Officer and Director

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by § 906 has been provided to Gyre Therapeutics, Inc. and will be retained by Gyre Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Catalyst Biosciences, Inc. (the "Company") for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ruoyu Chen, hereby certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2024

/s/ Ruoyu Chen

Ruoyu Chen
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Note: A signed original of this written statement required by § 906 has been provided to Gyre Therapeutics, Inc. and will be retained by Gyre Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

GYRE THERAPEUTICS, INC.

INCENTIVE COMPENSATION CLAWBACK POLICY

Recoupment of Incentive-Based Compensation

It is the policy of Gyre Therapeutics, Inc. (the "***Company***") that, in the event the Company is required to prepare an accounting restatement of the Company's financial statements due to material non-compliance with any financial reporting requirement under the federal securities laws (including any such correction that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period), the Company will recover on a reasonably prompt basis the amount of any Incentive-Based Compensation Received by a Covered Executive during the Recovery Period that exceeds the amount that otherwise would have been Received had it been determined based on the restated financial statements (each as defined below). This Incentive Compensation Clawback Policy (this "***Policy***") has been adopted by the Compensation Committee (the "***Committee***") of the Company's Board of Directors (the "***Board***") effective October 2, 2023 (the "***Effective Date***"). The Committee may amend or change the terms of this Policy at any time for any reason, including as required to comply with any laws, rules, regulations and listing standards that may be applicable to the Company.

Policy Administration and Definitions

This Policy is administered by the Committee and is intended to comply with, and as applicable to be administered and interpreted consistent with, and subject to the exceptions set forth in, Listing Rule 5608 adopted by the Nasdaq Stock Market ("***Nasdaq***") to implement Rule 10D-1 under the Securities Exchange Act of 1934, as amended (collectively, "***Rule 10D-1***").

For purposes of this Policy:

- "***Covered Executive***" means any "executive officer" of the Company as defined under Rule 10D-1.
- A "***Financial Reporting Measure***" is (i) any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements and any measure derived wholly or in part from such a measure, and (ii) any measure based in whole or in part on the Company's stock price or total shareholder return.
- "***Incentive-Based Compensation***" means any compensation granted, earned or vested based in whole or in part on the Company's attainment of a Financial Reporting Measure that was Received by a person (i) on or after the Effective Date and after the person began service as a Covered Executive, and (ii) who served as a Covered Executive at any time during the performance period for the Incentive-Based Compensation.

- Incentive-Based Compensation is deemed to be "***Received***" in the fiscal period during which the relevant Financial Reporting Measure is attained, regardless of when the compensation is actually paid or awarded.

- "***Recovery Period***" means the three completed fiscal years immediately preceding the date that the Company is required to prepare the accounting restatement described in this Policy and any transition period of less than nine months that is within or immediately following such three fiscal years, all as determined pursuant to Rule 10D-1.

Determination by the Committee

If the Committee determines the amount of Incentive-Based Compensation Received by a Covered Executive during a Recovery Period exceeds the amount that would have been Received if determined or calculated based on the Company's restated financial results, such excess amount of Incentive-Based Compensation shall be subject to recoupment by the Company pursuant to this Policy. For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the Committee will determine the amount based on a reasonable estimate of the effect of the accounting restatement on the relevant stock price or total shareholder return. In all cases, the calculation of the excess amount of Incentive-Based Compensation to be recovered will be determined on a pre-tax basis (*i.e.*, without regard to any taxes paid with respect to such compensation). The Company will maintain and will provide to Nasdaq documentation of all determinations and actions taken in complying with this Policy. Any determinations made by the Committee under this Policy shall be final and binding on all affected individuals.

Methods of Clawback

The Company may effect any recovery pursuant to this Policy in any manner consistent with applicable law, including by requiring payment of such amount(s) to the Company, by set-off, by reducing future compensation, or by such other means or combination of means as the Committee determines to be appropriate. The Company need not recover the excess amount of Incentive-Based Compensation if and to the extent that the Committee determines that such recovery is impracticable, subject to and in accordance with any applicable exceptions under the Nasdaq listing rules and not required under Rule 10D-1, including if the Committee determines that the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered after making a reasonable attempt to recover such amounts. The Company is authorized to take appropriate steps to implement this Policy with respect to Incentive-Based Compensation arrangements with Covered Executives.

Not Exclusive Remedy

Any right of recoupment or recovery pursuant to this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any other policy, any employment agreement or plan or award terms, and any other legal remedies available to the Company (including, but not limited to, Section 304 of the

Sarbanes-Oxley Act of 2002); provided that the Company shall not recoup amounts pursuant to such other policy, terms or remedies to the extent it is recovered pursuant to this Policy. The Company shall not indemnify any Covered Executive against the loss of any Incentive-Based Compensation pursuant to this Policy, nor will the Company pay or agree to pay any insurance premium to cover any such loss.

Certification

All Covered Executives subject to this Policy will be required to certify their understanding of and intent to comply with this Policy periodically.

ACKNOWLEDGMENT AND CERTIFICATION

By signing below, the undersigned covered executive (the "***Covered Executive***") acknowledges and confirms that the Covered Executive has received and reviewed a copy of the Gyre Therapeutics, Inc. (the "***Company***") Incentive Compensation Clawback Policy (the "***Policy***"), and in addition, the Covered Executive acknowledges and agrees that, for good and valid consideration, including continuing participation in the Company's incentive compensation programs, the receipt and sufficiency of which the Covered Executive hereby acknowledges, the Covered Executive will be bound by and abide by the Policy as follows:

(a) the Covered Executive is and will continue to be subject to the Policy and the Policy will apply both during and after the Covered Executive's employment with the Company;

(b) to the extent necessary to comply with the Policy, the Company hereby amends any employment agreement, equity award agreement or similar agreement that the Covered Executive is a party to with the Company;

(c) the Covered Executive shall abide by the terms of the Policy, including, without limitation, by returning any compensation to the Company to the extent required by, and in a manner permitted by, the Policy, and understands and agrees that the Company is not permitted to, and will not, indemnify the Covered Executive for the loss of any compensation that is subject to recovery by the Company;

(d) any amounts payable to the Covered Executive shall be subject to the Policy as may be in effect and interpreted or modified from time to time in the sole discretion of the Compensation Committee of the Company's Board of Directors (the "***Committee***") or as required by applicable law or the requirements of any securities exchange on which the Company's securities are listed, and that such interpretation or modification will be covered by this acknowledgment;

(e) the Company may recover compensation paid to the Covered Executive through any method of recovery the Committee or its delegate deems appropriate, including without limitation by reducing any amount that is or may become payable to the Covered Executive, and the Covered Executive agrees to comply with any request or demand for repayment by the Company in order to comply with the Policy; and

(f) the Company is not responsible for and shall not make the Covered Executive whole for any effect under any tax law or regulation of the recovery of any compensation pursuant to the Policy, or for any taxes paid by the Covered Executive on compensation that is subject to recovery or is recovered pursuant to the Policy.

[ACKNOWLEDGMENT AND CERTIFICATION]

Signature

Print Name

Date