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, 2025

OR

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

For the transition period from _____ to

Commission file number: 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)**

(858) 567-7770

(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, 2025, the last business day of the registrant's most recently completed second fiscal quarter) was approximately $72.6 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 2, 2026, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 96,963,611, which includes 5,649,604 shares of common stock issued in the name of the registrant to a stock plan administrator of the registrant (see Note 8—Stockholders' Equity).

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 2026 (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:

- satisfying the conditions to closing of the potential Merger with Cullgen (each as defined herein), including obtaining approval pursuant to The Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act");
- meeting expectations regarding timing and completion of the Merger;
- uncertainties as to the timing and costs of the consummation of the transactions contemplated by the Merger Agreement (as defined herein);
- the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Merger Agreement;
- the risk that the Merger Agreement may be terminated in circumstances that require us to pay a termination fee;
- the outcome of any legal proceedings that may be instituted against us, Cullgen, or any of each company's respective directors or officers related to the Merger Agreement or the transactions contemplated thereby;
- our ability to conduct extensive clinical trials to demonstrate safety and efficacy of our product candidates;
- 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: (i) F351 (hydronidone) from the Phase 2 trial in the United States for the treatment of metabolic dysfunction-associated steatohepatitis (“MASH”) associated liver fibrosis; (ii) ETUARY® from the Phase 3 clinical trial in the People’s Republic of China (“PRC”) for pneumoconiosis (“PD”); (iii) ETUARY® from an adaptive Phase 2/3 trial in the PRC for radiation-induced lung injury (“RILI”) with or without immune-related pneumonitis; (iv) F573 from the Phase 2 clinical trial in the PRC for the treatment of acute/acute-on-chronic liver failure (“ALF/ACLF”); and (v) F230 from the Phase 1 clinical trial in the PRC for the treatment of pulmonary arterial hypertension (“PAH”); and (vi) other product candidates we may develop, including F528, 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 U.S., PRC and comparable foreign regulatory filings and approvals, including timing of investigational new drug (“IND”) applications and final U.S. Food and Drug Administration (“FDA”) and National Medical Products Administration ("NMPA") approval of Hydronidone for the treatment of liver fibrosis associated with MASH and chronic hepatitis B (“CHB”), respectively, ETUARY® for the treatment of PD and RILI, F528 for the treatment of chronic obstructive pulmonary disease (“COPD”), F230 for the treatment of PAH, and any other future product candidates;
- 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;
- 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 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®, Etorel® (nintedanib ethanesulfonate soft capsules), Contiva® (avatrombopag maleate tablets), Hydronidone, 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 ("KOLs"), 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 of, reimbursement of, and potential impact of the PRC's national centralized drug procurement policy on ETUARY®, Etorel®, Contiva®, Hydronidone, F573, F528, and F230, and other product candidates we may develop, if approved and commercialized;
- the rate and degree of market acceptance and clinical utility of Hydronidone, and other product candidates we may develop;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- global economic conditions, including new or increased tariffs imposed by the U.S. government and potential retaliatory measures by foreign governments and other barriers to trade, trade and other international disputes, inflation and fluctuating interest rates, slower growth or recession, tighter credit, volatility in financial markets, high unemployment, labor availability constraints, public health crises, significant natural disasters, including as a result of climate change, changes to fiscal and monetary policy or government budget dynamics, particularly in the pharmaceutical and biotech areas, government shutdowns, political and military conflict;
- 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; and
- the impact of laws and regulations.

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").

Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of small-molecule therapies for the treatment of organ fibrosis and inflammatory diseases. We operate through our majority indirectly owned subsidiary, Gyre Pharmaceuticals, in the PRC, and through our U.S. operations headquartered in San Diego, California.

In the PRC, we have established a strong commercial and operational foundation in fibrotic diseases through the successful development and commercialization of ETUARY® (pirfenidone), which has generated consistent revenue and positioned us as a leading participant in the treatment of pulmonary fibrosis.

Fibrotic diseases affect large patient populations worldwide and involve complex, multi-stage biological processes driven by multiple molecular pathways. Given this complexity, therapies that modulate key profibrotic signaling pathways may offer meaningful clinical benefit; however, effective treatment may require targeting mechanisms across different stages of disease progression.

Building on our commercialization experience and infrastructure in the PRC, we have expanded our presence into the United States to advance the clinical development of our innovative pipeline, including F351 (Hydronidone), our lead product candidate for liver fibrosis.

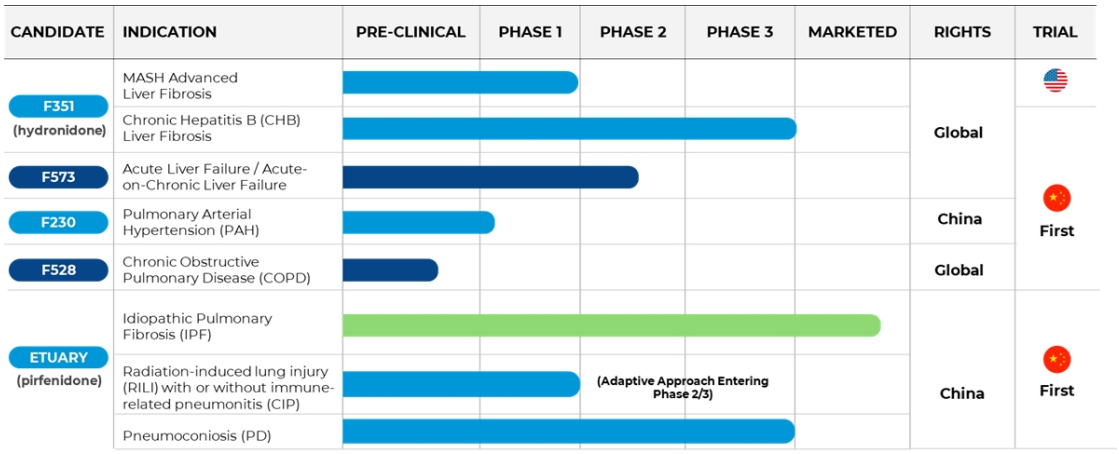
Our strategy is to leverage our established commercial portfolio to support and de-risk the advancement of late-stage product candidates, expand approved products into additional indications, and build a diversified pipeline targeting significant unmet medical needs in fibrosis and related inflammatory diseases.

On March 2, 2026, we entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with Cullgen Inc., a Delaware corporation ("Cullgen"), and Helix Merger Sub Corp., a Delaware corporation and wholly owned subsidiary of Gyre ("Merger Sub"), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Cullgen, with Cullgen continuing as a wholly owned subsidiary of Gyre and the surviving corporation of the merger (the "Merger"). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

The consummation of the Merger is subject to certain closing conditions, including, among other things, (1) approval by the requisite Cullgen stockholders of the adoption and approval of the Merger Agreement and the transactions contemplated thereby, and (2) a filing under the HSR Act.

There can be no assurances that the Merger will be successfully consummated, and the intended benefits of the Merger may not be realized.

Our Core Pipeline



Our Commercial Portfolio

Our commercial portfolio establishes our presence as a revenue-generating biopharmaceutical company and serves as the operational and financial platform for our long-term growth strategy. In the PRC, we have built a focused commercial franchise centered on fibrosis and related diseases, anchored by ETUARY® (pirfenidone) and expanded by Etorel® (nintedanib), the two standard-of-care antifibrotic therapies approved for the treatment of idiopathic pulmonary fibrosis ("IPF"). We have further broadened our commercial reach with Contiva® (avatrombopag), extending into hematologic conditions associated with chronic liver disease. These products provide recurring revenue, strengthen our market relationships, and support our investment in an innovative pipeline.

Pulmonary Fibrosis

We are focused on commercializing therapies for the treatment of pulmonary fibrosis and working to solidify our position as a leader in this space.

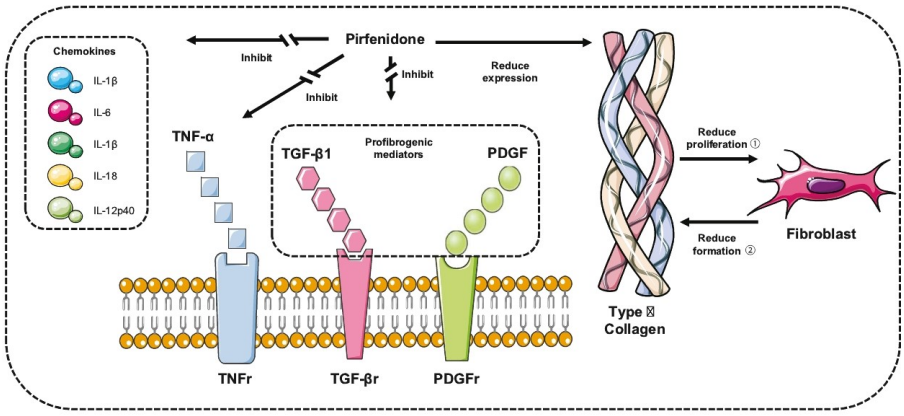
ETUARY® (pirfenidone)

Pirfenidone is a small-molecule anti-fibrotic therapy for the treatment of IPF. It was first approved in Japan and subsequently approved in the PRC, the European Union ("EU"), and the United States. These approvals were obtained by different sponsors in their respective jurisdictions under separate regulatory frameworks.

ETUARY® 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 ETUARY® (pirfenidone):



Source: Frost & Sullivan Analysis

In the PRC, we conducted independent research and development to support our regulatory submission and received first-in-class approval in 2011 as a National Category 1.1 New Drug. We commercialized pirfenidone under the brand name ETUARY®, which was included in the National Reimbursement Drug List ("NRDL") in 2017 and has since maintained a leading market position.

Clinical studies have demonstrated that pirfenidone inhibits transforming growth factor-β1 ("TGF-β1"), tumor necrosis factor-α ("TNF-α"), and other mediators associated with fibrosis and inflammation, and can slow the decline in lung function and disease progression in IPF patients. In 2025, ETUARY® generated annual sales of $106.1 million.

In addition to IPF, we are pursuing potential label expansion in the PRC into additional indications, including PD and RILI. We have completed enrollment of 272 patients in our 52-week Phase 3 trial evaluating ETUARY® for the treatment of PD. In March 2025, the NMPA approved our trial application for RILI, including cases with or without immune-related pneumonitis, and we expect to initiate an adaptive Phase 2/3 study in the first half of 2026.

Etorel® (nintedanib esilate soft capsules)

In May 2024, Gyre Pharmaceuticals entered into a comprehensive agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. to obtain the drug registration certificate for Etorel® (nintedanib) and become the marketing authorization holder in the PRC. Etorel® is approved as a standard-of-care therapy for IPF, systemic sclerosis-associated interstitial lung disease ("SSc-ILD"), and progressive fibrosing interstitial lung disease ("PF-ILD"). The addition of Etorel® to our commercial portfolio expanded treatment options for patients and strengthened Gyre's leading position in the pulmonary fibrosis market. Gyre Pharmaceuticals launched Etorel® in the PRC in June 2025 and generated $4.6 million in sales in 2025.

Hematology and Liver-Related Complications

We entered the hematology space to expand our presence in hospital-based specialty care and strengthen our engagement with hepatologists and related specialists in the PRC. This expansion enhances our commercial platform and supports our broader organ-focused development strategy.

Contiva® (avatrombopag maleate tablets)

In June 2021, Gyre Pharmaceuticals acquired avatrombopag maleate tablets pursuant to a transfer agreement with Nanjing Healthnice Pharmaceutical Technology Co., Ltd. Avatrombopag is an oral thrombopoietin receptor agonist. In June 2024, the NMPA approved avatrombopag maleate tablets for the treatment of thrombocytopenia ("TP") associated with chronic liver disease ("CLD") in adult patients undergoing elective diagnostic procedures or therapy. In January 2025, the NMPA approved an additional indication for chronic idiopathic thrombocytopenia ("ITP"). Gyre Pharmaceuticals launched avatrombopag under the brand name Contiva® in the PRC in March 2025 and generated $5.5 million in sales in 2025.

Our Product Candidate Pipeline

Hydronidone

Hydronidone is our lead development candidate for the treatment of liver fibrosis. It is a structurally modified derivative of pirfenidone designed to optimize metabolic properties while targeting the TGF-β1 signaling pathway, a key mediator of fibrogenesis.

We are developing Hydronidone for two primary indications: CHB-associated liver fibrosis in the PRC and MASH-associated liver fibrosis in the United States. Hydronidone represents our primary liver-focused development program and reflects our commitment to advancing therapies targeting both viral- and metabolic-associated liver fibrosis.

Hydronidone Mechanism of Action in CHB-Associated Liver Fibrosis

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. Hydronidone is expected to treat and reverse liver fibrosis in CHB by inhibiting the proliferation of hepatic stellate cells ("HSCs") and the TGF-ß1 signaling pathway.

Hydronidone Mechanism of Action in MASH-Associated Liver Fibrosis

Hydronidone is designed to treat liver fibrosis by inhibiting the activation of 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.

Hydronidone 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 Hydronidone were also confirmed in several established in vivo rodent models of liver fibrosis, such as carbon tetrachloride ("CCl4")-induced liver fibrosis mouse model, DMN-induced liver fibrosis rat model, and HSA-induced liver fibrosis rat model, as well as mouse model of MASH fibrosis (CCl4 + Western [High Fat] Diet). In the MASH mouse model, Hydronidone 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 CCl4 and WD-induced fibrosis and cell ballooning MASH models at doses of 15-50 mg/kg bid (corresponding to estimated human equivalent doses ("HEDs") of approximately 144–480 mg) which are relevant to human exposure. Thus, the key attributes of Hydronidone'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 MASH.

CHB-Associated Liver Fibrosis in the PRC

For CHB-associated liver fibrosis, antiviral therapy may suppress viral infection but is not able to prevent, slow or reverse fibrosis progression, and anti-fibrotic treatment is recommended for intermediate and advanced liver fibrosis and early-stage cirrhosis. As of December 31, 2025, no small molecule or biologic drugs treating CHB-associated liver fibrosis have been approved globally. In recognition of the severity of the disease and the preliminary clinical evidence generated to date, the Center for Drug Evaluation ("CDE") of the NMPA granted Hydronidone Breakthrough Therapy designation in March 2021.

We conducted a Phase 3 randomized, double-blind, placebo controlled, Entecavir-based, multi-center trial in the PRC assessing Hydronidone in CHB-associated liver fibrosis. This trial was designed to randomize 248 patients, with a primary endpoint of ≥1-stage reduction in Ishak fibrosis score at Week 52 for Hydronidone in combination with Entecavir.

In May 2025, we reported that in the pivotal Phase 3 trial, Hydronidone met its primary endpoint: 52.85% of treated patients achieved ≥1-stage fibrosis regression at Week 52, compared with 29.84% in the placebo group (p=0.0002), based on centralized, blinded Ishak histologic assessment. Hydronidone also met a key secondary endpoint with statistically significant inflammation improvement without fibrosis progression at Week 52 versus placebo. Hydronidone was well tolerated, with a comparable incidence of serious adverse events (4.88% vs. 6.45% in placebo) and no discontinuations due to adverse events in the Hydronidone group.

Following our pre-New Drug Application ("NDA") meeting in December 2025, the CDE indicated that the existing Phase 3 data support submission for conditional approval and potential priority review eligibility, subject to formal acceptance and approval by the NMPA. We currently expect to submit an NDA seeking conditional approval in the first half of 2026, subject to completion of regulatory and technical preparations.

MASH-Associated Liver Fibrosis in the United States

In the United States, we have completed a Phase 1 clinical trial in healthy volunteers evaluating Hydronidone's safety, tolerability, and pharmacokinetics ("PK"). We continue to engage with the FDA regarding IND requirements for a Phase 2 clinical trial in MASH-associated liver fibrosis. Pending regulatory feedback, we intend to file a U.S. IND in 2026 and, if the IND becomes effective, initiate a Phase 2 clinical trial.

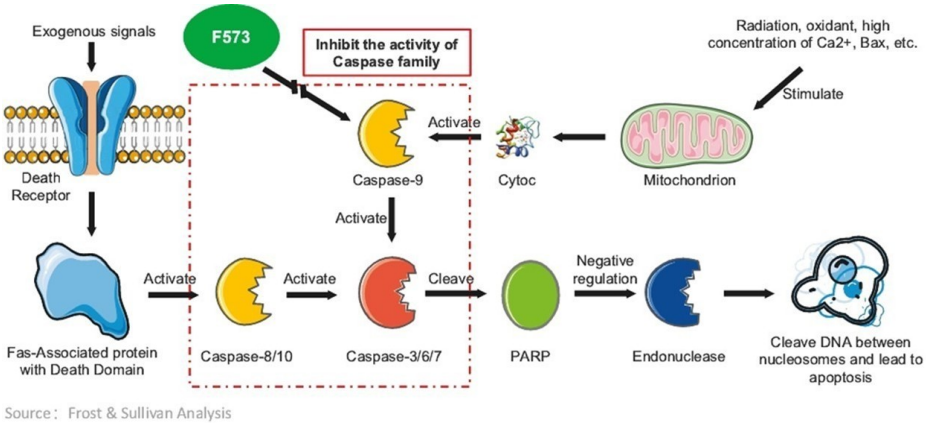
F573 for Acute Liver Failure (ALF) and Acute-on-Chronic Liver Failure (ACLF)

F573 is our clinical-stage product candidate for the treatment of ALF and ACLF in the PRC. F573 is a caspase inhibitor designed to reduce hepatocyte apoptosis and mitigate severe liver injury.

F573 Mechanism of Action in ALF/ACLF

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:



ALF/ACLF is associated with high morbidity and mortality and currently relies primarily on supportive care, artificial liver support systems and liver transplantation, highlighting the need for additional therapeutic options. F573 complements our broader liver-focused pipeline by targeting acute liver injury and liver failure, expanding our development efforts across multiple stages of liver disease progression.

We have completed a Phase 1 clinical trial of F573 in healthy volunteers in the PRC and are currently evaluating it in a multi-stage Phase 2 clinical trial initiated in March 2023 in patients with liver injury and liver failure.

F230 for Pulmonary Arterial Hypertension (PAH)

F230 is our clinical-stage product candidate for the treatment of PAH in the PRC. F230 is a selective endothelin receptor A antagonist designed to address vascular remodeling and elevated pulmonary arterial pressure associated with PAH. F230 complements our broader organ-focused portfolio by expanding our development efforts into pulmonary vascular disease while remaining aligned with our strategy of targeting fibrotic and inflammatory pathways across organ systems.

PAH is a rare, progressive and life-threatening disorder characterized by increased pressure in the pulmonary arteries, which can lead to right ventricular dysfunction and eventual heart failure. A key pathological feature of PAH is vascular remodeling, including thickening and stiffening of pulmonary arterial walls, resulting in restricted pulmonary blood flow. The disease is associated with poor prognosis and significant mortality if not effectively treated.

We submitted an IND application for F230 to the NMPA in March 2024, and the IND was approved in May 2024. The first subject was enrolled in the Phase 1 clinical trial in June 2025.

F528 for Chronic Obstructive Pulmonary Disease (COPD)

F528 is our preclinical-stage product candidate for the treatment of COPD in the PRC. F528 is an anti-inflammatory small-molecule compound designed to inhibit multiple inflammatory cytokines and potentially modify disease progression. F528 expands our pulmonary-focused development efforts beyond fibrosis and vascular disease into chronic inflammatory respiratory conditions, supporting our broader strategy of addressing organ diseases driven by inflammatory and fibrotic pathways.

COPD is a chronic inflammatory lung disease characterized by persistent airflow limitation and progressive decline in lung function. It encompasses conditions such as emphysema and chronic bronchitis and is commonly associated with long-term exposure to harmful particles or gases.

COPD represents a significant global health burden, with substantial morbidity and mortality. Current therapies are primarily aimed at symptom control and exacerbation reduction, and there remains a need for treatments that may slow long-term disease progression.

In preclinical studies, F528 demonstrated reductions in lung injury markers, including decreased lung index, reduced alveolar space enlargement and improved lung injury scores in animal models of COPD. We anticipate submitting an IND application to the NMPA for F528 in the first quarter of 2027.

Market Overview of Existing Commercial Portfolio and Label Expansion Opportunity

Idiopathic Pulmonary Fibrosis (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%. While lung scarring is irreversible, antifibrotic therapies may slow disease progression, preserve lung function, and improve quality of life.

According to Frost & Sullivan, the prevalence of IPF in the PRC increased from 89,144 patients in 2018 to 161,000 patients in 2024 at a compound annual growth rate (“CAGR”) of 10.24%, and it is expected to increase to 332,000 patients by 2032 at a CAGR of 9.42% from 2024 to 2032. The total market size of IPF in the PRC increased from $23.9 million in 2018 to $196.1 million in 2024 at a CAGR of 42%, and is expected to reach $789.5 million by 2032 at a CAGR of 19% from 2024 to 2032. Pirfenidone and nintedanib are conditionally recommended by international treatment guidelines with moderate-quality evidence.

Competition for ETUARY® in the PRC IPF Market

Sales of ETUARY® reached $106.1 million in 2025. Although ETUARY® remains a leading therapy in the IPF market, its market share has declined in recent periods primarily due to increased competition from other approved IPF therapies, including OFEV® (nintedanib), which generated $76.9 million in PRC sales in 2024.

Despite the recent decline in IPF market share, we continue to expect stable sales performance driven by sustained growth in IPF prevalence and potential future indication expansion of ETUARY® into additional fibrotic diseases, including PD and RILI.

We believe there are meaningful barriers to entry in the organ fibrosis market. Commercialization requires a specialized sales, marketing and medical distribution infrastructure, as go-to-market strategies for fibrosis therapies differ significantly from those for etiological treatments. In addition, long-term collaboration with KOLs and major treatment centers is critical for market education, product positioning, and patient recruitment.

Pneumoconiosis (PD)

PD 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. PD is widespread 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 PD increased from 873,000 patients in 2018 to 944,389 patients in 2024, and it is expected to increase to 975,000 patients by 2028 and 1,005,000 patients by 2032. The market size of anti-fibrosis drugs for PD is expected to reach $76.2 million by 2032 a CAGR of 52% from 2024 to 2032. As of December 31, 2025, no small-molecule or biologic product had been approved in the PRC for the treatment of PD.

Radiation-Induced Lung Injury (RILI) and Checkpoint Inhibitor Pneumonitis (CIP)

RILI and CIP are inflammatory and fibrotic pulmonary complications associated with oncology treatments.

According to Frost & Sullivan, in the PRC, the prevalence of RILI increased from 69,300 patients in 2018 to 91,800 patients in 2024, and it is expected to increase to 120,500 patients by 2032. The market size of drugs for RILI is $350.5 million and is expected to reach $495.6 million by 2032 with a CAGR of 4.43% from 2024 to 2032. The prevalence of CIP increased from 142,700 patients in 2018 to 210,800 patients in 2024, and it is expected to increase to 344,500 patients by 2032 in the PRC. The market size of drugs for CIP is $392.1 million in 2024 and is expected to reach $676.3 million by 2032 with a CAGR of 7.05% from 2024 to 2032.

Market Overview of Pipeline Products

Hydronidone for CHB-Associated Liver Disease in the PRC

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 hepatocellular carcinoma ("HCC"), without intervention. In the PRC, about 70% of cirrhosis cases 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 228.9 million patients in 2018 to 272.2 million patients in 2024. The prevalence of CHB-associated liver fibrosis in the PRC from 2018 to 2024 ranges from 65.9 million to 62.6 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 $144.8 million in 2018 to $174.1 million in 2024 with a CAGR of 3.12%. We expect the market to grow to $817.2 million in 2032, at a CAGR of 21.32%.

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, 2025, no chemical or biological drugs treating CHB-associated liver fibrosis have been approved globally. 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, Hydronidone is the most clinically advanced product candidate in the PRC that has the potential to effectively reverse the fibrosis process.

F351 (Hydronidone) for MASH-Associated Liver Disease in the U.S.

MASH, a severe form of 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 HCC.

MASH 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 MASLD, which affects approximately 25% of the global population, and MASH, which develops in approximately 20% to 30% of MASLD patients, is driven primarily by the worldwide obesity epidemic. As a result, the prevalence of MASH 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 MASH include reduced ability to metabolize clear lipids, increased insulin resistance, injury to hepatocytes and liver fibrosis in response to hepatocyte injury. MASH 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 MASH can contain more than 20% fat. This abnormal liver fat contributes to the progression to MASH, a liver necro-inflammatory state, which 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. MASH is a complex, multifaceted disease that does not just affect the liver. Patients with MASH 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.

Competition for MASH-Associated Liver Fibrosis in the U.S.

The biopharmaceutical industry is highly competitive and characterized by rapid innovation and significant technological advancements. We believe the key competitive factors that will affect the development and commercial success of Hydronidone and any future product candidates include efficacy, safety and tolerability profile, reliability, dosing convenience, pricing, 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 prevalence of MASH, we expect continued investment and increasing competition in the development of therapies for liver and cardiometabolic diseases, including MASH.

If Hydronidone is approved for the treatment of MASH-associated liver fibrosis, future competition could arise from five main classes of drugs aiming to reach the market in the current MASH 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 MASH 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, a 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. (which was acquired by Roche in 2025); 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, and an FGFR1/KLB agonist antibody from Genentech.

F573 for Acute Liver Failure (ALF) and Acute-on-Chronic Liver Failure (ACLF) in the PRC

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 symptoms 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.

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.

According to Frost & Sullivan, the prevalence of ALF/ACLF in the PRC was 42,440 patients in 2018 and 37,050 patients in 2024 and is expected to be 29,020 patients in 2032. The market size of ALF/ACLF in the PRC was $274.2 million in 2018 and $240.6 million in 2024 and it is expected to be $191.1 million in 2032. While prevalence and market size are projected to decline, ALF/ACLF remains a severe condition with significant unmet medical need and limited treatment options, and we believe it continues to represent a meaningful commercial opportunity.

F230 for Pulmonary Arterial Hypertension (PAH) in the PRC

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. 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 50,600 patients in 2018 to 61,700 patients in 2024 and it is expected to increase to 71,300 patients by 2032. The market size of PAH in the PRC increased from $310 million in 2018 to $400 million in 2024 and it is expected to increase to $480 million by 2032 with 2.28% CAGR from 2024 to 2032.

F528 for Chronic Obstructive Pulmonary Disease (COPD) in the PRC

COPD is a chronic, progressive inflammatory lung disease characterized by persistent airflow limitation. It includes conditions such as emphysema and chronic bronchitis and is associated with destruction of alveolar structures and airway inflammation. COPD typically develops over many years and is often diagnosed at later stages of disease progression.

Current COPD treatments primarily focus on symptom management and reduction of exacerbations. There remains limited clinical evidence demonstrating meaningful modification of long-term lung function decline, and significant unmet medical need persists, particularly in patients with moderate to severe disease.

According to Frost & Sullivan, the prevalence of COPD in the PRC increased from 103.5 million patients in 2018 to 108.4 million patients in 2024 and is projected to reach 118.7 million patients by 2032. The COPD pharmaceutical market in the PRC grew from $880 million in 2018 to $1.13 billion in 2024 and is expected to reach $1.62 billion by 2032, representing a CAGR of 4.66% from 2024 to 2032.

Clinical Development

Hydronidone's Clinical Trials in MASH-Associated Liver Fibrosis

Phase 1 U.S. Clinical Trial of Hydronidone for MASH-Associated Liver Fibrosis

We have completed a Phase 1 clinical trial evaluating the safety, tolerability, and PK of single and multiple doses of Hydronidone in healthy volunteers in the United States. The trial generated bridging data to previously obtained PK data in healthy volunteers in the PRC. This Phase 1 clinical trial was conducted under an IND application that was filed in 2016 for Hydronidone as an anti-fibrotic agent targeting liver fibrosis associated with a spectrum of chronic liver diseases.

In Part I of the trial, single oral doses of Hydronidone (30 mg or 120 mg) were rapidly absorbed and demonstrated a linear PK exposure pattern. The mean elimination half-life of Hydronidone was approximately five to six hours, and five to seven hours for its M3 and M4 metabolites.

In Part II of the trial, repeated oral doses of Hydronidone (30 mg or 120 mg three times daily) were administered for seven consecutive days. Hydronidone exhibited PK characteristics consistent with those observed following single-dose administration, including rapid absorption and similar half-life. Modest accumulation (less than 1.5-fold) was observed for Hydronidone, M3 and M4 following repeated dosing. Dose-normalized Cmax and AUC values were comparable between male and female subjects.

Hydronidone was generally well tolerated following both single and repeated dosing. There were no premature discontinuations due to adverse events ("AEs"), no serious adverse events, and no deaths reported in the trial. Treatment-emergent AEs reported following single-dose administration included one case of rhinorrhea and scattered, isolated, reversible laboratory abnormalities. Following repeated-dose administration, reported treatment-emergent AEs included headache (25.0%), constipation (16.7%), and somnolence (12.5%). Abdominal discomfort and flatulence were each reported in one subject. There were no clinically significant changes in safety laboratory parameters attributable to the trial drug, including no evidence of significant drug-induced liver injury, and no clinically significant changes in vital signs, electrocardiogram parameters, or physical examinations attributable to Hydronidone.

Anticipated Phase 2 U.S. Clinical Trial of Hydronidone for MASH-Associated Liver Fibrosis

We continue to engage with the U.S. FDA regarding the IND requirements for a Phase 2 clinical trial evaluating Hydronidone for the treatment of MASH-associated liver fibrosis. Pending regulatory feedback, we intend to file a new U.S. IND in 2026 and, if the IND becomes active, initiate a Phase 2 clinical trial.

The objective of the planned Phase 2 clinical trial is to obtain preliminary proof-of-concept data in subjects with MASH-associated liver fibrosis to inform potential advancement into a broader Phase 2/3 development program. The proposed trial will be conducted under a new IND to reflect the distinct risk-benefit considerations in a MASH patient population.

To support the IND submission, we intend to cross-reference applicable nonclinical and clinical data generated under the currently active U.S. IND, as well as data from prior clinical studies conducted in the PRC. These data are expected to contribute to the overall clinical and safety package supporting the proposed Phase 2 trial.

Hydronidone Manufacturing and Supply

The manufacturing of Hydronidone active pharmaceutical ingredients ("API") and drug product required to support the planned Phase 2 clinical trial will be completed by WuXi STA, located in the PRC. The API and drug product will be manufactured in accordance with current Good Manufacturing Practice ("cGMP") requirements, and batch release and stability testing will be conducted in compliance with applicable regulatory standards.

In light of the legislation commonly referred to as the BIOSECURE Act, enacted on December 18, 2025, we are actively monitoring potential implications for our manufacturing and supply chain arrangements. We have implemented measures to enhance supply chain flexibility and are evaluating contingency plans, including identifying alternative contract development and manufacturing organizations that could support future U.S. clinical supply, if necessary. We will continue to assess geopolitical and regulatory developments and implement additional mitigation measures as appropriate. 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.*"

PRC Clinical Trial of pirfenidone for the treatment of PD

Phase 3 Trial

We are conducting a Phase 3 trial in the PRC of pirfenidone for the treatment of PD, for which we completed enrollment in 2025. A total of 272 patients have been enrolled in this multicenter, randomized, double-blind, placebo-controlled trial, which is being conducted at 18 clinical research centers across the PRC. The trial is designed to evaluate the efficacy and safety of 52 weeks of pirfenidone capsule treatment in patients with PD.

PRC Clinical Trial of F573 for the treatment of ALF/ACLF

Phase 1 Trial

We initiated the Phase 1 clinical trial of F573 in January 2022 to evaluate the safety, tolerability and PK of single and multiple ascending doses in healthy volunteers. A total of 100 healthy subjects were enrolled, and the study was completed in July 2022.

Across the evaluated dose range of 0.5 mg/kg to 2.0 mg/kg, Cmax was not dose-proportional, while area under the concentration-time curve (AUC_{0}–t and AUC_{0}–∞) demonstrated linear PK. Differences in absorption rate were observed between male and female subjects. F573 was administered once daily for seven consecutive days, with no evidence of drug accumulation.

Phase 2 Trial

We initiated the Phase 2 clinical trial of F573 in March 2023 to evaluate the efficacy and safety of F573 for injection in patients with liver injury or liver failure. The Phase 2 program is designed in three stages:

- *First Stage*: A total of 16 patients with grade 1 or 2 drug-induced liver injury (“DILI”) or other liver injury and 9 patients with CHB were enrolled. Patients with DILI or other liver injury were randomized in a 1:1:1:1 ratio to receive F573 at doses of 0.5 mg/kg, 1.0 mg/kg, 2.0 mg/kg, or placebo. CHB patients received F573. The first stage was completed in December 2024.
- *Second Stage*: An additional 24 patients with liver injury (including DILI and intrahepatic cholestatic liver injury) are expected to be enrolled. Eligible subjects will be randomized in a 3:1 ratio to receive F573 or placebo once daily for 14 consecutive days. Based on a review of efficacy and safety data from the first stage, the planned dose levels are 0.5 mg/kg and 2.0 mg/kg. The 0.5 mg/kg cohort (12 subjects) will be conducted first, followed by the 2.0 mg/kg cohort (12 subjects).
- *Third Stage*: The third stage is expected to employ a randomized, double-blind, placebo-controlled design. The study will include a 14-day screening period, a treatment period of 7 days (with dosing encouraged to extend to 14 days), and a follow-up period of up to 90 days. Three sequential dose cohorts are planned at 0.5 mg/kg, 2.0 mg/kg and 2.7 mg/kg. In each of the first three cohorts, 16 eligible subjects will be randomized in a 3:1 ratio to receive F573 or placebo once daily for 7 consecutive days (with dosing encouraged to extend to 14 days). Enrollment of the subsequent cohort may begin after completion of dosing in the prior cohort. After completion of the first three dose cohorts, a fourth cohort of 16 subjects is planned. Subjects in this cohort will be randomized in a 1:1 ratio to receive F573 for either a 7-day or 14-day treatment course. The dose level will be determined based on a comprehensive evaluation of efficacy and safety data from the first three cohorts.

PRC Clinical Trial of F230 for the treatment of PAH

Preclinical Data

In a preclinical study using a hypoxia-induced PAH rat model, treatment with F230 was associated with reductions in mean pulmonary arterial pressure, right ventricular systolic pressure, right ventricular hypertrophy index (right ventricle/(left ventricle plus septum)), and pulmonary artery wall thickness across evaluated dose groups. At the minimum effective dose tested, these parameters were statistically different from those observed in the untreated PAH control group.

Phase 1 Trial

In March 2024, we submitted an IND application for F230 to the NMPA in the PRC, which was approved In May 2024. The first subject in the Phase 1 clinical trial of F230 was enrolled in May 2025.

The Phase 1 clinical program consists of three components: a single ascending dose ("SAD") study, a multiple ascending dose ("MAD") study, and a food-effect study.

The SAD portion is a randomized, double-blind, placebo-controlled, single-center dose-escalation study designed to evaluate the safety, tolerability and PK of single oral doses of F230 in healthy volunteers. Six dose cohorts are planned, with cohort sizes ranging from 8 to 14 subjects and randomization ratios of 3:1 or 6:1 (F230:placebo). Subjects receive a single oral dose under fasting conditions.

The MAD portion evaluates repeated oral dosing for seven consecutive days using a randomized, double-blind, placebo-controlled design. Three dose levels (6 mg, 12 mg and 20 mg) are planned, with 14 subjects per cohort randomized 6:1 (F230:placebo), for a total planned enrollment of 42 subjects.

The food-effect portion is a randomized, open-label, two-period crossover study designed to assess the impact of food on the PK profile of F230. Sixteen healthy volunteers will receive F230 under both fasting and fed (high-fat meal) conditions, separated by an approximately 72-hour washout period. Safety and PK assessments will be conducted in accordance with the study protocol.

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 18 granted patents globally, four pending patent applications in the United States, four pending Patent Cooperation Treaty ("PCT") patent applications, and 29 pending foreign patent applications in Europe, Australia, Canada, China, Israel, South Korea, Mexico, India, New Zealand, and Japan that are material to our business. As of the date of this Annual Report, we are the owner of all the patents and patent applications that 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. 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 Canada, Europe, Japan, China, and the U.S.

For our Hydronidone programs, as of the date of this Annual Report, our patent portfolio includes two pending U.S. patent applications, three PCT applications, as well as issued and pending foreign patents and patent applications in Europe, Australia, Canada, China, Israel, South Korea, Mexico, India, New Zealand, and Japan. A majority of the pending patent applications relate to use of Hydronidone for the treatment of various diseases, including CHB-associated liver fibrosis, MASH and MASH fibrosis, kidney fibrosis, and pulmonary fibrosis. These pending patent applications, if issued, would be expected to expire between 2041 to 2046, subject to possible patent term adjustment and/or extension. Gyre also owns issued patents in Japan and pending patent applications in China expiring or expected to expire in 2028 to 2037 that relate to methods of making Hydronidone. In addition, Gyre owns an issued patent in China expiring in 2041 that relates to a novel crystal form of Hydronidone and preparation method therefor.

For F573, as of the date of this Annual Report, Gyre owns three granted patents in China, one pending U.S. patent application, one PCT application, as well as pending patent applications in China, Europe, Japan, and South Korea. These patents and patent applications, which expire or are expected to expire in 2031 - 2044, subject to possible patent term adjustment and/or extension, generally relate to the F573 composition, preparation methods therefor, and uses thereof, for example for improving liver function in liver failure patients.

For F528, as of the date of this Annual Report, Gyre owns one issued patent in each of the PRC and Japan, and pending patent applications in Europe and the U.S. These patents and patent applications expire or are expected to expire in 2040 and relate to F528 compositions and uses thereof, or example for treating chronic respiratory diseases.

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 Hydronidone 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, 2025, we own four registered artwork copyrights, 28 registered software copyrights and 65 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 six countries and regions including the EU and Japan. As of the same date, we also hold 44 active domain names.

Our Business Operations in the United States: Gyre Therapeutics, Inc.

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 Hydronidone for the treatment MASH-associated liver fibrosis.

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, 2025, we had seven full-time employees in the United States. 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 a business combination to acquire an indirect controlling interest in Gyre Pharmaceuticals and became Gyre Therapeutics, Inc. Our corporate headquarters are in San Diego, California. We conduct 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 is not incorporated into, and is not considered part of, this filing.

Government Regulation in the United States

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drug products such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or post-marketing may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications from the sponsor, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our company and our products or product candidates.

U.S. Drug Regulation

In the United States, drugs are subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA") and other federal, state, local, and foreign statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative action and judicial sanctions. The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent institutional review board ("IRB"), or ethics committee at each clinical site before the trial is commenced;
- manufacture of the proposed drug candidate in accordance with cGMPs;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice ("GCP") requirements to establish the safety and efficacy of the proposed drug product candidate for its intended purpose;
- preparation of and submission to the FDA of an NDA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of an NDA to file the application for review;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the drug product's continued safety and efficacy, and of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of an NDA to permit commercial marketing of the product for particular indications for use in the United States.

Preclinical and Clinical Development

Prior to beginning any clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol or protocols for preclinical studies and clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, PK, pharmacology and pharmacodynamic characteristics of the product, chemistry, manufacturing and controls information, and any available human data or literature to support the use of the investigational product. In April 2025, the FDA published a roadmap to reduce animal testing in preclinical safety studies, including those required in INDs, with scientifically validated new approach methodologies. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing preclinical studies and clinical trials and clinical study results to public registries.

For purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1. The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2. The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3. The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the NDA. Concurrently with clinical trials, companies may complete additional animal studies and develop additional information about the pharmacological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain 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.

NDA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. The NDA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the product, or from a number of alternative sources, including studies initiated and sponsored by investigators. The submission of an NDA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the biological product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a drug product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial pediatric study plan within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any drug product for an indication for which orphan designation has been granted, except that the PREA will apply to an original NDA for a new active ingredient that is orphan-designated if the drug is a molecularly targeted cancer product intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer.

Within 60 days following submission of the application, the FDA reviews an NDA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA must be resubmitted with the additional information. Once an NDA has been accepted for filing, the FDA's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Before approving an NDA, the FDA will typically 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 cGMP requirements and adequate to ensure 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 GCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, 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 will describe all of the deficiencies that the FDA has identified in the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the NDA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a REMS to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre-and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. The fast track program is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and data demonstrate the potential to address unmet medical needs for the disease or 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 fast track product has opportunities for more frequent interactions with the review team during product development and, once an NDA is submitted, the product may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. 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. Products receiving accelerated approval may be subject to expedited withdrawal procedures 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 as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

A product intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, 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 includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any marketing application for a drug submitted to the FDA for approval, including a product with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if there is evidence it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition. For original NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to ten months under standard review).

Fast track designation, breakthrough therapy designation, and priority review do not change the standards for approval but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act of 1983, the FDA may grant orphan drug designation to a product candidate 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, or 200,000 or more individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that product candidate. 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. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA, to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety or providing a major contribution to patient care or if the holder of the orphan drug exclusivity cannot assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan drug designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

There is some uncertainty with respect to the FDA's interpretation of the scope of orphan drug exclusivity. Historically, exclusivity was specific to the orphan indication for which the drug was approved. As a result, the scope of exclusivity was interpreted as preventing approval of a competing product. However, in 2021, the federal court in Catalyst Pharmaceuticals, Inc. v. Becerra suggested that orphan drug exclusivity covers the full scope of the orphan-designated "disease or condition" regardless of whether a drug obtained approval for a narrower use.

Combination Therapy

Combination therapy is a treatment modality that involves the use of two or more drugs to be used in combination to treat a disease or condition. If those drugs are combined in one dosage form, such as one pill, it is known as a fixed dose combination product and it is reviewed pursuant to the FDA's Combination Rule at 21 CFR 300.50. The rule provides that two or more drugs may be combined in a single dosage form when each component contributes to the claimed effects and the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug.

But not all combination therapy falls under the category of a fixed dose combination. For example, the FDA recognizes that two drugs in separate dosage forms and in separate packaging, that otherwise might be administered as monotherapy for an indication, also may be used in combination for the same indication. In 2013, the FDA issued guidance to assist sponsors that were developing the range of combination therapies that fall outside the category of fixed dose combinations. That guidance provides recommendations and advice on such topics as: (1) assessment at the outset whether two or more therapies are appropriate for use in combination; (2) guiding principles for nonclinical and clinical development of the combination; (3) options for regulatory pathways to seek marketing approval of the combination; and (4) post-marketing safety monitoring and reporting obligations. Given the wide range of potential combination therapy variations, the FDA indicated it intends to assess each potential combination on a case-by case basis and encouraged sponsors to engage in early and regular consultation with the relevant review division at the agency throughout the development process for its proposed combination.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of 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 user fee requirements, under which the FDA assesses an annual program fee for each product identified in an approved NDA. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented.

FDA regulations also require investigation and correction of any deviations from cGMPs and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drugs. A company can make only those claims relating to safety and efficacy that are approved by the FDA 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. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Abbreviated New Drug Applications for Generic Drugs

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. Upon approval of an ANDA, the FDA indicates that the generic product is "therapeutically equivalent" to the drug product previously approved under an NDA, known as the reference listed drug ("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.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of nonpatent exclusivity for the RLD has expired. The FDCA provides a period of five years of data exclusivity for NDAs containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification (discussed further below), in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30 Month Stay

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. 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.

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.

505(b)(2) New Drug Applications

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 Extension

In the U.S., after an NDA is approved, owners of relevant drug patents may apply for up to a five-year patent extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory process. The allowable patent term extension is typically calculated as one-half the time between, the latter of the effective date of an IND and issue date of the patent for which extension is sought, and the submission date of an NDA, plus the time between NDA submission date and the NDA approval date up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue licensure with due diligence. The total patent term after the extension may not exceed 14 years from the date of product approval. Only one patent applicable to an approved drug product is eligible for extension and only those claims covering the product, a method for using it, or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent in question. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Some, but not all, foreign jurisdictions possess patent term extension or other additional patent exclusivity mechanisms that may be more or less stringent and comprehensive than those of the U.S.

Other U.S. Healthcare Laws and Compliance Requirements

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation: the federal Anti-Kickback Statute ("AKS"); the federal False Claims Act ("FCA"); the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar foreign, federal and state fraud, abuse and transparency laws.

The AKS prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under any federal healthcare program. The term remuneration has been interpreted broadly to include anything of value. The AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand, and prescribers and purchasers on the other. The government often takes the position that to violate the AKS, only one purpose of the remuneration need be to induce referrals, even if there are other legitimate purposes for the remuneration. There are a number of statutory exceptions and regulatory safe harbors protecting some common commercial activities from AKS prosecution, but they are drawn narrowly and practices that involve remuneration, such as consulting agreements, for persons in a position to refer or recommend federally reimbursable healthcare business may be alleged to be intended to induce prescribing, purchasing or recommending, and may be subject to scrutiny if they do not qualify for an exception or regulatory safe harbor. Qualifying for a statutory exception or regulatory safe harbor requires satisfying all of the criteria for the exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS, but it does increase the risk of regulatory scrutiny. Ultimately, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The FCA, which can be enforced through civil whistleblower or qui tam actions, prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of federal government funds, including in federal healthcare programs, that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for engaging in a variety of different types of conduct that caused the submission of false claims to federal healthcare programs. Under the AKS, for example, a claim resulting from a violation of the AKS is deemed to be a false or fraudulent claim for purposes of the FCA.

HIPAA created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private third-party payors, and making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate the statute in order to have committed a violation.

The FDCA addresses, among other things, the design, production, labeling, promotion, manufacturing, and testing of drugs, biologics and medical devices, and prohibits such acts as the introduction into interstate commerce of adulterated or misbranded drugs or devices. The PHSA also prohibits the introduction into interstate commerce of unlicensed or mislabeled biological products.

The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicaid & Medicare Services (“CMS”) information related to payments or other transfers of value to various healthcare professionals including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, certified nurse-midwives, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning on January 1, 2023, California Assembly Bill 1278 requires California physicians and surgeons to notify patients of the Open Payments database established under the federal Physician Payments Sunshine Act.

We are also subject to federal price reporting laws and federal consumer protection and unfair competition laws. Federal price reporting laws require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/ or discounts on approved products. Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

We are also subject to additional similar U.S. state and foreign law equivalents of each of the above federal laws, which, in some cases, differ from each other in significant ways, and may not have the same effect, thus complicating compliance efforts. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations.

Data Privacy and Security

Numerous state, federal, and foreign laws govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations, govern the collection, use, disclosure, and protection of health-related and other personal information and could apply to our operations or the operations of our partners.

For example, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and their respective implementing regulations impose data privacy, security, and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates and their covered subcontractors that perform certain services that involve using, disclosing, creating, receiving, maintaining, or transmitting individually identifiable protected health information (“PHI”) for or on behalf of such covered entities. These requirements imposed by HIPAA and HITECH on covered entities and business associates include entering into agreements that require business associates protect PHI provided by the covered entity against improper use or disclosure, among other things; following certain standards for the privacy of PHI, which limit the disclosure of a patient’s past, present, or future physical or mental health or condition or information about a patient’s receipt of health care if the information identifies, or could reasonably be used to identify, the individual; ensuring the confidentiality, integrity, and availability of all PHI created, received, maintained, or transmitted in electronic form, to identify and protect against reasonably anticipated threats or impermissible uses or disclosures to the security and integrity of such PHI; and reporting of breaches of PHI to individuals and regulators.

Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with the Department of Health and Human Services ("HHS") to settle allegations of HIPAA non-compliance. A covered entity or business associate is also liable for civil money penalties for a violation that is based on an act or omission of any of its agents, which may include a downstream business associate, as determined according to the federal common law of agency. HITECH also increased the civil and criminal penalties applicable to covered entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions. To the extent that we submit electronic healthcare claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and HITECH, payments to us may be delayed or denied.

In addition, state health information privacy laws, such as California's Confidentiality of Medical Information Act and Washington's My Health My Data Act, that govern the privacy and security of health-related information, specifically, may apply even when HIPAA does not and impose additional requirements.

Even when HIPAA and state health information privacy laws do not apply, according to the FTC and state attorneys general, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act and state consumer protection laws.

In addition, certain state laws, such as the California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020, govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA in various ways. Numerous other states have passed similar laws, but many differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. The CCPA applies to personal data of consumers, business representatives, and employees, and imposes obligations on certain businesses that do business in California, including providing specific disclosures in privacy notices, and affords rights to California residents in relation to their personal information. Health information falls under the CCPA's definition of personal information where it identifies, relates to, describes, or is reasonably capable of being associated with or could reasonably be linked, directly or indirectly, with a particular consumer or household and is included under a new category of personal information, "sensitive personal information," which is offered greater protection. The CCPA and numerous other comprehensive privacy laws that have passed or are being considered in other states, as well as at the federal and local levels, exempt PHI that is subject to HIPAA; and others exempt covered entities and business associates subject to HIPAA altogether, further complicating compliance efforts, and increasing legal risk and compliance costs for us and the third parties upon whom we rely.

Additionally, our use of artificial intelligence and machine learning may be subject to laws and evolving regulations regarding the use of artificial intelligence and machine learning, controlling for data bias, and antidiscrimination.

Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and Reimbursement

In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates 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. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow it to establish or maintain pricing sufficient to realize a sufficient return on its investment. 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.

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological product for which we obtain regulatory approval. Sales of any product, if approved, depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state, and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement, if any, for such product by third-party payors. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- cost-effective; and
- neither experimental nor investigational.

Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product that receives approval. Decreases in third-party reimbursement for any product or a decision by a third-party not to cover a product could reduce physician usage and patient demand for the product.

For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. The Inflation Reduction Act of 2022 (the "IRA") provides CMS with significant new authorities intended to curb drug costs and to encourage market competition. For the first time, CMS will be able to directly negotiate prescription drug prices and to cap out-of-pocket costs. Each year, CMS will select and negotiate a preset number of high-spend drugs and biologics that are covered under Medicare Part B and Part D that do not have generic or biosimilar competition. On August 29, 2023, HHS announced the list of the first ten drugs subject to price negotiations. These price negotiations occurred in 2024. In January 2025, CMS announced a list of 15 additional Medicare Part D drugs that will be subject to price negotiations. The IRA also provides a new "inflation rebate" covering Medicare patients that took effect in 2023 and is intended to counter certain price increases in prescriptions drugs. The inflation rebate provision requires drug manufacturers to pay a rebate to the federal government if the price for a drug or biologic under Medicare Part B and Part D increases faster than the rate of inflation. To support biosimilar competition, beginning in October 2022, qualifying biosimilars may receive a Medicare Part B payment increase for a period of five years. Separately, if a biologic drug for which no biosimilar exists delays a biosimilar's market entry beyond two years, CMS will be authorized to subject the biologics manufacturer to price negotiations intended to ensure fair competition. In addition, an executive order issued by the White House on May 12, 2025, [directs the HHS to implement a "Most Favored Nation" drug pricing policy], and the recently-enacted One Big Beautiful Bill Act ("OBBBA") imposes new restrictions on funding for government health care programs and on individual eligibility for coverage under those programs, which may lead to lower reimbursements for drugs covered by those programs. More recently, HHS has begun announcing new drug payment models to lower drug prices for government health care program beneficiaries, such as the GUARD and GENEROUS models announced by the agency in late 2025. These models would use the prices other countries pay for drugs as benchmarks for determining whether manufacturers are required to offer additional rebates. Notwithstanding these provisions, the IRA's impact on commercialization and competition remains largely uncertain.

In addition, 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 U.S. 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. We cannot be sure that reimbursement will be available for any product candidate that we may commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Finally, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

The ACA, which was enacted in March 2010, substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program.

Other legislative changes have been proposed and adopted since the ACA was enacted, including automatic aggregate reductions of Medicare payments to providers of on average 2% per fiscal year as part of the federal budget sequestration under the Budget Control Act of 2011. These reductions went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2032 unless additional action is taken by Congress. In addition, the Bipartisan Budget Act of 2018, among other things, amended the Medicare Act (as amended by the ACA) to increase the point-of-sale discounts that manufacturers must agree to offer under the Medicare Part D coverage discount program from 50% to 70% off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs being covered under Medicare Part D.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state measures designed to, among other things, reduce the cost of prescription drugs, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, in May 2019, CMS adopted a final rule allowing Medicare Advantage Plans the option to use step therapy for Part B drugs, permitting Medicare Part D plans to apply certain utilization controls to new starts of five of the six protected class drugs, and requiring the Explanation of Benefits for Part D beneficiaries to disclose drug price increases and lower cost therapeutic alternatives, which went into effect on January 1, 2021. In May 2025, the Trump Administration renewed the idea of international reference pricing through an executive order entitled "Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients," which, among other things, directs the HHS and other agencies to communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for U.S. patients in line with comparably developed nations and to facilitate direct-to-consumer purchasing programs. The HHS subsequently issued guidance indicating the MFN target price will be the lowest price paid in an Organisation for Economic Co-operation and Development country with a gross domestic product ("GDP") per capita of at least 60% of the U.S. GDP per capital. In addition, in December 2025, CMS proposed new drug payment models to lower drug prices for Medicare beneficiaries; under the models, CMS would explore potential adjustments to Medicare drug inflation rebate calculations by comparison to international drug pricing information. It is currently unclear whether and to what extent these measures will be implemented and what impact any such implementation would have on our business.

Notwithstanding the IRA, continued legislative and enforcement interest exists in the United States with respect to specialty drug pricing practices. Specifically, we expect government authorities to continue pushing for transparency to drug pricing, reducing the cost of prescription drugs under Medicare, reviewing the relationship between pricing and manufacturer patient programs, and reforming government program reimbursement methodologies for drugs.

Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for its drugs or put pressure on its drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

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.

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.

We are 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®.

Through in-house R&D efforts and collaborative arrangements with GNI Group, Ltd. ("GNI Japan"), we have developed, in addition to ETUARY®, a pipeline of pharmaceutical product candidates at various phases of clinical development, including Hydronidone, F528, F230 and F573.

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.

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.*"

Employees in the PRC

As of December 31, 2025, we had 618 total employees, including 172 employees in Beijing, 43 employees in Cangzhou and 403 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, 2025 and 2024.

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, 2025, 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, 2025, 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.

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, 2025, we have received all material permissions and approvals required for our business operations. As of December 31, 2025, 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	August 2025 – July 2030	Beijing Medical Products Administration
Registration of Network Information Service for Drugs and Medical Devices	August 26, 2025	Beijing Medical Products Administration
Zhongguancun High-tech Enterprise	December 2024 – December 2027	Administrative Commission of Zhongguancun Science Park
High-tech Enterprise Certificate	October 2025 – October 2028	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)	Valid until August 2028	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 66 employees in the PRC as of December 31, 2025. 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 and 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 year ended December 31, 2025, 100% of ETUARY® 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 of 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, 2025, 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, 2025, our in-house sales and marketing team included 405 employees, with an average of more than ten 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 in the PRC*" 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 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 include 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—Government Regulations in the PRC —Regulations Relating to the Development, Manufacture and Sale of Pharmaceuticals—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 PRC 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 January 1, 2026. For further details, see *"—Our Operations in the PRC: Gyre Pharmaceuticals—Government Regulations in the PRC —Regulations Relating to the Development, Manufacture and Sale of Pharmaceuticals—National Medical Insurance, its Reimbursement Standards and the NRDL."*

Two-Invoice System

On December 26, 2016, the Healthcare Reform Committee of the State Council of the PRC, the former National Health and Family Planning Commission (the "NHFC"), the National Development and Reform Commission of the PRC and other relevant PRC 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—Government Regulations in the PRC —Regulations Relating to the Development, Manufacture and Sale of Pharmaceuticals—Drug Distribution and Two-Invoice System*." To comply with these 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.

Government Regulations 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 R&D activities and require the expenditure of substantial time and financial resources.

Principal Regulatory Authorities

The primary drug regulatory bodies in the PRC include 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, the National Health Commission (the "NHC"), the predecessor of which is the NHFC, 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.

Regulations Relating to the Development, Manufacture and Sale of Pharmaceuticals

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 PRC Drug Administration Law (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 Chinese drugs, chemical drugs and biological products. The Drug Administration Law and the Implementing Regulations of the PRC Drug Administration Law 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 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 provincial counterparts of the NMPA 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, and the validity of such certification is five years.

The Administrative Regulations on Laboratory Animals, the Administrative Measures on Good Practice of Experimental Animals and the Administrative Measures on the Certificate for Laboratory Animals (for Trial Implementation) stipulate that permits shall be obtained for the use and breeding of laboratory animals and performing experimentation on animals.

Approval and Reform for Clinical Trials of New Drugs

Under the Administrative Measures for Drug Registration, the Drug Administration Law and the Implementing Regulations of the PRC Drug Administration Law, NDAs 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 an 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 on Several Policies on the Evaluation and Approval of Drug Registration further simplifies the evaluation and approval process of drug registrations and provides that the process of an IND application is subject to a one-off umbrella approval procedure, rather than a by-stage approval procedure. According to the Announcement on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs, within 60 days after the acceptance of the IND application and the payment of the associated fees, the applicant may conduct 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 clarifies that a fast-track mechanism for the review and approval during the drug registration process can be available to innovative drugs that meet certain criteria.

Regarding International Multi-Center Clinical Trials

Pursuant to the International Multi-Center Drug Clinical Trial Guidelines (for Trial Implementation), promulgated by the NMPA, international multi-center drug clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement international multi-center clinical trials in the PRC, the applicants must comply with the Drug Administration Law, the Implementing Regulations of the PRC Drug Administration Law and the Administrative Measures for Drug Registration. Additionally, applicants must abide by 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 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 the relevant 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 Communication with the CDE

According to the Administrative Measures for Drug Registration, a clinical trial consists of Phase 1, 2, 3 and 4 trials and a 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 R&D 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 R&D of breakthrough therapeutic drugs. Type II meetings are held during the key R&D periods of drugs, and mainly include meetings before the IND, 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

The Administrative Regulations on Human Genetic Resources of the PRC 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 participating entities must file the type, quantity and usage of the human genetic resource to be used with the NHC before clinical trials commence.

On June 1, 2023, The Ministry of Science and Technology of the PRC promulgated the Implementation Rules for the Administrative Regulation on Human Genetic Resources (the "HGR Implementation Rules"), which came into effect on July 1, 2023. The HGR Implementation Rules have refined the Administrative Regulations on 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 approval, 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 all phases of clinical trials before submitting the application for registration for marketing authorization. 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 form a group of pharmacists, medical professionals and other technical specialists to analyze the drug's safety, effectiveness and quality control. After the comprehensive review, if the drug is approved for marketing, a drug registration certificate shall be issued.

Marketing Authorization Holder System

Pursuant to the Drug Administration Law, a drug marketing authorization holder system is implemented 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 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 or 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 Administrative Measures for Drug Registration, drugs are classified into traditional Chinese drugs, chemical drugs, biological products and others. According to the Announcement on the Issuance of the Reform Plan for the Registration Classification of Chemical Drugs, the registration classification of the chemical drugs is 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 Administrative Measures for 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 Circular 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 (i) 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; (ii) 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; (iii) new drugs with distinctive clinical treatment advantages for diseases such as AIDS, malignant tumor or other rare diseases; or (iv) 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, drug manufacturers shall comply with the Good Manufacturing Practice ("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 NMPA and 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.

The GMP for Drugs provided guidance for, among others, 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 Manufacturing Permit

Under the Administrative Measures for the Supervision of Drug Manufacturing promulgated by SAMR, persons engaging in drug manufacturing activities shall be subject to approval by the provincial counterparts of the NMPA where the persons engaging in pharmaceutical manufacturing activities are located, obtain a drug manufacturing permit pursuant to these measures, comply strictly with the pharmaceutical manufacturing quality control rules and ensure that the manufacturing process complies with statutory requirements at all times. The period of validity of a drug manufacturing permit is five years. In the event the permit holder needs to continue to manufacture drugs upon the expiration of the permit, the holder shall apply to the original issuing authorities for reissuance six months before the expiration date of the permit.

Drug Business Permit and Good Supply Practice Requirements

According to Drug Administration Law and the Implementing Regulations of the PRC Drug Administration Law, before engaging in the wholesale distribution and/or retailing of drugs, the relevant entity must obtain a drug business permit with an appropriate scope of distribution from the local counterpart of the NMPA and comply with the Good Supply Practice for Drugs. Under the Measures for the Supervision and Administration of Drug Quality in Trading and Usage, which became effective on January 1, 2024, a drug business permit is valid for five years. Each holder of the drug business permit 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 another drug business permit is granted.

Drug Recall

According to the Administrative Measures for 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 R&D, production, storage and transportation, labeling and other reasons.

Administrative Protection and Monitoring Periods for New Drugs

Pursuant to the Implementing Regulations of the PRC Drug Administration Law, 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, the packaging of drugs must include a label and an instruction. According to the Administrative Measures for the Packaging of Drugs, the packaging of drugs must comply with national and professional standards. Drugs with packaging that does not meet the relevant 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 drugs must indicate that the drug is for clinical trial use only, and must provide information related to the clinical trial and the drug used in the trial. The packaging shall also ensure the maintenance of blind states in blind trials.

Insert Sheet and Labels of Drugs

Pursuant to Administrative Provisions for Drug Insert Sheets and Labels, 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 reasonable 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 for Drugs

Pursuant to the Interim Administrative Measures for the Review 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 NMPA. 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 over-the-counter drug advertisements must also add the non-prescription drug label in a prominent place and state "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 its owner to a drug manufacturer and the application for drug registration by the drug manufacturer pursuant to the 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 counterparts of the NMPA for review and approval. 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 information on drugs (including medical devices) 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.

National Medical Insurance, its Reimbursement Standards and the NRDL

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 Insurance 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 in the PRC.

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.

Pursuant to the Interim Measures for the Scope of Basic Medical Insurance Coverage for Drugs for Urban Employees, which set the standard for the drugs to be included in the NRDL, a drug must be clinically necessary, safe, effective, reasonably priced, easy to use, available in sufficient quantity to be included in the NRDL, and must meet one of the following requirements: (i) be set forth in the pharmacopoeia of the PRC, (ii) satisfy the standards promulgated by the NMPA and (iii) be approved by the NMPA as imported drugs.

The Ministry of Labor and Social Security of the PRC, together with other government authorities, has the power to determine the drugs included in the NRDL. 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 as a result may differ from region to region in the PRC.

Price Controls

The Drug Administration Law requires that, for drugs subject to market-determined prices, the relevant marketing authorization holders, manufacturers and distributors of drugs and medical institutions shall determine the price applying the principles of fairness, reasonableness, 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 relevant competent authorities to determine the prices of drugs and are prohibited from making exorbitant profits, conducting price monopoly and price fraud, among others.

According to PRC Price Law, 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 drugs 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 Implementing Current Drug Price Administration issued by the NHSA seek to further improve the drug pricing formation mechanism and emphasizes the market-oriented drug pricing mechanism. Although narcotic drugs and category I psychotropic drugs are subject to government-guided prices, other drugs are subject to market-determined prices. 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 Implementation Opinions on Promoting the “Two-Invoice System” for Drug Procurement by Public Medical Institutions (For Trial Implementation) (the “Two-Invoice System Notice”) establishes a system requiring the issuance of only two invoices during the distribution of drugs in other words, in the whole drug procurement process, there should be only one layer of pharmaceutical distributor between the drug manufacturer and the procuring public medical institution. The Two-Invoice System Notice prohibits the sale of drugs through a chain of distributors which will, as a result, increase the price of drugs paid by the public medical institutions. The Two-Invoice System was first promoted in pilot areas and has been implemented nationwide by 2018. Drug manufacturers and distributors must comply with the Two-Invoice System in order to engage in procurement processes with public hospitals.

Regulations Relating to Work Safety

The PRC Work Safety Law applies to all entities engaged in production and business activities in the PRC. Such entities shall, according to the PRC Work Safety Law, strengthen work safety management, establish and improve an all-staff work safety responsibility system and internal rules and regulations in relation to work safety, increase investment in funds, materials, technologies and staff for work safety, improve working conditions, strengthen the development of a standardized, information technology- enabled work safety system, establish a dual prevention mechanism for managing safety risks and addressing hidden dangers, and improve risk prevention and resolution mechanism to ensure work safety. Violations of the PRC Work Safety Law may result in administrative penalties such as fine, suspension of operation and revocation of license.

Regulations Relating to Intellectual Property Rights

Patents

Pursuant to the PRC Patent Law and the Implementation Regulations of the PRC Patent Law, 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 China National Intellectual Property Administration 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 China National Intellectual Property Administration 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 PRC 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 China National Intellectual Property Administration for confidentiality examination.

Trademarks

Pursuant to the PRC Trademark Law and the Implementation Regulations of the PRC Trademark Law, 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

According to the PRC Copyright Law, works protected by copyright refer to original intellectual achievements in the fields of literature, art and science which can be expressed in a certain form, including: (i) written works; (ii) oral works; (iii) musical, drama, opera, dance, and acrobatic artistic works; (iv) fine arts and architectural works; (v) photographic works; (vi) audio-visual works; (vii) graphic works and model works, such as engineering design plans, product design plans, maps, and schematic diagrams; (viii) computer software; and (ix) any other intellectual achievements which share the same characteristics of the aforementioned works. Copyright is a collection of personal and property rights, which, among others, includes the right of publication, the right of authorship, the right of modification, the right of distribution, the right of reproduction, and the right of internet information transmission.

According to the Measures for the Registration of Computer Software Copyright, and the Regulations on Computer Software Protection, the National Copyright Administration of the PRC shall be the competent authority for the nationwide administration of software copyright registration, and the Copyright Protection Centre of China is designated as the authority responsible for the whole registration process of computer software. The Copyright Protection Centre of China issues registration certificates to applicants for computer software copyrights that comply with the aforementioned measures and regulations.

Domain Names

Domain names are protected under the Administrative Measures on Internet Domain Names promulgated 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 the China Internet Network Information Center. The MIIT is the regulatory body responsible for the administration of PRC internet domain names. Prior to the establishment of domain name root servers, domain name root server operation institutions, domain name registration management institutions and domain name registration service institutions within the PRC, the corresponding permits shall be obtained from the MIIT or its local counterparts. 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 PRC Anti-Unfair Competition Law 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 operators are prohibited from infringing others' trade secrets by: (i) acquiring a trade secret from its holder by theft, bribery, fraud, coercion, electronic intrusion or any other illicit means; (ii) disclosing, using or allowing another person to use a trade secret acquired from the right holder by any means as specified in clause (i); (iii) 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 its holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential.

Regulations Relating to Environmental Protection

According to the PRC Environmental Protection Law, the Administrative Regulations on the Environmental Protection of Construction Project, the PRC Environmental Impact Assessment Law and PRC Law 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 authority. 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 Permit and the Regulations on the Administration of Pollutant Discharge Permit, a pollutant-discharging entity must legally obtain a pollutant discharge permit prior to discharging any pollutants, and shall discharge pollutants in compliance within the scope specified in the pollutant discharge permit. A pollutant discharge permit is valid for five years from the date of issuance.

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 chemical drug substance is strictly regulated under the current regulatory framework, and the manufacturer shall obtain a pollutant discharge permit in accordance with the prescribed time limit.

Hazardous Chemicals

Regulations on Safety Administration of Hazardous Chemicals provide 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 is 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 Quality

Pursuant to the PRC 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 PRC Civil Code, 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.

Regulations Relating to Labor Protection, Social Insurance and Housing Provident Fund

Labor Protection

According to the PRC Labor Law, 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 PRC Labor Contract Law and the Implementation Regulations of the PRC 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 contract 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 Provident Fund

According to the PRC Social Insurance Law (the "Social Insurance Law"), the Interim Regulations on the Collection and Payment of Social Insurance Premiums, the Regulations on Work-Related Injury Insurance, the Regulations on Unemployment Insurance, the Trial Measures for Maternity Insurance of Enterprises Employees, and the Administrative Regulations on Housing Provident Fund, an enterprise established within the PRC shall pay a premium for basic pensions insurance, basic medical insurance, maternity insurance, work-related injury insurance and unemployment insurance, and contribute to the housing provident fund for its employees at a rate stipulated by the relevant authorities. 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 Administrative Regulations on Housing Provident Fund, employers must register with the competent managing center for housing provident funds and complete procedures for opening an account at a 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 fines.

Regulations on Foreign Investment

The PRC Foreign Investment Law and the Implementing Regulations for the PRC Foreign Investment Law, apply 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 PRC Foreign Investment Law, 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 Regulations 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 (the "MOFCOM") and 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 a dedicated registration system.

Investment activities in the PRC by foreign investors are principally governed by the Special Administrative Measures (Negative List) for Foreign Investment Access (2024 Version) (the "Negative List 2024"). The Negative List 2024, which became effective on November 1, 2024, sets out the special administrative measures in respect of foreign investment access on a unified basis. The Negative List 2024 prohibits foreign investors from investing in certain specified sectors and requires them to meet investment conditions for certain other sectors. Sectors not covered in the Negative List 2024 shall be subject to administration under the principle of equal treatment for both domestic and foreign investments.

Regulations Relating to Overseas Investment

Pursuant to the Administrative Measures on Overseas Investments, the MOFCOM and its counterparts at provincial level are one of the regulatory bodies of overseas investment of PRC enterprises. According to these measures, overseas investment refers to the acquisition of ownership in an overseas non-financial enterprise by means of incorporation, merger, acquisition or any other method by an enterprise incorporated in the PRC. Any overseas investments involving sensitive countries, regions or industries shall be subject to the approval of the MOFCOM or its provincial counterparts. Overseas investments that do not fall into the aforementioned category shall be subject to filing with the relevant provincial counterparts of the MOFCOM.

Pursuant to the Administrative Measures for the Overseas 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 Overseas Investment (2018 Edition) to list the sensitive industries in detail.

Regulations Relating to Overseas Listing

The China Securities Regulatory Commission (the "CSRC") promulgated the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Companies in 2023, and issued several corresponding guidelines thereof (together, the "Overseas Listing Trial Measures"), requiring PRC companies' overseas offerings and listings of equity securities be filed with the CSRC.

The Overseas Listing Trial Measures clarify the scope of overseas offerings and listings by PRC companies that are subject to the filing and reporting requirements thereunder. According to the Overseas Listing Trial Measures, if an issuer of securities meets both of the following criteria, the relevant offering and/or listing shall be considered as indirect overseas offering and/or listing of a PRC company: (i) 50% or more of the issuer's operating revenue, total profit, total assets or net assets, as documented in its audited consolidated financial statements for the most recent accounting year, is accounted for by PRC companies; and (ii) the primary business activities of the issuer are conducted in the PRC, or its main places of business are located in the PRC, or most members of the issuer's management team are citizens or long-term residents of the PRC. The Overseas Listing Trial Measures further provide that the determination on whether an offering and/or listing constitutes an indirect offering and/or listing of a PRC company shall follow the principle of "substance over form," making it possible for an offering and/or listing that does not meet the above criteria to still be considered an indirect overseas offering and/or listing of a PRC company, thus subject to the CSRC filing obligation.

The Overseas Listing Trial Measures further stipulate that PRC companies that have already directly or indirectly offered or listed securities in overseas markets shall fulfil their filing obligations and report relevant information to the CSRC within three working days after conducting a follow-on offering of equity securities on the same overseas market. They must also comply with relevant reporting requirements within three working days upon the occurrence of any specified circumstances. Failure to comply with the filing procedures may result in warnings and fines imposed by the CSRC or other competent PRC authorities.

Regulations Relating to PRC Taxation

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 Enterprise Income Tax ("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 most recently renewed in 2022. This renewed certificate entitled us to enjoy a preferential income tax rate of 15% for a period of three years from 2022 to 2025 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 basis price of the original investment. 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 Interim 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 Value-Added Tax Law of the PRC (the “VAT Law”) promulgated by the SCNPC on December 25, 2024 and effective on January 1, 2026, and the Implementation Rules for the VAT Law of the PRC promulgated by the State Council and effective as of the same date, all enterprises and individuals that engage in the sale of goods, the provision of processing, repair and replacement services, sales of service, intangible assets and real estate and the importation of goods within the territory of the PRC shall pay value-added tax at the rate of 0%, 6%, 9% and 13%, respectively, for the different goods it sells and different services it provides, except when specified otherwise.

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.

Regulations Relating to Foreign Exchange

The Regulations on Foreign Exchange Administration of the PRC apply to the receipt and payment of foreign currency or foreign exchange business activities conducted by PRC organizations and individuals or conducted by foreign organizations and individuals within the territory of the PRC. 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 State Administration of Foreign Exchange (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 SAFE or its local counterparts. 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 SAFE and its branches shall indirectly regulate the foreign exchange registration of direct investment through banks.

According to the Circular on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts, 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.

The Circular of the State Administration of Foreign Exchange on Issues Relating to Foreign Exchange Administration for Overseas Investment and Round-trip Investment by Chinese Residents through Special Purpose Vehicles 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.

The SAFE issued the Circular on Issues Concerning the Foreign Exchange Administration for Domestic Individuals Participating in Stock Incentive Plans of Overseas Listed Companies (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 listed company shall, through itself (if its securities are listed overseas) or a domestic company which is affiliated with the overseas listed company (the “PRC Entity”), collectively entrust a domestic agency (the agency can be the PRC Entity or a qualified PRC organization as appointed by the PRC Entity) 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.

Failure to comply with the abovementioned foreign exchange regulations and requirements may result in warnings, fines, confiscation of illegal gains and even criminal liabilities.

Regulations Relating to 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 PRC 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, as such company’s mandatory 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.

PRC Taxation

Under Article 2 of the EIT 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 PRC Enterprise Income Tax purposes, dividends (if any) paid by us to our direct offshore institutional shareholders which are not PRC resident enterprises for PRC tax purposes 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 in the PRC of such offshore shareholders. 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, 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.*

Government Regulation Outside of the United States and PRC

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, quality control, labeling, packaging, storage, record keeping, distribution, reporting, export and import, advertising, marketing and other promotional practices involving pharmaceutical products as well as authorization, approval and post-approval monitoring and reporting of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for 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.

The requirements and process governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market a product in a country until an appropriate approval application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product, which would make launch of such products commercially unfeasible in such countries.

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. Moreover, some of the factors, events and contingencies discussed below may have occurred in the past, but the disclosures below are not representations as to whether or not the factors, events or contingencies have occurred in the past and instead reflect our beliefs and opinions as to the factors, events, or contingencies that could materially and adversely affect us in the future.

Summary of Risk Factors

Investing in our securities involves a high degree of risk. Below please find a summary of the principal risks we face. These risks are discussed more fully below.

- There is no assurance when or if the Merger will be completed. Any delay in completing the Merger may substantially reduce the potential benefits that we expect to obtain from the Merger.
- Our business is significantly dependent on the sales of ETUARY®, one of our marketed products 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 products in the PRC, ETUARY®, Etorel® and Contiva®, along with any other products that we may receive approval for and commercialize 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 preclinical stages, such as ETUARY® for future indications in the PRC, F573 in the PRC, and Hydronidone 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.
- We may fail to win bids to sell our commercialized products, ETUARY®, and any other future products, if approved and commercialized, to PRC public hospitals through the centralized tender process.
- 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 Hydronidone 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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 Hydronidone 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.
- 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.
- There are uncertainties regarding the interpretation and enforcement of PRC laws, rules and regulations.
- The market price of our common stock has been, and may continue to be, volatile.
- 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 the Merger with Cullgen

There is no assurance when or if the Merger will be completed. Any delay in completing the Merger may substantially reduce the potential benefits that we expect to obtain from the Merger.

Completion of the Merger is subject to the satisfaction or waiver of a number of conditions, as set forth in the Merger Agreement, including (1) approval by the requisite Cullgen stockholders of the adoption and approval of the Merger Agreement and the transactions contemplated thereby, and (2) a filing under HSR Act. There can be no assurance that we and Cullgen will be able to satisfy the closing conditions or that closing conditions beyond our or Cullgen's control will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or may not be completed within the expected timeframe, and we may materially and adversely lose some or all of the potential benefits that we expect to achieve as a result of the Merger and could result in additional transaction costs or other effects associated with uncertainty about the Merger. Moreover, we have incurred and expect to continue to incur significant expenses related to the Merger, such as legal and accounting fees, some of which must be paid even if the Merger is not completed.

We and Cullgen can agree at any time to terminate the Merger Agreement, even if the Cullgen securityholders have already adopted the Merger Agreement and thereby approved the Merger and the other transactions contemplated by the Merger Agreement. We and Cullgen can also terminate the Merger Agreement under other specified circumstances.

The issuance, or expected issuance, of our common stock in connection with the Merger could decrease the market price of our common stock.

In connection with the Merger and as part of the merger consideration, we expect to issue shares of common stock to Cullgen stockholders. The anticipated issuance of our common stock in the Merger may result in fluctuations in the market price of our common stock, including a stock price decrease. In addition, the perception in the market that the holders of a large number of shares of our common stock may intend to sell shares could reduce the market price of our common stock.

The intended benefits of the Merger may not be realized.

The Merger poses risks for our ongoing operations, including, among others:

- that senior management's attention may be diverted from the management of our current operations and development of our products;
- costs and expenses associated with any undisclosed or potential liabilities; and
- unforeseen difficulties may arise in integrating Cullgen's and our business.

As a result of the foregoing, we may be unable to realize the full strategic and financial benefits currently anticipated from the Merger, and we cannot assure you that the Merger will be accretive to us in the near term or at all. Furthermore, if we fail to realize the intended benefits of the Merger, the market price of our common stock could decline to the extent that the market price reflects those benefits. Our stockholders will have experienced substantial dilution of their ownership interests in us without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent we are able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

Because the lack of a public market for Cullgen common stock makes it difficult to evaluate the fairness of the Merger, Cullgen stockholders may receive consideration in the Merger that is greater than or less than the fair market value of Cullgen common stock.

The outstanding Cullgen common stock is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of Cullgen shares. Since the percentage of our common stock to be issued to Cullgen stockholders was determined based on negotiations between the parties, it is possible that the value of our common stock to be issued in connection with the Merger will be greater than the fair market value of Cullgen shares. Alternatively, it is possible that the value of the shares of our common stock to be issued in connection with the Merger will be less than the fair market value of Cullgen shares.

Our directors and officers may have interests in the Merger that are different from, or in addition to, those of our stockholders generally that may influence them to support or approve the Merger.

Our officers and directors may have interests in the Merger that are different from, or are in addition to, those of our stockholders generally. Effective upon the Closing, Ying Luo, Ph.D., current President and Chief Executive Officer of Cullgen, is expected to be employed as Chief Executive Officer and President and appointed as a director of Gyre. Each outstanding option to acquire shares of Cullgen common stock held by Cullgen executive officers and directors will be converted into an option to acquire shares of our common stock.

In addition, our directors and executive officers also have certain rights to indemnification or to directors' and officers' liability insurance that will survive the completion of the Merger. These interests may have influenced our directors and executive officers to support or recommend the proposals presented to our stockholders.

The announcement and pendency of the Merger could have an adverse effect on our business, financial condition, results of operations or business prospects.

The announcement and pendency of the Merger could disrupt our business in the following ways, among others:

- Our current and prospective employees could experience uncertainty about their future roles, and this uncertainty might adversely affect our ability to retain, recruit and motivate key personnel;
- the attention of our management may be directed towards the completion of the Merger and other transaction-related considerations and may be diverted from our day-to-day business operations, as applicable, and matters related to the Merger may require commitments of time and resources that could otherwise have been devoted to other opportunities that might have been beneficial to us;
- customers, prospective customers, suppliers, collaborators and other third parties with business relationships with us may decide not to renew or may decide to seek to terminate, change or renegotiate their relationships with us as a result of the Merger, whether pursuant to the terms of their existing agreements with us; and
- the market price of our common stock may decline to the extent that the current market price reflects a market assumption that the proposed Merger will be completed.

Should they occur, any of these matters could adversely affect our business, or harm our financial condition, results of operations or business prospects.

During the pendency of the Merger, we may not be able to enter into a business combination with another party and will be subject to contractual limitations on certain actions because of restrictions in the Merger Agreement.

Covenants in the Merger Agreement impede our ability to make dispositions or acquisitions or complete other transactions that are not in the ordinary course of business pending completion of the Merger. As a result, if the Merger is not completed, we may be at a disadvantage to our competitors. In addition, while the Merger Agreement is in effect and subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to the entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition, a tender offer, a merger or other business combination outside the ordinary course of business. These restrictions may prevent us from pursuing otherwise attractive business opportunities or other capital structure alternatives and making other changes to our business or executing certain of our business strategies prior to the completion of the Merger, which could be favorable to our stockholders.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the arrangements contemplated by the Merger Agreement.

The terms of the Merger Agreement prohibit each of us and Cullgen from soliciting competing proposals or cooperating with persons making unsolicited takeover proposals, except in limited circumstances if our board of directors determines in good faith, after consultation with its independent financial advisor and outside counsel, that an unsolicited competing proposal constitutes, or would reasonably be expected to result in, a superior competing proposal and that failure to take such action would be reasonably likely to result in a breach of the fiduciary duties of our board of directors.

The Exchange Ratio is not adjustable based on the market price of our common stock, so the Merger consideration at the Closing may have a greater or lesser value than at the time the Merger Agreement was signed.

The Merger Agreement has fixed the Exchange Ratio (as defined in the Merger Agreement) for the Cullgen common stock, and the Exchange Ratio is not adjustable. Any changes in the market price of common stock before the completion of the Merger will not affect the number of shares Cullgen securityholders will be entitled to receive pursuant to the Merger Agreement. Therefore, if before the completion of the Merger, the market price of our common stock declines from the market price on the date of the Merger Agreement, then Cullgen securityholders could receive merger consideration with substantially lower value. Similarly, if before the completion of the Merger, the market price of our common stock increases from the market price on the date of the Merger Agreement, then Cullgen securityholders could receive merger consideration with substantially more value for their shares of Cullgen common stock than the parties had negotiated for in the establishment of the Exchange Ratio.

We are expected to incur substantial expenses related to the Merger with Cullgen.

We expect to continue to incur, substantial expenses in connection with the Merger, as well as operating as a public company. We will incur significant fees and expenses relating to legal, accounting, financial advisory and other transaction fees and costs associated with the Merger. Actual transaction costs may substantially exceed our estimates and may have an adverse effect on our financial condition and operating results.

Failure to complete the Merger could negatively affect the value of our common stock and our future business and financial results.

If the Merger is not completed, our ongoing business could be adversely affected. Moreover, we will be subject to a variety of risks associated with the failure to complete the Merger, including without limitation the following:

- diversion of management focus and resources from operational matters and other strategic opportunities while working to implement the Merger;
- reputational harm due to the adverse perception of any failure to successfully complete the Merger; and
- having to pay certain costs relating to the Merger, such as legal, accounting, financial advisory, filing and printing fees.

If the Merger is not completed, the market price of our common stock and our business and financial results could be materially affected.

The Merger may be completed even though material adverse changes may result from the announcement of the Merger, industry-wide changes or other causes.

In general, either party can refuse to complete the Merger if there is a material adverse effect affecting the other party between March 2, 2026, the date of the Merger Agreement, and the Closing of the Merger. However, some types of changes do not permit either party to refuse to complete the Merger, even if such changes would have a material adverse effect on us or Cullgen, as the case may be:

- general economic or political conditions or conditions generally affecting the industries in which the parties operate;
- any natural disaster, calamity or epidemics, pandemics or other force majeure events, or any act or threat of terrorism or war, any armed hostilities or terrorist activities (including any escalation or general worsening of any of the foregoing) anywhere in the world or any governmental or other response or reaction to any of the foregoing; or
- changes in GAAP or other applicable law or the interpretation thereof.

If adverse changes occur but we and Cullgen must still complete the Merger, the market price of our common stock may suffer.

We and/or our board of directors may become involved in securities litigation or stockholder derivative litigation in connection with the Merger, and this could divert the attention of our management and harm our business, and insurance coverage may not be available or sufficient to cover all related costs, expenses, and damages.

Securities litigation or stockholder derivative litigation frequently follows the announcement of certain significant business transactions, such as the sale of a business division or announcement of a business combination transaction. We or our board of directors may become involved in this type of litigation in connection with the Merger, and we may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

We are substantially dependent on our remaining employees, key contractors and consultants to facilitate the consummation of the Merger.

Our ability to successfully complete the Merger depends in large part on our ability to retain certain remaining personnel, in addition to key contractors and consultants. Despite our efforts to retain these employees, as well as key contractors and consultants, one or more may terminate their employment or services with us on short notice. The loss of the service of certain employees, key contractors or consultants could potentially harm our ability to consummate the Merger and run our day-to-day business operations, as well as fulfill our reporting obligations as a public company.

Risks Related to Our Financial Condition and Capital Requirements

Our business is significantly dependent on the sales of ETUARY®, one of our marketed products 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 primarily generated revenues from the commercial sale of ETUARY®, which is approved in the PRC, Etorel®, Contiva® and certain generic drugs. We only have three products 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 91.0% and 99.3% of our total revenue in 2025 and 2024, respectively, and we expect that sales of ETUARY® will continue to comprise a substantial portion of our total revenue in the near future. In 2025, we initiated commercialization of Etorel® and Contiva®, which accounted for 4.0% and 4.7% of our total revenue in 2025, respectively. However, our commercialization efforts, including increasing market access, physician education and patient support programs, for Etorel® and Contiva® may not successful and we may not be able to develop sufficient sales volume, optimal pricing or sustained profitability of Etorel® or Contiva®, and sales of Etorel® and Contiva® may not offset any future declines in ETUARY® sales. 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 several pirfenidone and nintedanib products approved and commercialized, in addition to our products ETUARY®, Etorel® and Contiva®. 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 ETUARY®, Etorel® and Contiva® may decrease. For details, see *"—Business—Our Commercial Portfolio—Pulmonary Fibrosis—ETUARY® (pirfenidone)"* in this Annual Report. New entrants to the IPF market in the PRC may exert downward pressure on our average selling price of ETUARY®, Etorel® and/or Contiva®, which may negatively impact sales and/or profit of ETUARY®, Etorel® and/or Contiva®, respectively.

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®, Etorel®, Contiva® 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®, Etorel® and Contiva® 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 achieve expected sales of Etorel® and Contiva® or 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 preclinical stages, such as ETUARY® for future indications in the PRC, F573 in the PRC, and Hydronidone 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 Hydronidone 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 preclinical 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 increasing commercial sales of Etorel® and Contiva®, which commercially launched in 2025, and successfully launching future products;
- 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®, Etorel® and Contiva®;
- 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 obtaining or not being able to obtain approval for and/or successful commercialization of our products, ETUARY®, Etorel® and Contiva®, 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®, Etorel®, Contiva® and certain generic drugs in the PRC and will not be able to generate any product revenues in addition to those generated by ETUARY®, Etorel®, Contiva® and certain generic drugs until we receive approval to sell our other product candidates from the NMPA, FDA or other regulatory authorities or acquire and maintain the rights to commercially approved products. As we have only generated revenue from commercial sales of ETUARY®, Etorel®, Contiva® 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. 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 Hydronidone in the PRC and potentially additional markets beyond the PRC, and depending on the availability of capital, may need to delay or cease development of some or all of our product candidates. Even if we raise additional capital, we may elect to focus our efforts on one or more development programs and delay or cease other development programs.

While we expect that the implementation of our strategies and business plans will require us to rely in part on external financing sources, including our at-the-market offering program (the "ATM Program") with Jefferies LLC, as sales agent ("Jefferies LLC"), our ability to obtain additional capital on commercially reasonable terms is subject to a variety of factors, many of which are outside of our control, including our future financial condition, results of operations and cash flows, the global economic conditions, industry and competitive conditions, interest rates, prevailing conditions in the credit markets and government policies on lending. Additional funds may not be available when we need them on terms that are acceptable, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate some or all of our research or development programs, and we may not be able to execute our strategies and business plans as currently contemplated, which could have a material adverse effect on our business, financial condition and results of operations.

Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the costs and results of preclinical studies or clinical trials of ETUARY®, Hydronidone, 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 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®, Etorel® and Contiva® 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 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 or the conflicts in the Middle East. For details regarding the risks related to the relations between the PRC and the United States, see "*—Risks Related to Our Business Operations in the PRC—Changes in the 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.

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 ATM Program with Jefferies LLC 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.

The process of proposing, negotiating and implementing an acquisition is lengthy and complex. We may devote resources to potential acquisitions that are never completed, or our plan to grow our business through such acquisitions may not materialize as expected, or we may fail to realize the anticipated benefits.

Our high gross margin during the years ended December 31, 2025 and 2024 may not be sustainable.

During the years ended December 31, 2025 and 2024, we maintained a high level of gross margin. Our profit margins were 95.4% and 96.3% for the years ended December 31, 2025 and 2024, 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®, Etorel® and/or Contiva®, 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, 2025 and 2024, which subjects us to concentration risks.

Our five largest customers accounted for a substantial amount of our revenue for the years ended December 31, 2025 and 2024. 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, 2025 and 2024, we had certain concentrations of credit risk of 10%. In addition, as of December 31, 2025, 53.3% and 87.2%, and as of December 31, 2024, 54.3% and 84.9%, 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®, Etorel® or Contiva® 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®, Etorel® or Contiva® 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, 2025 and 2024, our inventories were valued at $10.2 million and $6.3 million, respectively. During the years ended December 31, 2025 and 2024, 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, 2025 and 2024. 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, 2025 and 2024, our trade receivables amounted to $31.1 million and $19.6 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, 2025 and 2024, our trade receivables turnover days were 79 days and 60 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, 2025 and 2024, which subjects us to concentration risks.*" in this Risk Factors section. If significant amounts due to us are not settled in a timely manner, we may incur significant write-offs and our liquidity and cash flow may be adversely affected.

We have historically received government grants and have been entitled to preferential tax treatment, but we may not continue to receive government financial incentives in the future.

We have historically received government grants in connection with certain of our research and development and manufacturing activities, and recognized government grants under other income and gains of $0.8 million and $0.1 million for the years ended December 31, 2025 and 2024, respectively. For details of the amounts of our other recognized income, see Note 4—Balance Sheet Components 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, 2025 and 2024 as a High and New Technology Enterprise. In addition, our products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, have been entitled to a preferential VAT treatment at the tax rate of 3%, 3% and 13%, respectively. 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 products in the PRC, ETUARY®, Etorel® and Contiva®, along with any other products that we may receive approval for and commercialize 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 marketed products, ETUARY®, Etorel® and Contiva®, and future approved and commercialized 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. For example, early-year supply chain and distribution delays moderated Etorel®'s launch initiation, and uncertainty related to the PRC government's volume-based procurement led customers to cautious purchasing behavior of Etorel®. We experienced lower than expected sales of Etorel® and Contiva® relative to internal budget expectations. Such factors affecting the market acceptance of a current or future approved product, if any, may include:

- the clinical indications for which the product is approved;
- the safety and efficacy of the product;
- the potential and perceived advantages and disadvantages of the product, relative to competing or alternative products or treatments;
- the affordability of the product;
- the cost of treatment in relation to alternative treatments and therapies;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our relationships with patient communities;
- the availability of third-party coverage and adequate reimbursement;

- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- the strength of marketing and distribution support;
- the prevalence and severity of any side effects;
- the current diagnostic conditions of the disease for which the product is indicated, which may be influenced by the number of physicians from the relevant department and their respective experiences, available diagnostic methods and equipment therefor; and
- the effectiveness of our sales and marketing efforts.

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

If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Doctors may not accept or use ETUARY® as a treatment for PD even if ETUARY® receives marketing approval for such indication. Doctors may not accept or use Hydronidone as a treatment for liver fibrosis even if Hydronidone 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.

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 Hydronidone 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 that we developed, ETUARY® for the treatment of IPF in the PRC, and it is possible that none of our existing product candidates in development or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Events that may prevent successful or timely completion of clinical development may include:

- regulators, IRBs 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, site management organizations 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 preclinical 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 Hydronidone 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 Hydronidone 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 Hydronidone 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 Hydronidone 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 Hydronidone. Our future clinical trials for Hydronidone may not be successful.

We expect to invest a substantial amount of our efforts and financial resources into the research and development of Hydronidone. In May 2025, Gyre Pharmaceuticals completed a pivotal Phase 3 trial of Hydronidone in the PRC evaluating its safety and efficacy for the treatment of liver fibrosis in patients with CHB-associated liver fibrosis. In January 2026, Gyre Pharmaceuticals completed a Pre-NDA Application communication meeting with the CDE of the NMPA regarding Hydronidone. Based on these positive results, we currently expect to submit an NDA for conditional approval of Hydronidone in the first half of 2026, subject to final data readiness and applicable regulatory procedures.

In addition, we continue to engage with the FDA regarding the IND requirements for a Phase 2 trial evaluating Hydronidone for the treatment of MASH-associated liver fibrosis. Pending regulatory feedback, we plan to file the U.S. IND for Hydronidone for the treatment of MASH-associated liver fibrosis in 2026 and, subject to clearance, initiate a Phase 2 clinical trial. We plan to conduct a hepatic impairment study in U.S. subjects under our active U.S. IND. Results from this study are expected to help optimize dose selection and safe enrollment criteria in populations with reduced hepatic function, supporting a more robust Phase 2 development plan. Our clinical trials may be adversely affected by the March 2024 marketing approval for Rezdiffra®, the August 2025 marketing approval for Wegovy® for the treatment of MASH or the potential regulatory approvals for one or more investigational MASH products.

Hydronidone 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 Hydronidone, 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 Hydronidone 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 Hydronidone, even if approved. If we are not successful in commercializing Hydronidone, 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 MASH patients, which can currently only be definitively diagnosed through a liver biopsy. Specifically, identifying patients most likely to meet MASH enrollment criteria on biopsy is an on-going challenge, with existing clinical indicators lacking both sensitivity and specificity. As a result, MASH trials often suffer from high levels of screen failure following central review of the baseline liver biopsy, which can lead to lower enrollment. As a result of such difficulties and the significant competition for recruiting MASH patients in clinical trials, we or our future collaborators may be unable to enroll the patients we need to complete clinical trials on a timely basis, or at all. In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical trials for the same indications and seek to enroll patients in their studies that may otherwise be eligible for our clinical studies or trials. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical trials in these sites. The availability of other approved products, including Rezdiffra® and Wegovy®, 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 commercialized products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and any other future product, if approved and commercialized, 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.

ETUARY® has been included in the NRDL as a Category B drug for the treatment of IPF since 2017. There can be no assurance that ETUARY® 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 products, ETUARY®, Etorel® and Contiva® and future products, if approved and commercialized, and adversely impact our sales.

We may face pressure to lower the prices of our commercialized products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and any other future product, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and any other future product, if approved and commercialized, in order to have such product candidates included in the medical insurance reimbursement lists, while such low price and reimbursement may not necessarily lead to increased sales. It is difficult to estimate the net effect of decreased prices and the potential of increased sales on our profitability, and our profits from the sales of our future products may decrease if we significantly lower prices without a greater increase in sales.

In addition, it is typical that the prices of pharmaceutical products will decline over the life of the product as a result of, among other things, increased competition from substitute products, the tender process by the hospitals or the government authorities, pricing policies of the relevant government authorities, or voluntary price adjustments by pharmaceutical companies. Any strategic downward price adjustments of our existing or future approved products due to market competition could have a materially adverse effect on our business and results of operations.

Moreover, our marketed product, ETUARY® is subject to the risk of being included in the PRC's centralized volume-based procurement scheme. For details, see "*—In the future, the policies of centralized volume-based procurement set by the PRC government may cover our commercialized product, ETUARY®, and any other future products, if approved and commercialized, 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 products, ETUARY®, and any other future products, if approved and commercialized, 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 products, ETUARY®, and any other future products, if approved and commercialized, 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 products and price our bids in a manner that enables us to succeed in the centralized tender process at profitable levels.

In November 2025, the NHSA released the *Announcement of the Winning Bids for the National Centralized Drug Procurement*, under which Etorel® was selected. However, the impact on our future operating performance as a result of this announcement remains uncertain.

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 products, ETUARY®, and any other future products, if approved and commercialized, 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 commercialized, 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—Our Operations in the PRC: Gyre Pharmaceuticals—Product Pricing—Centralized Tender Process and Centralized Volume-Based Procurement System*" and "*Our Operations in the PRC: Gyre Pharmaceuticals—Government Regulations in the PRC—Regulations Relating to the Development, Manufacture and Sale of Pharmaceuticals—Centralized Tender Process and Centralized Volume-Based Procurement System*" 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.

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. In addition, nintedanib and avatrombopag were both included in the 2025 national volume-based procurement catalog, and Etorel® was selected in the Winning Bids for the National Centralized Drug Procurement, which resulted in market uncertainties related to these products. 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 products ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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 Hydronidone are approved and become profitable.

According to Frost & Sullivan, the prevalence of IPF in the PRC has increased from 89,000 patients in 2018 to 162,000 patients in 2024, and is expected to increase to 332,000 patients by 2032. 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®, Etorel® and Contiva® 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®, Etorel® and Contiva® 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®, Etorel® and Contiva® 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and any other future products, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and any other future products, if approved and commercialized, or further expand our distribution channel.

As we primarily rely on our network of distributors to distribute commercialized products, ETUARY®, Etorel® and Contiva®, in the PRC, and intend to continue engaging distributors to sell our commercialized products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized. 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 products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized. Further, we may fail to find an appropriate group of distributors suitable for our commercialized products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized, 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 conflicts between Russia and Ukraine and in the Middle East may impact our third-party supply of the raw materials and components needed for our products, ETUARY®, Etorel® and Contiva®, and product candidates, including ETUARY® for future indications, F573, F528, and F230 in the PRC, and Hydronidone 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 products, ETUARY®, Etorel® and Contiva®, or product candidates, including ETUARY® for future indications, F573, F528, and F230 in the PRC, and Hydronidone in the PRC and potentially additional markets beyond the PRC, are significantly delayed, or if the third parties that we engage to supply any materials or to manufacture any products for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the effects of global economic conditions, including new or increased tariffs imposed by the U.S. government and potential retaliatory measures by foreign governments and other barriers to trade, especially in light of recent comments and executive orders made by the Trump administration, trade and other international disputes, inflation and fluctuating interest rates, slower growth or recession, tighter credit, volatility in financial markets, high unemployment, labor availability constraints, public health crises, significant natural disasters, including as a result of climate change, changes to fiscal and monetary policy or government budget dynamics, particularly in the pharmaceutical and biotech areas, government shutdowns, political and military conflict, including the conflicts between Russia and Ukraine and in the Middle East, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us.

For example, trade policies and geopolitical disputes (including as a result of China-Taiwan relations) and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect our business, particularly if these measures occur in regions where we source our components or raw materials. In addition, tensions between the United States and the PRC have led to a series of tariffs being imposed by the United States on imports from China mainland, as well as other business restrictions. Since February 2025, the United States government has imposed various tariffs on imports from most countries, including tariffs on imports from the PRC and South Korea. In September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity, although the effective date of such tariffs has been delayed. Certain major drug producers and manufacturers are in negotiations with the U.S. Presidential Administration to receive relief from such tariffs. As a result of these negotiations, certain manufacturers, such as Pfizer, have announced their participation in a new direct purchasing platform called “TrumpRx.gov,” designed to offer discounts on their products and some specialty brands. Details regarding potential platform, as well as any potential impact on our business are unclear at this time. It is not yet clear whether these tariffs would apply to the importation of API and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. There still remains substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified or suspended. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Tariffs increase the costs of the components and raw materials we source. Countries may also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact the Company’s operations and supply chain.

In addition, if we are not able to obtain adequate supplies of our product, generic drugs or product candidates or the substances used to manufacture them, it will be more difficult for us to commercialize, market or develop our product, generic drugs or product candidates, as applicable, and compete effectively.

Our current and anticipated dependence upon third-party suppliers may adversely affect our ability to develop our product, generic drugs, and product candidates and could delay our clinical trials and development programs as well as marketing and commercialization efforts, and otherwise harm our operations and financial condition and increase our costs and expenses. See “*—Risks Related to Our Reliance on Third Parties—Because we rely on a limited number of suppliers for certain of our raw materials, we may experience supply interruptions that could harm our ability to manufacture products*.”

For details regarding the risks related to the relations between the PRC and the United States, see *“—Risks Related to Our Business Operations in the PRC—Changes in the 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®, Etorel®, Contiva®, 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®, Hydronidone 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 do not mean that future clinical trials will yield the same results. For instance, while ETUARY® is approved in the PRC for the treatment of IPF, it may not be approved for the treatment of other indications, such as PD or RILI, or in other markets. In addition, we do not know whether Hydronidone will perform in future clinical trials in the United States as Hydronidone has performed in preclinical studies and early clinical trials conducted by us in the PRC, and, despite Hydronidone's Phase 1 trial in the United States showing promising evidence of tolerability and PK, our Phase 2 clinical trial in the PRC demonstrating results in the reversal of CHB-associated fibrosis. To date, there are no approved therapies for CHB-associated liver fibrosis and Hydronidone's Phase 3 trial in the PRC demonstrating histologic improvement in liver fibrosis as measured by the Ishak fibrosis score. 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. In addition, we do not know whether F230 will perform in its Phase 1 clinical trial in the PRC for the treatment of PAH. Product candidates, including ETUARY®, Hydronidone 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 trial for the treatment of PD or Phase 2/3 clinical trial of ETUARY® for the treatment of RILI. In addition, we plan to file the U.S. IND for Hydronidone for the treatment of MASH-associated liver fibrosis in 2026 and, subject to clearance, initiate a Phase 2 clinical trial. Although data from our Phase 3 trial in the PRC demonstrated histologic improvement in liver fibrosis as measured by the Isak fibrosis score, that does not mean that future clinical trials in the United States or for the treatment of MASH-associated liver fibrosis will yield similar results.

In addition to the pre-IND guidance provided, at the time of review of the IND, 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 2 trial in MASH-associated liver fibrosis. Furthermore, if the NMPA or FDA believes that additional data is necessary to supplement our clinical study data, Phase 2 clinical trial data and Phase 3 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. For example, in January 2026, as part of the agreed regulatory pathway, we plan to conduct an additional confirmatory clinical trial designed to evaluate liver-related clinical outcomes to support conditional approval of Hydronidone to regular approval for the treatment of CHB-associated liver fibrosis. 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 2 trial in the United States sufficient to allow us to expand the development of Hydronidone 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 MASH clinical trials after achieving positive results in earlier development, and we may face similar setbacks. Many companies that believed their product candidates performed satisfactorily in preclinical studies and early clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we believe that the results of clinical trials for our product candidates warrant marketing approval, the NMPA, FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. Any Phase 2, Phase 3 or other clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates.

Preliminary, "top-line" or interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures.

We have publicly disclosed and may in the future publicly disclose preliminary or top-line data from our clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We also make assumptions, estimations, calculations and conclusions as part of our analyses of these data without the opportunity to fully and carefully evaluate complete data. As a result, the preliminary or top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated or subsequently made subject to audit and verification procedures.

Any preliminary or top-line data should be viewed with caution until the final data are available. From time to time, we have also disclosed and may in the future disclose interim data from our preclinical studies and clinical trials. Interim data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the likelihood of approval or commercialization of the particular product candidate and our company in general. In addition, from time to time we may disclose top line or summary information regarding a particular preclinical study or clinical trial. Such summary information is necessarily based on more fulsome and extensive information, and investors or regulators may not agree with what we determine is material or otherwise determine is appropriate information to include in our disclosure. If the preliminary, top-line or interim data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and product candidates, including ETUARY® for future indications, F573, F528, and F230 in the PRC, and Hydronidone 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and our product candidates, including ETUARY® (for future indications), Hydronidone, 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 and commercialized, 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 API, 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 Hydronidone 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 Hydronidone 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 Hydronidone in MASH may differ from that shown in HBV liver fibrosis patients and there is always a risk that the severity and frequency of the adverse events may worsen. See the section entitled "*—Business—Our Product Candidate Pipeline—F351 (Hydronidone)*."

In addition, the patient populations treated with our product candidates in our various Phase 3 clinical trials have serious diseases that make them susceptible to significant health risks. Therefore, these patients may experience adverse events, including serious adverse events.

In conducting drug research and development, we face potential liabilities; in particular, product liability claims or lawsuits that could cause us to incur substantial liabilities.

We face an inherent risk of product liability as a result of clinical trials if our product candidates cause, or are perceived to cause, injury, or are found to be otherwise unsuitable during clinical testing. Regardless of the merits or eventual outcome, such liability claims may, among others, result in:

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

To cover such liability claims arising from clinical trials, we have clinical trial insurance for all of our trials, which are necessary for the approval of commercialization of our pipeline products. However, it is possible that our liabilities could exceed our insurance coverage or that our insurance will not cover all situations in which a claim against us could be made. We may also not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise.

Adverse drug reactions and negative results from off-label use of our commercialized products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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 products, ETUARY®, Etorel® and Contiva®, 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.

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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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 use Hydronidone capsules manufactured by Wuxi Biologics, and may continue to use foreign CROs and contract manufacturing organizations ("CMOs") in the future. Wuxi Biologics has completed manufacturing one lot of the Hydronidone capsules for our planned Phase 2 clinical trial in the U.S. WuXi Biologics is identified in the U.S. legislation known as the BIOSECURE Act, which was enacted into law on December 18, 2025, as a "biotechnology company of concern." The BIOSECURE Act as it was enacted into law on December 18, 2025, will prohibit U.S. federal agencies from entering into, extending or renewing procurement contracts with, as well as providing grants and loans to, an entity that uses biotechnology equipment or services from a "biotechnology company of concern," and includes a grandfathering provision allowing biotechnology equipment and services provided or produced by named biotechnology companies of concern under a contract or agreement entered into before the effective date of revisions to the Federal Acquisition Regulation designating an entity a biotechnology company of concern until five years from such effective date. The timing for implementation of the BIOSECURE Act is uncertain. Depending on how the BIOSECURE Act is implemented by U.S. federal agencies, we could be potentially restricted from pursuing U.S. federal government business or grants in the future if we continue to use WuXi Biologics and if WuXi Biologics or other parties we contract with are identified as "biotechnology companies of concern" beyond the grandfathering period. Foreign CMOs may be the target of U.S. legislation, including the BIOSECURE Act, 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, restrict or even prohibit our ability to work with such CMOs, or have an adverse effect on our ability to secure significant commitments from governments to purchase potential therapies.

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 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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®, Etorel®, Contiva®, 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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, 2025, 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, 2025 and 2024.

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

To produce ETUARY®, Etorel®, Contiva®, 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®, Etorel®, Contiva® 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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 products, ETUARY®, Etorel® and Contiva®, which is approved and commercialized by us in the PRC, generic drugs and any other future products, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved. Further, demand for our commercialized products, ETUARY®, Etorel® and Contiva®, generic drugs and any other future products, if approved, could change significantly between the time 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, generic drugs and product candidates, including ETUARY®, Hydronidone, 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 GCPs, and the investigational plan and protocols contained in the relevant regulatory application, such as an IND. In addition, the CROs with whom we contract 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 and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, generic drugs and future products, if approved and commercialized.

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, 2025 and 2024, 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and product candidates. In order to protect the technologies, products and product candidates that we consider commercially important, we have filed and continue to file patent applications in the PRC, United States and other countries. However, applying for patent protection is an expensive and time-consuming process, and we may not be able to successfully file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may not be able to prevent competitors from developing and commercializing competitive products in all such fields and territories.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. For example, there can be no assurance that we were the first to make the inventions claimed in our patents or pending patent applications because of the delay between publications of discoveries in scientific or patent literature and actual discoveries and patent applications. Under the “first-to-file” system adopted by the PRC, and the United States, even after reasonable investigation, we may be unable to determine with certainty whether our product, product candidates, processes, technologies, improvement and other related matters are or may become unpatentable because a third-party filed or may file a patent application earlier than we have or do for inventions thereunder that are the same or substantially similar to our inventions. Additionally, the USPTO and patent offices in other jurisdictions have often required that patent applications directed to pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Accordingly, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated. Thus, there is no assurance as to the degree and range of protections any of our patents, if issued, may afford us or whether patents will be issues. Third parties may challenge the validity, enforceability or scope of our patents, which may result in those patents being narrowed or invalidated. The patent applications that we own may fail to result in issued patents with claims that cover our product and product candidates in the PRC, United States or in other foreign countries. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product or product candidates or prevent others from designing around our claims. Certain of our patents also cover processes, for which enforcement can be difficult. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

If the patents or patent applications we hold or have in-licensed for ETUARY®, Etorel®, Contiva®, our programs or product candidates are invalidated or fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product or product candidates, it could threaten our ability to commercialize future products. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. In the PRC, the amendment to the PRC Patent Law (the "Amended PRC Patent Law") provides for patent term extension and patent linkage. The Amended PRC Patent Law and relevant implementing regulations provide a cause of action to allow a patent holder to initiate a declarative action during the regulatory review process of a drug to determine whether the drug in review falls within the relevant scope of the patent of such patent holder, which may be comparable to the patent linkage system in the United States. The system requires that the NMPA continue to review the potentially infringing follow-on application during any lawsuit by the innovator. However, the NMPA may not approve the follow-on application pending resolution of the patent litigation in favor of the follow-on application or for a specified period of time, whichever is shorter. The Amended PRC Patent Law and relevant implementing regulations also provide patent term extension, similar to the United States, for the patent term lost during the regulatory review process of a new drug upon the patent holder's request. The extended term shall not exceed five years, and the total patent term of the new drug from the date of its market approval shall not exceed 14 years. However, subject to the decision of relevant authorities, the patents we have in-licensed or own in the PRC may not be eligible to be extended for any patent term lost during the regulatory review process. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Once the patent life has expired for a product, we may be subject to competition from generic medications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent and other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises and physical and electronic security of our information technology systems. Enforcing a claim that a party illegally obtained and is using our trade secrets is challenging and the outcome is unpredictable. In addition, courts outside of the United States may be less willing to protect trade secrets. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors.

Although we expect all of our employees and consultants to assign their applicable inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide guarantee that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. Moreover, some of our employees, including senior management, may have been employed at other pharmaceutical companies, including our competitors or potential competitors. Such employees may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. We may be subject to claims these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. In the event that litigation is necessary to defend against such claims, we may be subject to monetary damages and lose valuable intellectual property rights or personnel.

Further, filing, prosecuting and defending patents on our products, ETUARY®, Etorel® and Contiva®, 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 products, ETUARY®, Etorel® and Contiva®, 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 products, ETUARY®, Etorel® and Contiva®, 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 products, ETUARY®, Etorel® and Contiva®, 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, products, ETUARY®, Etorel® and Contiva®, 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, redesigning infringing products or obtaining 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®, Etorel®, Contiva® 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 products, ETUARY®, Etorel® and Contiva®, continue to be marketed, such products' 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®, Etorel®, Contiva® 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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 Hydronidone 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 three successfully approved and commercialized products: (i) ETUARY®, which is approved in the PRC for the treatment of IPF; (ii) Etorel®, which is approved in the PRC for the treatment of IPF; and (iii) Contiva® for the treatment of TP associated with CLD in adult patients undergoing elective diagnostics procedures or therapy. We also received approval to expand the indication for Contiva® to include ITP in January 2025. ETUARY® is currently in its Phase 3 clinical trial for the treatment of PD and Phase 2/3 clinical trial of ETUARY® for the treatment of RILI. 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, we plan to submit an NDA for conditional approval of Hydronidone for the treatment of CHB-associated liver fibrosis in the PRC in the first half of 2026, subject to final data readiness and applicable regulatory procedures. In addition, we plan to file a U.S. IND for Hydronidone for the treatment of MASH-associated liver fibrosis in 2026, and, subject to clearance, initiate a Phase 2 clinical trial, and we may file additional INDs 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, we initiated a Phase 1 clinical trial in F230 in the PRC for the treatment of PAH, our product that demonstrated the potential to significantly alleviate PAH in animal studies.

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 Hydronidone 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 Hydronidone in the PRC and potentially additional markets beyond the PRC, may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval.

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

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

- the approval policies or regulations of the NMPA, FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

The approval requirements for our product candidates are likely to vary by jurisdiction such that success in one jurisdiction is not necessarily predicative of success elsewhere.

We may experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- the availability of financial resources to commence and complete the planned trials;
- inability to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an IRB;
- recruiting suitable patients to participate in trials;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; and
- manufacturing sufficient quantities of qualified materials under cGMP 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 Hydronidone 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 Hydronidone 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 Hydronidone 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 Hydronidone for the treatment of liver fibrosis associated with MASH. The requirements for approval of Hydronidone 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 Hydronidone for the treatment of liver fibrosis associated with MASH. Although there are guidelines issued by the FDA for the development of drugs for the treatment of MASH, the development of a novel product candidate such as Hydronidone 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 MASH therapies, we expect that the path for regulatory approval for MASH therapies may continue to evolve in the near term as these other companies refine their regulatory approval strategies and interact with regulatory authorities. Such evolution may impact our future clinical trial designs, including trial size and endpoints, in ways that we cannot predict today. In particular, regulatory authority expectations about liver biopsy data may evolve especially as more information is published about the inherent variability in liver biopsy data.

Certain of our competitors have experienced regulatory setbacks for MASH therapies following communications from the FDA. We currently do not know the impact, if any, that these setbacks could have on the path for regulatory approval for MASH therapies generally or for Hydronidone.

Our anticipated development costs would likely increase if development of Hydronidone 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 MASH indications, we may be required to perform additional trials, which would result in increased costs and may affect the timing or outcome of our clinical trials. In addition, Hydronidone 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 Hydronidone'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 products, ETUARY®, Etorel® and Contiva®, and future products, if approved and commercialized. 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 AKS 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 AKS, 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 products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized, may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, ETUARY®, Etorel® and Contiva®, and future products, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, and future products, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, and future products, if approved and commercialized, or in our decreased ability to export such products to, existing or potential customers with international operations. Any decreased use of our products, ETUARY®, Etorel® and Contiva®, and future products, if approved and commercialized, 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

The price of pharmaceuticals has been a topic of considerable public discussion that could lead to price controls or other price-limiting strategies by payors that have the effect of lowering payment and reimbursement rates for drugs or otherwise making the commercialization of pharmaceuticals less profitable. Many federal and state legislatures have considered, and adopted, healthcare policies intended to curb rising healthcare costs, such as the Inflation Reduction Act of 2022. These cost-containment measures may include, among other measures: requirements for pharmaceutical companies to negotiate prescription drug prices with government healthcare programs; controls on government-funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare programs, including if drug prices increase at a higher rate than inflation; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third-party payors to make coverage and payment decisions. Political, economic and regulatory developments may further complicate developments in healthcare systems and pharmaceutical drug pricing. These developments could, for example, impact our potential licensing agreements as commercial and collaborative partners may also consider the impact of these pressures on their licensing strategies.

Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our product candidates. The implementation of any price controls, caps on prescription drugs or price transparency requirements could adversely affect our business, operating results and financial condition.

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 products, ETUARY®, Etorel® and Contiva®, and future products, if approved and commercialized. 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and any other future product, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized 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 products, ETUARY®, Etorel® and Contiva®, and future products, if approved and commercialized, or imposed 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 PHI (as defined in HIPAA) 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 processing of personal data, including health-related personal data in the European Economic Area ("EEA") is mainly governed by the provisions of the GDPR, and related data protection laws in individual EEA countries. In the United Kingdom, the processing of personal data is mainly governed by the GDPR as incorporated into UK law pursuant to the European Union (Withdrawal) Act 2018 (the "UK GDPR"). The GDPR and UK GDPR impose a number of strict obligations and requirements for the processing, including collecting, analyzing and transferring of personal data of individuals in the EEA or in the UK, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR and UK GDPR include 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 personal data breaches which may have to be notified to the national data protection authorities and data subjects, the measures to be taken when engaging processors, and obligations relating to the security and confidentiality of the personal data. EEA countries may also impose additional requirements in relation to the processing of health, genetic and biometric data through their national legislation.

Failure to comply with the requirements of the GDPR or UK GDR and the related national data protection laws of the EEA countries may result in significant monetary fines for noncompliance of up to €20.0 million or £17.5 million (as applicable), 4% of the total worldwide annual turnover (for higher-tier infringements). This is enforced by ICO and is entirely separate from fines under EU GDPR. In addition, violations of national laws can trigger additional, administrative penalties, investigations, corrective orders, temporary or definitive bans, and, in some jurisdictions, and a number of criminal offenses for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed.

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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us 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

The PRC government may exert influence over Gyre Pharmaceuticals' operations, which could result in an adverse change in our operations.

We have extensive business operations in the PRC, including manufacturing, sales and marketing, research and development and other business operations. Accordingly, the PRC government has some oversight and discretion over the conduct of our business in the PRC and may exert influence over our operations. The PRC government has recently published new policies that significantly affected certain industries, and we cannot rule out the possibility that it will in the future do the same regarding our industry, including policies that could require us to seek permission from the PRC authorities to continue to operate our business in the PRC.

In February 2023, the CSRC released the Trial Administrative Measures of Overseas Securities Offering and Listing by Domestic Enterprises (the "Trial Measures"), which came into effect on March 31, 2023. The Trial Measures comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and regulate both direct and indirect overseas offering and listing of PRC domestic companies' securities by adopting a filing-based regulatory regime.

In February 2023, the CSRC and other PRC governmental authorities jointly issued the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (the "Confidentiality Provisions"), which came into effect on March 31, 2023. According to the Confidentiality Provisions, PRC domestic companies that directly or indirectly conduct overseas offerings and listings shall strictly abide by the laws and regulations on confidentiality when providing or publicly disclosing, whether directly or through their overseas listed entities, materials to securities services providers. In the event such materials contain state secrets or working secrets of government agencies, PRC domestic companies shall first obtain approval from authorities, and file with the secrecy administrative department at the same level with the approving authority; in the event that such materials, if divulged, will jeopardize national security or public interest, PRC domestic companies shall comply with procedures stipulated by national regulations.

If (i) we mistakenly conclude that certain regulatory filings, permissions and approvals are not required, (ii) applicable laws, regulations, or interpretations change, or (iii) we are required to obtain such filings, permissions or approvals in the future, we may be unable to obtain them in a timely manner, or at all, and such filings, permissions or approvals may be denied or rescinded even if obtained. We may face adverse actions or sanctions by the CSRC or other PRC regulatory agencies if we are unable to comply with such requirements, which may result in fines and penalties, restrictions on our operations, having to delist from a stock exchange outside of China, the halting of securities offerings to foreign investors and/or other actions that could materially and adversely affect our operations.

Any such actions or sanctions, once taken by the PRC government, could significantly limit delay or 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 products, ETUARY®, Etorel® and Contiva®, 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—Our Operations in the PRC: Gyre Pharmaceuticals—Government Regulations 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.

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 products, ETUARY®, Etorel® and Contiva®, and any other future products, if approved and commercialized, 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 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 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. Our ability to successfully maintain or grow business operations in the PRC depends on various factors, which are beyond our control. These factors include, among others, macroeconomic and other market conditions, political stability, social conditions, measures to control inflation or deflation, changes in the rate or method of taxation, changes in laws, regulations and administrative directives or their interpretation, and changes in industry policies. If we fail to take timely and appropriate measures to adapt to any of the changes or challenges, our business, results of operations and financial condition could be materially and 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. In particular, as a result of the recency of implementation of certain laws and regulations, the non-precedential nature of court decisions, and the discretion regulators have in interpretation and enforcement of such laws, rules and regulations, the PRC legal system involves significant uncertainties, and can be inconsistent in its implementation, interpretation and enforcement. 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. These uncertainties may impede our ability to enforce our contracts 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 which may be amended from time to time with little advance notice. As a result, we may not be aware of our violation of these policies and rules until after the occurrence of the violation.

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. 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. The PRC government's enhanced measures relating to social insurance collection 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized in the PRC, have been entitled to a preferential VAT treatment at the tax rate of 3%, 3% and 13%, respectively. 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®, Etorel®, Contiva® and future approved product candidates.

Furthermore, under the PRC 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. This 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 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 preclinical studies or clinical trials conducted within the PRC) abroad or to our foreign partners in the PRC.

In addition, pursuant to the Service Guide for Administrative Licensing Items on the Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC, the sampling, collection or research activities of human genetic resources through clinical trials is required to be submit through applications with the relevant authority for such authority's review and approval. Furthermore, the Administrative Regulations on Human Genetic Resources of the PRC 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 health 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 health 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 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 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.

During the years ended December 31, 2025 and 2024, 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 products, ETUARY®, Etorel® and Contiva®, 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 products, ETUARY®, Etorel® and Contiva®, and future products, if approved and commercialized, 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. Changes in the state of relations between the PRC and the United States or other governments are difficult to predict and could adversely affect 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 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. Since February 2025, the United States government has imposed various tariffs on imports from most countries, including tariffs on imports from the PRC. In September 2025, President Trump announced plans to impose 100% tariffs on imported branded or patented pharmaceuticals, unless the importing company is building U.S. manufacturing capacity, although the effective date of such tariffs has been delayed. Certain major drug producers and manufacturers are in negotiations with the U.S. Presidential Administration to receive relief from such tariffs. As a result of these negotiations, certain manufacturers, such as Pfizer, have announced their participation in a new direct purchasing platform called “TrumpRx.gov,” designed to offer discounts on their products and some specialty brands. Details regarding potential platforms, as well as any potential impact on our business are unclear at this time. It is not yet clear whether these tariffs would apply to the importation of API and possibly bulk drug products that are intended for use in clinical trials and not for commercial sale, which could increase the costs of materials for our clinical trials. There still remains substantial uncertainty about the duration of existing tariffs and whether additional tariffs may be imposed, modified or suspended.

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 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 laws, regulations and guidelines relating to data security, cybersecurity and privacy 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 Cybersecurity Law and the Administrative Measures for the Hierarchical Protection of Information Security require 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 rules, regulations and guidelines relating to the multi-level protection scheme, 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 cybersecurity. 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 Cybersecurity Review 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 September 24, 2024, the State Council of the PRC published the Network Data Regulations, which became effective on January 1, 2025. The Network Data Regulations provide detailed implementing rules and guidance on various aspects of data compliance requirements under the existing data protection framework pillars of the Cybersecurity Law, the PRC Data Security Law and the PRC Personal Information Protection Law. The Network Data Regulations supplement the requirements on several aspects of the PRC Personal Information Protection Law regarding notification, consent, and the exercise of personal rights, provide more detail on compliance requirements for processors of important data, and also provide more guidance to streamline cross-border data transfers.

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 Cybersecurity Review Measures and Regulation on Network Data Security Management (the "Network Data Regulations"). Based on our understanding of the Cybersecurity Review Measures, and the Network Data Regulations, we believe it is unlikely that they will 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 do 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 Cybersecurity Review Measures, and the Network Data 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 Cybersecurity Review Measures, the Network Data Regulation or other laws and regulations related to cybersecurity, privacy and data 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 Cybersecurity Review 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 SAFE. In particular, if Gyre Pharmaceuticals finances by means of foreign debt from BJContinent Pharmaceuticals Limited or other foreign lenders, the amount is not allowed to, among other things, exceed the statutory limits and such loans must be registered with the local branch of SAFE. If Gyre Pharmaceuticals finances by means of additional capital contributions, these capital contributions are subject to registration with the State Administration for Market Regulation or its local branch, reporting of foreign investment information with the MOFCOM or its local branch, or registration with other governmental authorities in the PRC.

In light of the various requirements imposed by PRC regulations on loans to, and direct investment in, PRC-based entities by offshore holding companies, there can be no assurance that Gyre Pharmaceuticals will be able to complete the necessary government requirements or obtain the necessary government approvals on a timely basis, if at all, with respect to future loans or capital contributions by Gyre Pharmaceuticals. If Gyre Pharmaceuticals fails to adhere to such requirements or obtain such approval, Gyre Pharmaceuticals' ability to capitalize or otherwise fund Gyre Pharmaceuticals' PRC operations, including Gyre Pharmaceuticals' technology development may be negatively affected, which could materially and adversely affect Gyre Pharmaceuticals' ability to fund and expand Gyre Pharmaceuticals' business.

Gyre Therapeutics may not be able to transfer funds out of Gyre Pharmaceuticals, or Gyre Therapeutics might face difficulties in transferring funds from investors in the PRC should Gyre Therapeutics decide to solicit investments from investors in the PRC, in a timely manner due to restrictions imposed by the PRC authorities.

PRC regulations relating to the establishment of offshore special purpose companies by residents in the PRC may subject our PRC resident beneficial owners in the PRC to liability or penalties, or may otherwise adversely affect us.

The Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles ("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 in 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 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 are non-PRC citizens but 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.

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.

The PRC tax authorities have strict 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"), as amended and supplemented by the Notice of the Ministry of Finance and the State Administration of Taxation on Issues Concerning the Enterprise Income Tax Treatment for Promoting Enterprise Restructuring, and the Bulletin on Issues of Enterprise Income Tax and Indirect Transfers of Assets by Non-PRC Resident Enterprises ("Bulletin 7"), as amended and supplemented by the relevant SAT rules including but not limited to the Bulletin on Issues Relating to Withholding at Source of Income Tax of Non-resident Enterprises ("Bulletin 37"). Pursuant to 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 income tax payable overseas for the transaction of indirect transfer of taxable assets in PRC; 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 and acquisition of shares by non-resident enterprise 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, the applicable SAT rules, or to establish that its non-resident enterprises should not be taxed under the relevant rules.

The PRC tax authorities have the discretion under these applicable rules 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 Circular 59 or Bulletin 7 and Bulletin 37, Gyre Pharmaceuticals' income tax costs associated with such potential acquisitions will be increased, which may have an adverse effect on Gyre Pharmaceuticals' financial condition and results of operations.

The enacted "Holding Foreign Companies Accountable Act" and the "Accelerating Holding Foreign Companies Accountable Act" call for additional and more stringent criteria to be applied to emerging market companies upon assessing the qualification of their auditors, especially the non-U.S. auditors who are not inspected by the Public Company Accounting Oversight Board. These developments could add uncertainties to the market for our common stock.

The Holding Foreign Companies Accountable Act (the "HFCAA") requires certain issuers of securities to establish that they are not owned or controlled by a foreign government. Specifically, an issuer must make this certification if the Public Company Accounting Oversight Board (the "PCAOB") is unable to audit specified reports because the issuer has retained a foreign public accounting firm not subject to inspection by the PCAOB. Furthermore, if the PCAOB is unable to inspect the issuer's public accounting firm for three consecutive years, the issuer's securities are banned from trading on a national exchange or through other methods. In December 2022, the Accelerating Holding Foreign Companies Accountable Act amended the HFCAA by decreasing the number of non-inspection years from three to two, thus reducing the time period before our common stock may be prohibited from trading or delisted if the PCAOB were to determine that it could not inspect our auditor.

In March 2021, the SEC adopted interim final amendments to implement congressionally mandated submission and disclosure requirements of the HFCAA. The interim final amendments will apply to registrants that the SEC identifies as having filed an annual report on Forms 10-K, 20-F, 40-F or N-CSR with an audit report issued by a registered public accounting firm that is located in a foreign jurisdiction and that the PCAOB has determined it is unable to inspect or investigate completely because of a position taken by an authority in that jurisdiction. In December 2021, the SEC adopted amendments finalizing such rules to require that any such identified registrant is required to submit documentation to the SEC establishing that it is not owned or controlled by a governmental entity in that foreign jurisdiction, and is also required to disclose in the registrant's annual report the audit arrangements of, and governmental influence on, such a registrant.

In December 2021, the PCAOB issued a Determination Report which found that the PCAOB was then unable to inspect or investigate completely registered public accounting firms headquartered in: (1) mainland China of the PRC, because of a position taken by one or more authorities in mainland China; and (2) Hong Kong, a Special Administrative Region and dependency of the PRC, because of a position taken by one or more authorities in Hong Kong. The PCAOB has made such designations as mandated under the HFCAA. Pursuant to each annual determination by the PCAOB, the SEC will, on an annual basis, identify issuers that have used non-inspected audit firms and thus are at risk of such suspensions in the future.

In August 2022, the CSRC, the Ministry of Finance of the PRC, and the PCAOB signed a Statement of Protocol (the "Protocol"), governing inspections and investigations of audit firms based in mainland China and Hong Kong. Pursuant to the Protocol, the PCAOB shall have independent discretion to select any issuer audits for inspection or investigation and has the unfettered ability to transfer information to the SEC. In December 2022, the PCAOB determined that the PCAOB was able to secure complete access to inspect and investigate registered public accounting firms headquartered in mainland China and Hong Kong and voted to vacate its previous determinations to the contrary. While vacating those determinations, the PCAOB noted that, should it encounter any impediment to conducting an inspection or investigation of auditors in mainland China or Hong Kong as a result of a position taken by any authority there, the PCAOB will consider the need to issue a new determination. Notwithstanding the foregoing, if the PCAOB is not able to inspect and investigate completely our auditor's work papers in China, you may be deprived of the benefits of such inspection which could result in limitation or restriction to our access to the U.S. capital markets and trading of our securities may be prohibited under the HFCAA.

Our auditor, Grant Thornton Zhitong Certified Public Accountants LLP, an independent public accounting firm registered with the PCAOB, and an auditor of publicly traded companies in the U.S., is subject to laws in the U.S. pursuant to which the PCAOB conducts regular inspections to assess its compliance with the applicable professional standards. Our auditor is headquartered in mainland China and was inspected by the PCAOB for the first time in July 2024 and was identified as a firm subject to the determinations announced by the PCAOB in December 2021. Should the PCAOB be unable to fully conduct inspection of our auditor's work papers in mainland China, it will make it difficult to evaluate the effectiveness of our auditor's audit procedures or equity control procedures. Investors may consequently lose confidence in our reported financial information and procedures or quality of the financial statements, which would adversely affect us and our securities. Moreover, if trading in our securities is prohibited under the HFCAA in the future because the PCAOB determines that it cannot inspect or fully investigate our auditor at such future time, if our securities were then traded on an exchange, that exchange may determine to delist our securities.

Risks Related to Commercialization of Our Product and Product Candidates

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 PD 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 PD.

In addition, the regulatory authorities in the PRC, United States and the EU have not approved any products for the treatment of MASH, and while there are guidelines issued by the NMPA and FDA for the development of drugs for the treatment of MASH and an NMPA and FDA surrogate endpoint table for drug approval, respectively, it is unclear whether the requirements for approval will change in the future or whether the NMPA or FDA will rely on regulatory precedent for future regulatory approvals. Any such changes may require us to conduct new trials that could delay our timeframe and increase the costs of our programs related to Hydronidone or any future product candidate for the treatment of MASH. In addition, we cannot be certain which efficacy endpoints or presentation thereof clinical or regulatory agencies may require in a Phase 3 clinical trial of MASH or for approval of our product candidates.

Even if the NMPA, FDA or other regulatory agency approves our product candidates, the approval may impose significant restrictions on the indicated uses, conditions for use, labeling, advertising, promotion, marketing and/or production of such product and may impose ongoing commitments or requirements for post-approval studies, including additional research and development and clinical trials. The NMPA, FDA and other agencies also may impose various civil or criminal sanctions for failure to comply with regulatory requirements, including withdrawal of product approval.

Regulatory approval from authorities in foreign countries will be needed to market our product candidates in those countries. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. For example, ETUARY® is approved for the treatment of pulmonary fibrosis in the PRC but may not be approved in any other jurisdiction, such as the United States, for such indication. If we fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited.

We face substantial competition that may result in others discovering, developing, commercializing or marketing products, including our commercialized products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, before or more successfully than we do.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition, and a strong emphasis on proprietary products. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies, and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Although there is one approved therapeutic drug treatment for liver fibrosis in the United States, several companies are developing product candidates in clinical studies. For details, see "*—Business—Market Overview of Pipeline Products*" 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, MASH, PD, DKD, ALF/ACLF or COPD. If ETUARY®, Hydronidone, 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and future products, if approved and commercialized, 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 products, ETUARY®, Etorel® and Contiva®, and future products, if approved and commercialized. 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 products, ETUARY®, Etorel® and Contiva®, which are approved and commercialized by us in the PRC, and any other future product, if approved and commercialized, 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 they develop 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 product, ETUARY®, is subject to the risk of being included in the PRC's centralized volume-based procurement scheme. For details, see "*—In the future, the policies of centralized volume-based procurement set by the PRC government may cover our commercialized product, ETUARY®, and any other future products, if approved and commercialized, 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 has been, and may continue 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;
- 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 products, ETUARY®, Etorel® and Contiva®, 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 19,483,378 shares of common stock at a weighted average exercise price of $3.09 as of December 31, 2025. If such options are exercised and the shares are sold into the open market, such sales also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Conversion or exercise of these securities into shares of our common stock will cause dilution to the other holders of our common stock, and all such stock may be sold in the public market after conversion or exercise, subject to restrictions under the securities laws, which may lead to a decline in the market price of our common stock.

Provisions in our certificate of incorporation and bylaws and provisions under Delaware law could make an acquisition of the Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our management.

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

- continue the use of a classified board of directors such that not all members of our board of directors are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;

- provide for advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our board of directors;
- limit who may call stockholder meetings;
- limit actions by our stockholders by written consent;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the votes that all stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which generally prohibits a person who, together with their affiliates and associates, owns 15% or more of the company's outstanding voting stock from, among other things, merging or combining with the company for a period of three years after the date of the transaction in which the person acquired ownership of 15% or more of the company's outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation and bylaws generally provide that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees.

Our certificate of incorporation and bylaws provide that, unless the company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers, employees or stockholders to the company or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware or (4) any action asserting a claim arising pursuant to any provision of our restated certificate of incorporation or our bylaws (in each case, as they may be amended from time to time) or that is governed by the internal affairs doctrine. This choice of forum provision will not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

This exclusive forum provision may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees or stockholders, which may discourage such lawsuits against us and our directors, officers and other employees and stockholders. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation and bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

We 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 cease coverage of us or fail 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.

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, 2025, after consideration of certain limitations (see below), we had approximately $193.3 million federal and $21.7 million state net operating loss carryforwards. 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 net operating losses (“NOLs”) and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. A Section 382 “ownership change” is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization. We have experienced several ownership changes. Approximately $156.5 million and $75.2 million of the NOLs will expire unutilized for federal and California state income tax purposes, respectively. We may experience 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, 2025, 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. 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 products, ETUARY®, Etorel® and Contiva®, 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 products, ETUARY®, Etorel® and Contiva®, and future products, if approved, criminal liability and the revocation of our business licenses. PRC laws and regulations currently do not require us to, and we do not, maintain liability insurance to cover product liability claims. As a result, we may not be able to recover our losses resulting from future product liability claims.

Breach, failure or disruption in or to our information system could compromise sensitive information related to our business and expose us to liability or reputational harm, and our ability to effectively manage our business operations could be adversely affected.

Our information systems may fail and are subject to risks of breakdown, breach, interruption or damage from computer viruses, ransomware and other cyber-attacks, computer hackers, malicious code, employee error or malfeasance, theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromise. Any system damage or failure that interrupts data input, retrieval or transmission or increases service time could disrupt our normal operations, including the loss of clinical trial data from completed or future clinical trials. Loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. There can be no assurance that we will be able to effectively handle a failure of our information systems, or that we will be able to restore our operational capacity in a timely manner or at all to avoid disruption to our business. Further, cybersecurity breaches or other cybersecurity incidents may allow hackers access to our preclinical compounds, strategies, discoveries, trade secrets, and/or other confidential information. Additionally, sensitive data could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, vendors' or partners' use of generative AI technologies. To the extent that any disruption or cybersecurity incident were to result in a loss of, or damage to, our data or applications, or inappropriate use, disclosure of or access to confidential or proprietary information, we could incur liability, including under laws and regulations governing the protection of PHI and other personal data, our competitive position could be harmed and the further development and commercialization of our products, ETUARY®, Etorel® and Contiva®, and product candidates could be hindered or delayed. The risk of a cybersecurity incident or other informational technology disruption, particularly through cyber-attacks, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

We may collect and store sensitive personal data in the ordinary course of our business. For details, see "*—Risks Related to Our Business Operations in the PRC—Compliance with the PRC's laws, regulations and guidelines relating to data security, cybersecurity and privacy and any other future laws and regulations may entail significant expenses and could affect our business*" in this Risk Factors section. If personal data are compromised due to a material breach of our information, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations.

You may have difficulty enforcing judgments obtained against us.

Substantially all of our assets are located outside of the United States. Most of our operations and administrative and corporate functions are conducted in the PRC. In addition, several of our directors and officers are nationals and residents of countries other than the United States. A substantial portion of the assets of these persons are located outside the United States. As a result, due to the lack of reciprocity and treaties between the United States and some of these foreign jurisdictions, together with cost and time constraints, it may be difficult for you to effect service of process within the United States upon these persons. In particular, several of our officers and directors are generally located in the PRC, and it will be more difficult to enforce liabilities and enforce judgments on those individuals.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

Pursuant to Section 404(a) of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), our management is required to report upon the effectiveness of our internal control over financial reporting. Beginning with our annual report for our fiscal year ending December 31, 2024, we became an "accelerated filer." As an "accelerated filer," Section 404(b) of the Sarbanes-Oxley Act requires our independent auditors to express an opinion on our internal control over financial reporting. Ensuring that we have adequate internal controls in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, our independent registered public accounting firm may issue a report that is adverse, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the SEC or the Sarbanes-Oxley Act. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated.

Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We may identify material weaknesses or significant deficiencies in our internal control over financial reporting in the future or fail to maintain effective internal control over financial reporting, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of the registrant's financial reporting.

Remediation measures to remediate a material weakness or significant deficiency may be time consuming, may result in us incurring significant costs, and may place significant demands on our financial and operational resources.

Our failure to identify and address any material weaknesses or significant deficiencies that may be identified in the future could result in material misstatements to our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our securities.

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 Information Security 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. In the process of advancing the systematic development of information security, we seek to maintain a robust approach that encompasses policy formulation, organizational structuring, technological application enhancement, process optimization, and personnel training. 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 information security team, who reports to the Secretary of the General Manager at Gyre Pharmaceuticals, comprises of four employees with an average of 20 years of experience managing information technology and cybersecurity matters. The Secretary of the General Manager reports to the General Manager at Gyre Pharmaceuticals, and the General Manager reports to the Board of Directors and is responsible for assessing and managing Gyre Pharmaceuticals' cybersecurity risks. We consider cybersecurity, along with other significant risks that we face, within our overall enterprise risk management framework. Since the beginning of 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 eight properties with an aggregate gross floor area of 22,169 square meters. Gyre Pharmaceuticals' two production centers are in Beijing, PRC and Cangzhou, PRC.

Leased Properties

Gyre Pharmaceuticals leases 26 properties in the PRC. Among Gyre Pharmaceuticals' 26 leased properties, 11 are used as offices, and 15 are used as employee dormitories.

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 2, 2026, there were approximately 45 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

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 commercial-stage biopharmaceutical company focused on the development and commercialization of small-molecule therapies for the treatment of organ fibrosis and inflammatory diseases. We operate through our majority indirectly owned subsidiary, Gyre Pharmaceuticals, in the PRC, and through our U.S. operations headquartered in San Diego, California.

Our strategy is to leverage our established commercial portfolio to support and de-risk the advancement of late-stage product candidates, expand approved products into additional indications, and build a diversified pipeline targeting significant unmet medical needs in fibrosis and related inflammatory diseases.

On March 2, 2026, we entered into the Merger Agreement with Cullgen and Merger Sub, pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Cullgen, with Cullgen continuing as a wholly owned subsidiary of Gyre and the surviving corporation of the Merger. The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

The consummation of the Merger is subject to certain closing conditions, including, among other things, (1) approval by the requisite Cullgen stockholders of the adoption and approval of the Merger Agreement and the transactions contemplated thereby, and (2) a filing under the HSR Act.

There can be no assurances that the Merger will be successfully consummated, and the intended benefits of the Merger may not be realized.

Our Commercial Portfolio

ETUARY® (pirfenidone)

Pirfenidone is a small-molecule anti-fibrotic therapy for the treatment of IPF. It was first approved in Japan and subsequently approved in the PRC, the EU, and the United States. These approvals were obtained by different sponsors in their respective jurisdictions under separate regulatory frameworks.

In the PRC, we conducted independent research and development to support our regulatory submission and received first-in-class approval in 2011 as a National Category 1.1 New Drug. We commercialized pirfenidone under the brand name ETUARY®, which was included in the NRDL in 2017 and has since maintained a leading market position.

In addition to IPF, we are pursuing potential label expansion into additional indications in the PRC, including PD, for which, in 2025, we completed enrollment of 272 patients in our 52-week Phase 3 trial, and RILI, including cases with or without immune-related pneumonitis, for which the NMPA approved our clinical trial application in March 2025, and we expect to initiate an adaptive Phase 2/3 study in the first half of 2026.

Etorel® (nintedanib esilate soft capsules)

In May 2024, Gyre Pharmaceuticals entered into a comprehensive agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. to obtain the drug registration certificate for Etorel® (nintedanib) and become the marketing authorization holder in the PRC. Etorel® is approved as a standard-of-care therapy for IPF, SSc-ILD, and PF-ILD. The addition of Etorel® to our commercial portfolio expanded treatment options for patients and strengthened Gyre's leading position in the pulmonary fibrosis market. Commercialization of Etorel® in the PRC commenced in June 2025.

On November 7, 2025, the NHSA released the *Announcement of the Winning Bids for the National Centralized Drug Procurement*, under which Etorel® was selected. As of the filing date, we are in the process of entering into procurement contracts with various participating hospitals under the National Centralized Drug Procurement program. We are currently assessing the potential impact of this development on its future operating performance.

Contiva® (avatrombopag maleate tablets)

In June 2021, Gyre Pharmaceuticals acquired avatrombopag maleate tablets pursuant to a transfer agreement with Nanjing Healthnice Pharmaceutical Technology Co., Ltd. Avatrombopag is an oral thrombopoietin receptor agonist. In June 2024, the NMPA approved avatrombopag maleate tablets for the treatment of TP associated with CLD in adult patients undergoing elective diagnostic procedures or therapy. In January 2025, the NMPA approved an additional indication for chronic ITP. Gyre Pharmaceuticals commenced commercialization of avatrombopag under the brand name Contiva® in the PRC in March 2025.

Our Product Candidate Pipeline

Hydronidone

Hydronidone is our lead development candidate for the treatment of liver fibrosis. It is a structurally modified derivative of pirfenidone designed to optimize metabolic properties while targeting the TGF-β1 signaling pathway, a key mediator of fibrogenesis. We are developing Hydronidone for two primary indications: CHB-associated liver fibrosis in the PRC and MASH-associated liver fibrosis in the United States. Hydronidone represents our primary liver-focused development program and reflects our commitment to advancing therapies targeting both viral- and metabolic-associated liver fibrosis.

CHB-Associated Liver Fibrosis (PRC)

For CHB-associated liver fibrosis, antiviral therapy may suppress viral infection but is not able to prevent, slow or reverse fibrosis progression, and anti-fibrotic treatment is recommended for intermediate and advanced liver fibrosis and early-stage cirrhosis. As of December 31, 2025, no small molecule or biologic drugs treating CHB-associated liver fibrosis have been approved globally. In recognition of the severity of the disease and the preliminary clinical evidence generated to date, the CDE of the NMPA granted Hydronidone Breakthrough Therapy designation in March 2021.

We conducted a Phase 3 randomized, double-blind, placebo controlled, Entecavir-based, multi-center trial in the PRC assessing Hydronidone in CHB-associated liver fibrosis. This trial was designed to randomize 248 patients, with a primary endpoint of ≥1-stage reduction in Ishak fibrosis score at Week 52 for Hydronidone in combination with Entecavir.

In May 2025, we reported that in the pivotal Phase 3 trial, Hydronidone met its primary endpoint: 52.85% of treated patients achieved ≥1-stage fibrosis regression at Week 52, compared with 29.84% in the placebo group (p=0.0002), based on centralized, blinded Ishak histologic assessment. Hydronidone also met a key secondary endpoint with statistically significant inflammation improvement without fibrosis progression at Week 52 versus placebo. Hydronidone was well tolerated, with a comparable incidence of serious adverse events (4.88% vs. 6.45% in placebo) and no discontinuations due to adverse events in the Hydronidone group.

Following our pre-NDA meeting in December 2025, the CDE indicated that the existing Phase 3 data support submission for conditional approval and potential priority review eligibility, subject to formal acceptance and approval by the NMPA. We currently expect to submit an NDA seeking conditional approval in the first half of 2026, subject to completion of regulatory and technical preparations.

MASH-Associated Liver Fibrosis (United States)

In the United States, we have completed a Phase 1 clinical trial in healthy volunteers evaluating Hydronidone's safety, tolerability, and PK. We continue to engage with the FDA regarding IND requirements for a Phase 2 clinical trial in MASH-associated liver fibrosis. Pending regulatory feedback, we intend to file a U.S. IND in 2026 and, if the IND becomes effective, initiate a Phase 2 clinical trial.

Other Product Candidates

We have completed a Phase 1 clinical trial of F573 in healthy volunteers in the PRC and are currently evaluating it in a multi-stage Phase 2 clinical trial initiated in March 2023 in patients with liver injury and liver failure. The Phase 2 clinical trial is expected to be completed in 2026.

F230 is our clinical-stage product candidate for the treatment of PAH in the PRC. F230 is a selective endothelin receptor A antagonist designed to address vascular remodeling and elevated pulmonary arterial pressure associated with PAH. F230 complements our broader organ-focused portfolio by expanding our development efforts into pulmonary vascular disease while remaining aligned with our strategy of targeting fibrotic and inflammatory pathways across organ systems. We submitted an IND application for F230 to the NMPA in March 2024, and the IND was approved in May 2024. The first subject was enrolled in the Phase 1 clinical trial in June 2025.

F528 is our preclinical-stage product candidate for the treatment of COPD in the PRC. F528 is an anti-inflammatory small-molecule compound designed to inhibit multiple inflammatory cytokines and potentially modify disease progression. F528 expands our pulmonary-focused development efforts beyond fibrosis and vascular disease into chronic inflammatory respiratory conditions, supporting our broader strategy of addressing organ diseases driven by inflammatory and fibrotic pathways. We anticipate submitting an IND application to the NMPA for F528 in the first quarter of 2027.

Contingent Value Rights Agreement

Concurrent with the signing of the previously disclosed business combination agreement pursuant to which we acquired an indirect controlling interest in Gyre Pharmaceuticals, on December 26, 2022, the Company 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 (as defined in the CVR Agreement), excluding GNI Japan and GNI Hong Kong Limited, received one contractual contingent value right (a "CVR") issued by the Company for each share of common stock held by such holders. Each CVR entitles the CVR Holder thereof to receive certain cash payments in the future. In the first quarter of 2025, we had fully settled the CVR liability and collected all outstanding amounts related to CVR receivables.

Share Capital Increase Agreement

In the third quarter of 2025, pursuant to an agreement previously entered into by and among BJContinent Pharmaceuticals Limited ("BJC"), Gyre Pharmaceuticals and the other parties thereto, BJC increased its capital contribution in Gyre Pharmaceuticals by $1.28 million in exchange for 9,184,910 additional shares of Gyre Pharmaceuticals. As a result, our indirect interest in Gyre Pharmaceuticals increased from 65.2% to 69.7%.

Long-Term Investment Measured Under Equity Method

On June 28, 2024, Gyre Pharmaceuticals entered into a partnership agreement as a limited partner and is obligated to pay $4.2 million for an 18.93% equity interest in the partnership. In April 2025, a new investor joined the partnership agreement, and as a result, Gyre Pharmaceuticals' equity interest was adjusted to 18.35%. Pursuant to the partnership agreement, Gyre Pharmaceuticals, as a limited partner, shall not participate in any activities related to the management of the investment business. However, Gyre Pharmaceuticals may appoint a member to the advisory committee of the partnership.

As of December 31, 2025 and 2024, our total investment into the partnership was $1.7 million and $1.7 million, respectively, and the carrying value of the Company's long-term investment in this affiliate was $1.6 million and $1.6 million, respectively.

Financial Operations Overview

During the year ended December 31, 2025, we had net income of $9.9 million and net income attributable to common stockholders of $5.0 million. For the year ended December 31, 2024, our net income was $17.9 million and net income attributable to common stockholders was $12.1 million. As of December 31, 2025, we had an accumulated deficit of $68.4 million and cash and cash equivalents of $37.1 million. As of December 31, 2024, we had an accumulated deficit of $73.5 million and cash and cash equivalents of $11.8 million.

Components of Results of Operations

Revenues

Sales of Pharmaceutical Products

We generate revenue primarily through sales of ETUARY®, Etorel®, Contiva® and certain generic drugs in the PRC. Distributors are our direct customers, and sales to distributors accounted for 100.0% of the revenue from each of ETUARY®, Etorel® and Contiva®. Such distributors sell our products to certain outlets, including hospitals and other medical institutions, as well as pharmacies.

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, including stock-based compensation; (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 products in the PRC and consist of expenses incurred from hosting academic conferences, seminars and symposia; promotional expenses associated with market education on our products for their use in hospitals; and staff costs primarily consisting of salaries, benefits, and stock-based compensation 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 preclinical and clinical development of our product candidates, which include payroll and other personnel-related expenses, including stock-based compensation, laboratory supplies and reagents, contract research and development services for preclinical research and clinical trials, materials, and consulting costs, as well as allocations of facilities, depreciation and other overhead costs.

We manage our research and development expenses by identifying the research and development activities we expect to be performed during a given period and then prioritizing efforts based on anticipated probability of successful technical development and regulatory approval, market potential, available human and capital resources, scientific data and other considerations. We regularly review our research and development activities based on unmet medical need and, as necessary, reallocate resources among our research and development portfolio that we believe will best support the long-term growth of our business. Although we do track and allocate certain operational research and development costs, as described above, we do not fully track and allocate research and development expenses at the individual product candidate level.

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.

Loss on Disposal of Property and Equipment

The net loss on the sale and disposal of property and equipment is reflected in our consolidated statements of operations and comprehensive income.

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 (Expense) Income, Net

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.

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

Change in Fair Value of Warrant Liability

In connection with a private placement conducted in October 2023 with GNI USA, Inc., we issued (i) 811 shares of our Series X Convertible Preferred Stock, par value $0.001 per share (the “Convertible Preferred Stock”) and (ii) warrants to purchase up to 811 shares of Convertible Preferred Stock (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.

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 carryforwards for U.S. tax purposes, and fixed and intangible assets, net of valuation allowances.

On July 4, 2025, the OBBBA was enacted into law, which introduced several U.S. income tax provisions that have and may continue to potentially impact our provision for income taxes. The provisions include, but are not limited to, the immediate expensing of domestic research and development expenses beginning in 2025, as well as a modification to the Global Intangible Low-Taxed Income effective in 2026. We have recognized the effects of the OBBBA provisions on our financial results to the extent they are applicable to the year ended December 31, 2025. We will continue to evaluate the impact of the OBBBA on our 2026 and subsequent financial statements.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands, except percentage change):

	Year Ended December 31,			
	2025	2024	Change ($)	Change (%)
Revenues	$ 116,588	$ 105,757	$ 10,831	10.2%
Operating expenses:				
Cost of Revenues	5,416	3,884	1,532	39.4%
Selling and marketing	65,179	57,511	7,668	13.3%
Research and development	13,698	12,024	1,674	13.9%
General and administrative	20,804	16,109	4,695	29.1%
Loss on disposal of property and equipment	4	66	(62)	(93.9)%
Total operating expenses	105,101	89,594	15,507	17.3%
Income from operations	11,487	16,163	(4,676)	(28.9)%
Other income (expense), net:				
Interest income, net	1,747	1,547	200	12.9%
Other expense, net	(1,505)	(1,659)	154	(9.3)%
Change in fair value of warrant liability	2,707	7,167	(4,460)	(62.2)%
Income before income taxes	14,436	23,218	(8,782)	(37.8)%
Provision for income taxes	(4,556)	(5,320)	764	(14.4)%
Net income from operations	9,880	17,898	(8,018)	(44.8)%
Net income attributable to noncontrolling interest	4,853	5,813	(960)	(16.5)%
Net income attributable to common stockholders	$ 5,027	$ 12,085	$ (7,058)	(58.4)%

Comparison of the Years Ended December 31, 2025 and 2024

Revenues

Revenues for the years ended December 31, 2025 and 2024 were $116.6 million and $105.8 million, respectively. The $10.8 million, or 10.2%, increase in revenue was driven by $5.5 million in Contiva® sales and $4.6 million in Etorel® sales, along with a $1.1 million increase in ETUARY® sales, partially offset by a $0.4 million decline in generic drug revenue.

Sales of Contiva® and Etorel®, which commenced commercialization in March 2025 and June 2025, respectively, were primarily driven by the targeted allocation of commercial and marketing resources to support their respective launches during the first half of 2025. The increase in ETUARY® sales reflects a strategic realignment of marketing efforts in the third quarter of 2025 to optimize product mix and address evolving market dynamics.

Cost of Revenues

Cost of revenues for the years ended December 31, 2025 and 2024 was $5.4 million and $3.9 million, respectively. The $1.5 million, or 39.4%, increase was primarily driven by a $0.8 million increase in ETUARY®'s cost due to higher plant, property and equipment depreciation from a plant renovation completed in the second half of 2024, a $0.6 million increase in the cost of Contiva® and Etorel®, in line with the corresponding increase in their sales, and a $0.5 million increase in stock-based compensation expense. These factors were partially offset by a $0.4 million decrease in costs related to generic drugs due to the decrease in sales.

Selling and Marketing Expenses

Selling and marketing expenses increased by $7.7 million, or 13.3%, for the year ended December 31, 2025 compared with the prior-year period ended December 31, 2024. This increase was primarily driven by a $2.5 million increase in conference expenses and promotional expenses, attributable to the launch of additional promotional campaigns in the current year—particularly for our new products, a $2.6 million increase in staff costs, which was driven by expanded headcount and higher sales commissions, consistent with the corresponding growth in revenue, a $2.3 million increase in stock-based compensation expense, and a $0.3 million increase in traveling and other expense.

Research and Development Expenses

The table below details our costs for research and development for the years ended December 31, 2025 and 2024 (in thousands, except percentage change):

	Year Ended December 31,			
	2025	2024	Change ($)	Change (%)
Direct program expenses:				
Clinical trials	$ 5,284	$ 4,328	$ 956	22.1%
Materials and utilities	1,729	2,294	(565)	(24.6)%
Preclinical research	1,130	766	364	47.5%
Indirect expenses:				
Personnel-related costs including stock-based compensation	3,697	3,253	444	13.6%
Facilities, depreciation and other	1,858	1,383	475	34.3%
Total research and development expenses	$ 13,698	$ 12,024	$ 1,674	13.9%

Research and development expenses for the year ended December 31, 2025 increased by $1.7 million, or 13.9%, compared with the year ended December 31, 2024. This increase was primarily attributable to a $1.0 million increase in clinical trial costs, primarily as a result of data analysis costs for Hydronidone, PD and RILI, a $0.4 million increase in staff costs, which included $0.2 million in stock-based compensation expense, a $0.5 million increase in facilities, depreciation and other expenses, attributable mainly to professional and consulting fees incurred in connection with research and development operations, and a $0.4 million increase in preclinical research expenses. These expense increases were partially offset by a $0.6 million decrease in materials and utilities expenses.

For the year ended December 31, 2025, we refined the classification of our research and development expenses to better reflect the nature of our development activities. Gyre's research and development expenses relate to the development of Hydronidone are now classified entirely as preclinical research, because it has not yet been submitted for an NDA or entered formal clinical trial phases as of December 31, 2025. Prior period amounts have been reclassified to conform to the current year presentation. Such reclassification did not impact total research and development expenses previously reported.

General and Administrative Expenses

General and administrative expenses increased by $4.7 million, or 29.1%, for the year ended December 31, 2025 compared with the year ended December 31, 2024. This increase was primarily driven by a $3.3 million increase in stock-based compensation expense, a $1.3 million increase in functional and administrative department's personnel expense, and a $0.9 million increase in miscellaneous expense. These cost increases were partially offset by a $0.8 million decrease in professional service expenses.

Other Income (Expense), Net

Interest income increased by $0.2 million, or 12.9%, for the year ended December 31, 2025 compared to the year ended December 31, 2024, primarily due to additional investments in long-term certificates of deposit.

Other expense decreased by $0.2 million, or 9.3%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. The decrease was primarily attributable to a $0.7 million increase in government grant income, partially offset by a $0.5 million increase in donation-related expenses.

Change in fair value of warrant liability decreased by $4.5 million, or 62.2%, for the years ended December 31, 2025 compared with the year ended December 31, 2024. The decrease was related to the remeasurement of the Preferred Stock Warrants liability.

Provision for Income Taxes

Provision for income taxes was $4.6 million and $5.3 million for the years ended December 31, 2025 and 2024, respectively. The decrease was primarily attributable to a lower profit from Gyre Pharmaceuticals' operations and impact of option exercises for the year ended December 31, 2025 compared to the year ended December 31, 2024.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2025, we had cash and cash equivalents of $37.1 million, short-term bank deposit of $15.4 million and long-term certificates of deposit of $23.5 million, which are available to fund operations, and an accumulated deficit of $68.4 million. Our net income during the year ended December 31, 2025 was $9.9 million, while cash provided by operating activities was $1.0 million. We currently have in place an ATM Program with Jefferies LLC 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. 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 and thereafter for the foreseeable future.

Future Funding Requirements

We expect to use cash provided by operating activities, short-term deposits, and long-term certificate of deposits, as well as potential cash issuances to meet our current and future financial obligations, including funding our operations, research and development activities, clinical pipelines, 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. In particular, pending approval of an IND submission, we expect to initiate a Phase 2 trial to evaluate Hydronidone for the treatment of MASH-associated liver fibrosis in 2026. We cannot guarantee that a Phase 2 trial will be initiated or estimate the funding needed for such trial at this time, but may need to raise additional capital to fund this program. In addition, we anticipate that we will incur expenses related to and in connection with the Merger. 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,	
	2025	2024
Cash Flow Data:		
Net cash provided by (used in) operating activities	$ 1,010	$ (3,641)
Net cash used in investing activities	(474)	(19,884)
Net cash provided by financing activities	24,378	2,102
Effect of exchange rate changes on cash and cash equivalents	343	(273)
Net change in cash and cash equivalents	$ 25,257	$ (21,696)

Cash Flows from Operating Activities

Cash provided by operating activities for the year ended December 31, 2025 was $1.0 million, reflecting our net income of $9.9 million and non-cash items of $6.7 million, which primarily includes $7.2 million in stock-based compensation and $2.5 million in depreciation and amortization, offset by $2.7 million related to the change in fair value of warrant liability. Additionally, cash used in operating activities reflected changes in net operating assets and liabilities of $15.6 million.

The increase in cash provided by operating activities for the year ended December 31, 2025 compared with cash used in operating activities for the year ended December 31, 2024 was primarily attributable to higher customer collections, reduced payments for raw materials and services, and lower tax payments resulting from employee stock option exercises.

Cash used in operating activities for the year ended December 31, 2024 was $3.6 million, reflecting our net income of $17.9 million, offset by non-cash items of $5.9 million primarily related to the $7.2 million cash used in change in fair value of warrant liability, depreciation and amortization of $1.5 million, stock-based compensation of $0.8 million. Additionally, cash used in operating activities reflected changes in net operating assets and liabilities of $15.7 million.

Cash Flows from Investing Activities

Cash used in investing activities for the year ended December 31, 2025 was $0.5 million, which consisted of $14.0 million in purchases of certificates of deposit, $1.2 million in purchases of property and equipment, and $0.7 million in acquisitions of intangible assets, partially offset by $15.4 million of proceeds from the maturity of certificates of deposit.

Cash used in investing activities for the year ended December 31, 2024 was $19.9 million, which consisted of $15.5 million in purchases of certificates of deposit, $2.3 million in purchases of property and equipment, $1.7 million paid for equity method investment and $0.8 million in acquisition of intangible assets, partially offset by $0.4 million of cash acquired in connection with the sale of equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2025 was $24.4 million, and consisted of $23.0 million in proceeds from the issuance of 2,555,555 shares of common stock in a public offering, $2.4 million in proceeds from the exercise of stock options, and $0.5 million in proceeds from the issuance of common stock under our ATM Program with Jefferies LLC. These inflows were partially offset by $1.5 million of cash used in connection with deferred offering costs.

Cash provided by financing activities for the year ended December 31, 2024 was $2.1 million due to $1.9 million in proceeds from the exercise of stock options and $0.8 million in proceeds from the issuance of common stock under our ATM Program with Jefferies LLC, partially offset by $0.5 million of cash used in connection with deferred financing costs.

Restricted Net Assets

Under PRC laws and regulations, Gyre Pharmaceuticals 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 Gyre Pharmaceuticals 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 Gyre Pharmaceuticals. The aggregate amounts of restricted capital and statutory reserves of the relevant subsidiaries not available for distribution were $70.1 million and $64.3 million as of December 31, 2025 and December 31, 2024. We do not expect the restrictions described above to have a material impact on our ability to meet our cash obligations.

Contractual Obligations and Other Commitments

We expect to satisfy these contractual obligations and commitments through a combination of cash on hand, cash provided by operating activities, short-term deposits, and long-term certificate of deposits.

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 spaces, through May 2027. As of December 31, 2025, our fixed lease payment obligations were $1.0 million, with $0.7 million payable within 12 months.

Research and Development Programs

As of December 31, 2025, we have committed to allocating $52.8 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 $3.9 million as of December 31, 2025 and are expected to be incurred within one year.

Etorel® IP Rights

In May 2024, Gyre Pharmaceuticals entered into an agreement with Jiangsu Wangao Pharmaceuticals Co., Ltd. (the "Jiangsu Wangao Agreement"), effective from May 7, 2024 to May 6, 2035. Pursuant to the Jiangsu Wangao Agreement, Gyre Pharmaceuticals obtained the drug registration certificate for and became the marketing authorization holder of Etorel®, a small-molecule drug for the treatment of SSc-ILD and PF-ILD, within the PRC. The total minimum payments under the Jiangsu Wangao Agreement are RMB 35.0 million, or approximately $5.0 million, based on the December 31, 2025 spot exchange rate. This includes an upfront transfer fee of RMB 15.0 million, or approximately $2.1 million, payable in three installments, and subsequent payments based on annual sales over eight years following the commencement of commercial sales. Additionally, Gyre Pharmaceuticals will bear the costs associated with relocating the production site to a designated location and will cover all expenses related to the manufacturing process. As of December 31, 2025, we had paid three installments totaling RMB 15.0 million, or approximately $2.1 million, based on the December 31, 2025 spot exchange rate.

We are committed to annual payments to the Etorel® IP Rights transferor over eight years following the commencement of commercial sales. See Note 11—Commitments and Contingencies.

SDM Service Agreement

In December 2025, we entered into a clinical trial agreement with a third-party CRO for Hydronidone's Phase 3c confirmatory clinical trial. This trial is designed to evaluate clinical endpoint events and satisfy the safety exposure requirements to support the potential conditional approval and subsequent conventional marketing authorization of Hydronidone capsules. The agreement, with an aggregate value of Chinese Renminbi ("RMB") 114.0 million, or approximately $16.2 million, based on the December 31, 2025 spot exchange rate, covers full-cycle clinical trial services and features milestone-based payments. Under this agreement, we are obligated to make payments based on the achievement of specified clinical and operational milestones and the performance of clinical trial–related services, including trial preparation, patient enrollment and follow-up, site management, interim analyses, data management–related activities, and preparation of the clinical study report. All services under the agreement are related to our research and development activities and will be performed over the duration of the clinical trial. As of December 31, 2025, none of the payment conditions had been met, and no payments had been made under the agreement. Refer to Note 11—Commitments and Contingencies for further details.

Critical Accounting Policies and Estimates

The preparation of the consolidated financial statements and related disclosures in conformity with U.S. generally accepted accounting principles ("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 recognize 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.

For the sale of pharmaceutical products, revenue is recognized at a point in time when control of the asset is transferred to the customer, generally on completion of delivery of the pharmaceutical products. For the sales of pharmaceutical products, most of our customers are distributors.

Revenue from product sales is recognized as net of estimated rebates. These rebates are estimated based on sales volumes from the preceding months and applying the rebate percentages specified in each contract. The estimation process requires management judgment, particularly in determining the amount of rebates based on historical sales volumes and contractually agreed-upon rebate percentages. Additionally, variable consideration related to sales rebates is recorded as deductions from revenue based on historical experience and contract terms. Depending on the contract structure, we apply either the expected value method or the most likely amount method to estimate future rebates, selecting the approach that best predicts the amount of variable consideration. The estimates for these rebates are reviewed regularly, and adjustments are made as necessary.

Research and Development Expenses and Accruals

Research and development costs are expensed as incurred when the expenditures relate to ongoing research activities without alternative future use. A significant portion of our research and development expenses consists of preclinical and clinical trial costs, which involve contracts with third-party service providers such as contract research organizations. These costs are accrued based on management's estimates of the services performed during the respective period.

We estimate the amount of work completed through discussion 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. Accruals are based on progress reports, contractual terms, and management's judgment regarding the stage of completion of various projects. Since there is often a timing difference between service delivery and invoicing, we make adjustments as more information becomes available. We also assess the likelihood of milestone-based payments under contract terms.

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 Accounting Standards Codification 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 10—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 and Accelerated Filer 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 common stock 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 common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Based on the aggregate market value of our common stock held by non-affiliates of approximately $72.6 million as of June 30, 2025, we remain a smaller reporting company and continue to qualify as an “accelerated filer” as of December 31, 2025. As an accelerated filer, we are required, pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, to include in our Annual Report on Form 10-K for the year ending December 31, 2025 an attestation report as to the effectiveness of our internal control over financial reporting that is issued by our independent registered public accounting firm. We expect to continue to take advantage of the reduced reporting requirements applicable to smaller reporting companies.

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, 2025, 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, 2025 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, 2025 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, 2025, 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, 2025.

The effectiveness of our internal control over financial reporting as of December 31, 2025, has been audited by Grant Thornton Zhitong Certified Public Accountants LLP, an independent registered public accounting firm, as stated in their report that is included herein.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Gyre Therapeutics, Inc.

Opinion on internal control over financial reporting

We have audited the internal control over financial reporting of Gyre Therapeutics, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2025, based on criteria established in the 2013 *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in the 2013 *Internal Control —Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated financial statements of the Company as of and for the year ended December 31, 2025, and our report dated March 13, 2026 expressed an unqualified opinion on those financial statements

Basis for opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and limitations of internal control over financial reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Grant Thornton Zhitong Certified Public Accountants LLP

Beijing, China

March 13, 2026

Item 9B. OTHER INFORMATION.

Trading Arrangements

None of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during the three months ended December 31, 2025, as such terms are defined under Item 408(a) 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 2026 Annual Meeting of Stockholders (the "2026 Proxy Statement"), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2025, including under the heading "Corporate Governance," "Insider Trading Policy," 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 2026 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 2026 Proxy Statement, including under headings "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" 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 2026 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 2026 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
2.3	Agreement and Plan of Merger and Reorganization, dated March 2, 2026, by and among Gyre Therapeutics, Inc., Helix Merger Sub Corp., and Cullgen Inc.	8-K	000-51173	2.1	Mar. 2, 2026
3.1	Restated Certificate of Incorporation of the Company.	10-Q	000-51173	3.1	Nov. 13, 2024
3.2	Amended and Restated Bylaws of the Company.	8-K	000-51173	3.3	Oct. 30, 2023
3.3(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
3.3(b)	Certificate of Elimination of Series A Preferred Stock, filed with the Delaware Secretary of State on March 25, 2024.	10-K	000-51173	3.6(b)	Mar. 27, 2024
3.4(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
3.4(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
3.5(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
3.5(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
3.6	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.	8-K	000-51173	3.1	Mar. 2, 2026
4.1	Description of Securities.	10-K	000-51173	4.1	Mar. 17, 2025
4.2	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+	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
10.4+	Form of Incentive Stock Option Award Notice.	8-K	000-51173	10.1	July 14, 2017

Exhibit No.	Exhibit title	Incorporated by reference			
		Form	File No.	Exhibit No.	Filing Date
10.5+	Form of Non-qualified Stock Option Award Notice.	8-K	000-51173	10.2	July 14, 2017
10.6+	Catalyst Biosciences, Inc. 2018 Omnibus Incentive Plan.	DEF 14A	000-51173	Appendix A	May 1, 2020
10.7+	Catalyst Biosciences, Inc. 2018 Employee Stock Purchase Plan.	DEF 14A	000-51173	Appendix B	May 11, 2018
10.8+	Form of Stock Option Award Agreement.	10-K	000-51173	10.8	Mar. 31, 2022
10.9+	Gyre Therapeutics, Inc. 2023 Omnibus Incentive Plan	8-K	000-51173	10.2	Oct. 30, 2023
10.10+	Form of Indemnification Agreement	8-K	000-51173	10.3	Oct. 30, 2023
10.11+	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
10.12	Open Market Sale AgreementSM, dated November 27, 2024, by and between the Company and Jefferies LLC.	8-K	000-51173	1.1	Nov. 27, 2024
19.1	Insider Trading Policy of the Company.	10-K	000-51173	19.1	Mar. 17, 2025
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).				
31.1*	Certification of the Principal 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 Principal 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.				

Exhibit No.	Exhibit title	Incorporated by reference			
		Form	File No.	Exhibit No.	Filing Date
32.1**	Certification of the Principal 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 Principal 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	10-K	000-51173	97.1	Mar. 27, 2024
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 13, 2026

By: /s/ Ping Zhang

Ping Zhang
Executive Chairman and Interim Chief Executive Officer
(Principal Executive Officer)

Date: March 13, 2026

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 Ping Zhang 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/ Ping Zhang **Ping Zhang**	Executive Chairman and Interim Chief Executive Officer (Principal Executive Officer)	March 13, 2026
/s/ Ruoyu Chen **Ruoyu Chen**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 13, 2026
/s/ Songjiang Ma **Songjiang Ma**	President and Director	March 13, 2026
/s/ Thomas Eastling **Thomas Eastling**	Director	March 13, 2026
/s/ Gordon Carmichael, Ph.D. **Gordon Carmichael, Ph.D.**	Director	March 13, 2026

/s/ Dan Weng, M.D. **Dan Weng, M.D.**	Director	March 13, 2026
/s/ Rodney L. Nussbaum **Rodney L. Nussbaum**	Director	March 13, 2026
/s/ Renate Parry, Ph.D. **Renate Parry, Ph.D.**	Director	March 13, 2026
/s/ David M. Epstein, Ph.D. **David M. Epstein, Ph.D.**	Director	March 13, 2026

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, 2025 and 2024, the related consolidated statements of operations and comprehensive income, consolidated statements of convertible preferred stock and equity, and cash flows for each of the two years in the period ended December 31, 2025, and the related notes and the financial statements schedule included in Schedule I (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2025 based on criteria established in the 2013 *Internal Control—Integrated Framework*issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated March 13, 2026 expressed an unqualified opinion.

Basis for opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical audit matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Preferred stock warrants

As described in Note 3 and 9 to the consolidated 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 skills and knowledge.

Our audit procedures related to the preferred stock warrants 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 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.

Beijing, China

March 13, 2026

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

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 37,070	$ 11,813
Short-term bank deposits	15,355	14,858
Notes receivable	5,638	4,373
Accounts receivable, net	31,078	19,589
Other receivables from GNI	230	230
Inventories	10,171	6,337
Prepaid assets	1,338	1,189
Receivable from GCBP	—	4,961
Other current assets	1,489	1,436
Total current assets:	102,369	64,786
Property and equipment, net	23,599	23,880
Intangible assets, net	4,727	273
Right-of-use assets	1,131	1,818
Land use rights, net	1,425	1,432
Deferred tax assets	6,873	5,619
Long-term certificates of deposit	23,516	24,568
Other assets, noncurrent	2,492	3,030
Total assets	$ 166,132	$ 125,406
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 124	$ 108
Contract liabilities	14	61
Due to related parties	227	227
Accrued expenses and other current liabilities	14,345	10,615
Income tax payable	2,940	2,831
Operating lease liabilities, current	636	713
CVR derivative liability	—	4,961
Total current liabilities:	18,286	19,516
Operating lease liabilities, noncurrent	303	885
Deferred government grants	852	928
Warrant liability, noncurrent	2,961	5,668
Other noncurrent liabilities	1,448	7
Total liabilities	$ 23,850	$ 27,004
Commitments and Contingencies (Note 11)		
Stockholders' equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized; 91,314,007 shares and 86,307,544 shares issued and outstanding at December 31, 2025 and 2024, respectively	91	86
Additional paid-in capital	172,047	136,185
Statutory reserve	3,098	3,098
Accumulated deficit	(68,426)	(73,453)
Accumulated other comprehensive loss	(779)	(2,597)
Total Gyre stockholders' equity	106,031	63,319
Noncontrolling interest	36,251	35,083
Total equity	142,282	98,402
Total liabilities and stockholders' equity	$ 166,132	$ 125,406

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

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

	Year Ended December 31, 2025	2024
Revenues	$ 116,588	$ 105,757
Operating expenses:		
Cost of revenues	5,416	3,884
Selling and marketing	65,179	57,511
Research and development	13,698	12,024
General and administrative	20,804	16,109
Loss on disposal of assets, net	4	66
Total operating expenses	105,101	89,594
Income from operations	11,487	16,163
Other income (expenses):		
Interest income, net	1,747	1,547
Other expense, net	(1,505)	(1,659)
Change in fair value of warrant liability	2,707	7,167
Income before income taxes	14,436	23,218
Provision for income taxes	(4,556)	(5,320)
Net income	9,880	17,898
Net income attributable to noncontrolling interest	4,853	5,813
Net income attributable to common stockholders	$ 5,027	$ 12,085
Net income per share attributable to common stockholders:		
Basic	$ 0.06	$ 0.14
Diluted	$ 0.02	$ 0.05
Weighted average shares used in calculating net income per share attributable to common stockholders:		
Basic	89,344,622	85,094,948
Diluted	103,180,037	102,293,526
Other comprehensive income:		
Net income from operations	$ 9,880	$ 17,898
Foreign currency translation adjustments	2,636	(1,460)
Comprehensive income from operations	12,516	16,438
Net income attributable to noncontrolling interest	4,853	5,813
Foreign currency translation adjustments attributable to noncontrolling interest	818	(507)
Comprehensive income attributable to noncontrolling interest	5,671	5,306
Comprehensive income attributable to common stockholders	$ 6,845	$ 11,132

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	Statutory Reserve	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Gyre Stockholders' Equity	Non-controlling Interest	Total Equity
	Shares	Amount	Shares	Amount	Capital						
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
Stock-based compensation expense	—	—	—	—	831	—	—	—	831	—	831
Stock options exercised	—	—	874,328	1	1,864	—	—	—	1,865	—	1,865
Convertible preferred stock conversion	(13,151)	(64,525)	8,767,333	8	64,517	—	—	—	64,525	—	64,525
Issuance of Common Stock upon ATM program	—	—	70,267	—	773	—	—	—	773	—	773
CVR Liability settlement	—	—	—	—	30	—	—	—	30	—	30
Deferred Offering Costs Amortization	—	—	—	—	(9)	—	—	—	(9)	—	(9)
Foreign currency translation adjustment	—	—	—	—	—	—	—	(953)	(953)	(507)	(1,460)
Net income	—	—	—	—	—	—	12,085	—	12,085	5,813	17,898
Balances as of December 31, 2024	—	$ —	86,307,544	$ 86	$ 136,185	$ 3,098	$ (73,453)	$ (2,597)	$ 63,319	$ 35,083	$ 98,402
Stock-based compensation expense	—	—	—	—	7,157	—	—	—	7,157	—	7,157
Stock options exercised	—	—	2,396,174	2	2,354	—	—	—	2,356	—	2,356
Issuance of Common Stock upon ATM program			54,734	—	509	—	—	—	509	—	509
Issuance of Common Stock	—	—	2,555,555	3	22,997	—	—	—	23,000	—	23,000
CVR Liability settlement	—	—	—	—	25	—	—	—	25	—	25
Stock insurance cost	—	—	—	—	(1,676)	—	—	—	(1,676)	—	(1,676)
Deferred Offering Costs amortization	—	—	—	—	(7)	—	—	—	(7)	—	(7)
Capital injection in a subsidiary	—	—	—	—	4,503	—	—	—	4,503	(4,503)	—
Foreign currency translation adjustment	—	—	—	—	—	—	—	1,818	1,818	818	2,636
Net income	—	—	—	—	—	—	5,027	—	5,027	4,853	9,880
Balances as of December 31, 2025	—	$ —	91,314,007	$ 91	$ 172,047	$ 3,098	$ (68,426)	$ (779)	$ 106,031	$ 36,251	$ 142,282

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,	
	2025	2024
Operating Activities		
Net income from operations	$ 9,880	$ 17,898
Adjustments to reconcile net income to net cash provided (used) by operating activities:		
Stock-based compensation	7,157	831
Depreciation and amortization	2,481	1,549
Noncash lease expense	777	672
Amortization of land use rights	39	39
Deferred income taxes, net	(1,109)	(1,002)
Bad debt expense and other non-cash items	(63)	170
Accrued interest on bank deposit	28	(1,046)
Change in fair value of receivables from GCBP	(39)	(239)
Change in fair value of derivative liabilities	39	239
Change in fair value of warrant liability	(2,707)	(7,167)
Equity loss of unconsolidated affiliates	77	37
Loss on disposal of property and equipment	4	66
Changes in operating assets and liabilities:		
Notes receivable	(1,147)	(4,028)
Accounts receivable	(10,806)	(5,257)
Inventories	(3,631)	(2,139)
Prepaid and other assets	(206)	520
Income tax payable	44	(2,166)
Accounts payable	13	(245)
Other noncurrent liabilities	(47)	23
Due to related parties	(1)	(83)
Accrued expenses and other liabilities	946	(1,497)
Operating lease liabilities	(744)	(816)
Net proceeds from CVR liability settlement	25	—
Net cash provided by (used in) operating activities	1,010	(3,641)
Investing Activities		
Acquisition of intangible assets	(733)	(813)
Purchase of certificates of deposit	(14,010)	(15,471)
Purchase of property and equipment	(1,190)	(2,315)
Proceeds from sale of equipment	30	401
Purchase of equity method investment	—	(1,686)
Maturity of certificates of deposit	15,429	—
Net cash used in investing activities	(474)	(19,884)
Financing Activities		
Offering costs paid	(1,487)	(536)
Proceeds from the issuance of common stock in ATM program	509	773
Proceeds from the exercise of stock options	2,356	1,865
Proceeds from the issuance of common stock in a public offering	23,000	—
Net cash provided by financing activities	24,378	2,102
Effect of exchange rate changes on cash and cash equivalents	343	(273)
Net increase (decrease) in cash and cash equivalents	25,257	(21,696)
Cash and cash equivalents at beginning of the period	11,813	33,509
Cash and cash equivalents at end of period	$ 37,070	$ 11,813
Supplemental Disclosure of Non-Cash Financing and Investing Activities:		
Right-of-use asset obtained in exchange for operating lease liabilities	$ 63	$ 2,017
Convertible preferred stock conversion	$ —	$ 64,525
Supplemental Disclosure of Cash Flow Information:		
Cash paid for income taxes	$ 5,621	$ 8,518

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.

As of December 31, 2025, the Company holds a 69.7% indirect interest in Beijing Continent Pharmaceuticals Co., Ltd. (d/b/a Gyre Pharmaceuticals Co., Ltd., "Gyre Pharmaceuticals"), a commercial-stage biopharmaceutical company registered and established in the People's Republic of China ("PRC") in 2002. The majority shareholder of Gyre is GNI USA, Inc. ("GNI USA"), which is indirectly wholly owned by GNI Group Ltd. ("GNI Japan"). Gyre is a financially sustainable commercial-stage biotechnology company with a proven track record of success in developing and commercializing 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.

On November 7, 2025, the National Healthcare Security Administration ("NHSA") released the *Announcement of the Winning Bids for the National Centralized Drug Procurement*, under which Etorel® (nintedanib, ethanesulfonate soft capsules) has been selected. As of the filing date, the Company is in the process of entering into procurement contracts with various participating hospitals under the National Centralized Drug Procurement program. The Company is currently assessing the potential impact of this development on its future operating performance.

Contingent Value Rights Agreement

Concurrent with the signing of the previously disclosed business combination agreement pursuant to which the Company acquired an indirect controlling interest in Gyre Pharmaceuticals, 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 (a "CVR Holder"), excluding GNI Japan and GNI Hong Kong Limited ("GNI Hong Kong"), 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. In the first quarter of 2025, the Company had fully settled the CVR liability and collected all outstanding amounts related to CVR receivables.

Liquidity

For the year ended December 31, 2025, the Company had a net income of $9.9 million, while net cash provided by operating activities was $1.0 million. As of December 31, 2025, the Company had an accumulated deficit of $68.4 million and cash and cash equivalents of $37.1 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 and 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, 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 and comprehensive income attributed to the Company and NCI separately in the consolidated statements of operations and comprehensive income.

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 measure of segment profit or loss is reported on the income statement as consolidated net income. The CODM uses net income to evaluate income generated from segment assets in deciding whether to reinvest profits and monitor budget versus actual results in assessing the performance of the segment.

The Company's CODM, as a group, includes (i) the Executive Chairman of Gyre's Board of Directors ("Gyre's Board") who also serves as Gyre's Interim Chief Executive Officer and (ii) Gyre's Chief Operating Officer who also serves as Gyre Pharmaceuticals' General Manager. 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 receivable, note receivable, long-term certificates of deposits, and short-term bank deposits.

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 the United States, the Federal Deposit Insurance Corporation ("FDIC") insures deposits at federally insured financial institutions up to a limit of $250,000 per depositor, per insured bank, for each account ownership category. The Securities Investor Protection Corporation ("SIPC") protects customer assets held by registered broker-dealers, with a standard limit of $500,000 per customer. The Company maintains cash and deposits in excess of the amount protected by FDIC and SIPC insurance. in the event of failure or insolvency of one of these financial institutions, the Company may be unable to recover its deposits in full. Management believes that these financial institutions are of high credit quality and continually monitors the creditworthiness of these financial institutions. As of December 31, 2025 and 2024, the Company had cash and cash equivalents held in U.S. financial institutions of $25.9 million and $4.3 million, respectively. Of the 2025 balance, $5.6 million represented general bank deposits and $20.3 million represented investment related cash. The entire 2024 balance of $4.3 million represented general bank deposits. At December 31, 2025, the Company's U.S. cash balances exceeded FDIC insurance coverage by $5.3 million and exceeded SIPC coverage by $19.8 million. At December 31, 2024, the Company's U.S. cash balances exceeded FDIC insurance coverage by $4.1 million, with no SIPC coverage excess as there was no investment related cash.

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, or approximately $71,136, based on the December 31, 2025 spot exchange rate. 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. As of December 31, 2025 and 2024, the Company had cash and cash equivalents of $37.1 million and $11.8 million, and long-term certificates of deposit of $23.5 million and $24.6 million, respectively. In addition, the Company had short-term bank deposits of $15.4 million and $14.9 million as of December 31, 2025 and 2024, respectively. For the years ended December 31, 2025 and 2024, cash and cash equivalents, short-term bank deposits and long-term certificates of deposits exceeded the PRC DIS coverage by $49.4 million and $46.3 million, respectively.

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. Note receivable is also subject to credit risk. The Company monitors the creditworthiness and repayment performance of the borrower on an ongoing basis and has not experienced significant credit losses related to such receivable.

Concentration of Customer Risk

For the years ended December 31, 2025 and 2024, one customer, Sinopharm Group Co., Ltd., accounted for approximately 53.3% and 54.3% of accounts receivable, respectively. For the year ended December 31, 2025, three customers, Sinopharm Group Co., Ltd., China Resources Pharmaceutical Group Ltd, and Shanghai Pharmaceuticals Holding Co., Ltd accounted for approximately 51.7%, 13.3%, and 11.6% of total revenue, respectively. For the year ended December 31, 2024, three customers, Sinopharm Group Co., Ltd., China Resources Pharmaceutical Group Ltd, and Shanghai Pharmaceuticals Holding Co., Ltd accounted for approximately 48.5%, 13.6%, and 10.6% of total revenue, respectively. All customers are located in the PRC.

Regulatory and Pricing Risk

The Company's operating results are subject to risks and uncertainties arising from changes in government healthcare policies and pricing regulations in the PRC. On November 7, 2025, the NHSA released the Announcement of the Winning Bids for the National Centralized Drug Procurement, under which Etorel® was selected. As of December 31, 2025 the Company has not entered into or executed a procurement contract under this program.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand, demand deposits and 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 an entity to 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. The derivative liability was fully settled in the first quarter of 2025. Refer to Note 3 — *Fair Value Measurements and Financial Instruments* 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 (the "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 January 2027 and November 2028. 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, 2025 and 2024.

Short-term Bank Deposits

The short-term bank deposits will mature between January 2026 and July 2026. Short-term bank deposits consist of bank deposits with original maturities of one year or less, and long-term deposits that have a remaining maturity of less than one year. These deposits are recorded at amortized cost. Interest income from these deposits is recognized and reported within interest income. The Company recorded no allowance for credit losses associated with the short-term certificates of deposit as of December 31, 2025 and 2024.

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). The receivable was fully settled in the first quarter of 2025. Refer to Note 3 — *Fair Value Measurements and Financial Instruments* for additional information regarding the long-term receivable.

Long-term Investments

The Company's long-term investments include equity investments in an affiliate in which it does not have a controlling financial interest, but has the ability to exercise more than minor influence over the operating and financial policies of the investee. The investment is accounted for using the equity method of accounting in accordance with ASC Topic 323, Investments—*Equity Method and Joint Ventures* ("ASC 323"). Under the equity method, the Company initially records its investments at fair value. The Company subsequently adjusts the carrying amount of the investment to recognize the Company's proportionate share of the equity investee's net income or loss after the date of investment. The Company evaluates the equity method investment for impairment under ASC 323. An impairment loss on the equity method investments is recognized in losses when the decline in value is determined to be other-than-temporary. No impairment charge was recognized for the years ended December 31, 2025 and 2024.

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,	
	2025	**2024**
Accounts receivable	$ 31,229	$ 19,798
Note receivable	5,638	4,373
Allowance for credit losses	(151)	(209)
Accounts and note receivables, net	$ 36,716	$ 23,962

Changes in the allowance for credit losses as of December 31, 2025 and 2024 consisted of the following (in thousands):

	2025	2024
Balance, beginning of year	$ (209)	$ (41)
Provision for allowance for credit losses	(189)	(177)
Recoveries collected and write-off	251	7
Foreign currency translation adjustments	(4)	2
Balance, end of year	$ (151)	$ (209)

Inventories

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 ("PPE"), 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 of 3-5 years 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

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.

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, computer software and technology rights, 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.

Technology rights

Technology rights refer to the intellectual property (“IP”) associated with Etorel® (nintedanib, ethanesulfonate soft capsules), which were obtained upon the successful transfer of the marketing authorization holder following approval by the PRC’s National Medical Products Administration (the “NMPA”) in March 2025, and the commercial sales of Etorel® commenced in June 2025. Technology rights with finite lives are amortized on a straight-line basis over their estimated useful lives, beginning on the date the Company obtains control of the technology rights and the related product is available for its intended use.

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, 2025 and 2024.

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.

Sale of Pharmaceutical Products

The Company mainly sells its pharmaceutical products to distributors in mainland China, 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 upon delivery of the underlying 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. Based on historical experience and the limited nature of return rights, product returns have not been significant, and no material refund liability has been recorded as of December 31, 2025.

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.

The Company did not recognize any contract assets as of December 31, 2025 and 2024.

Contract liabilities

Contract liabilities are recognized when the payments are received from customers before the Company transfers the related goods or services. Contract liabilities are 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, 2025, the Company's Contract liability balance was $14 thousand. Contract liability balance was $61 thousand as of December 31, 2024 which has been recognized as revenue during the year ended December 31, 2025.

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, including stock-based compensation; (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 as 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.

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, including stock-based compensation, 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 consist of conference expenses incurred from hosting academic conferences, seminars and symposia; promotional expenses associated with market education for use in hospitals; and staff costs primarily consisting of salaries, benefits and stock-based compensation 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.

Advertising Cost

Advertising costs are expensed when incurred. Such costs approximated $11.0 million and $10.7 million for the 2025 and 2024 fiscal years, respectively. Advertising costs are included in selling expenses on the consolidated statements of operations and comprehensive income.

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. If a grant provides compensation for expenses previously incurred or provides immediate financial support with no future related costs or performance obligations, the grant income is recognized in the period in which the grant becomes receivable and all recognition criteria have been satisfied. 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 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

The Company is required to report all components of comprehensive income, including net income, in the accompanying consolidated financial statements in the period in which they are recognized. Comprehensive income 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 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 14 — *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 Gyre Pharmaceuticals 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 income (loss). During the years ended December 31, 2025 and December 31, 2024, the Company had translation gain of $2.6 million and loss of $1.5 million, respectively.

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 income (loss). The foreign currency transaction gains or losses for the years ended December 31, 2025 and 2024 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. 29.9% of the Company's cash and cash equivalents, and 100.0% of the Company's short-term bank deposits and long-term certificates of deposit as of December 31, 2025 in the amount of $11.1 million, $15.4 million and $23.5 million, respectively, were denominated in RMB.

Accounting Pronouncements Recently Adopted

In December 2023, the FASB issued Accounting Standards Update ("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 became effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is permitted. The Company adopted this ASU in its annual consolidated financial statements for the year beginning January 1, 2025. The adoption of this ASU did not have any material impact on the Company's annual consolidated financial statements.

New Accounting Pronouncements – Issued But Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06, *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative* ("ASU 2023-06"). ASU 2023-06 modifies the disclosure or presentation requirements of a variety of Topics in the Financial Accounting Standards Codification (the "Codification"). Certain of the amendments represent clarifications to or technical corrections of the current requirements. Because of the variety of Topics amended, a broad range of entities may be affected by one or more of those amendments. Many of the amendments allow users to more easily compare entities subject to the SEC's existing disclosures with those entities that were not previously subject to the SEC's requirements. Also, the amendments align the requirements in the Codification with the SEC's regulations. For entities subject to the SEC's existing disclosure requirements and for entities required to file or furnish financial statements with or to the SEC in preparation for the sale of or for purposes of issuing securities that are not subject to contractual restrictions on transfer, the effective date for each amendment will be the date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. For all other entities, the amendments will be effective two years later. The amendments in this update should be applied prospectively. For all entities, if by June 30, 2027, the SEC has not removed the applicable requirement from Regulation S-X or Regulation S-K, the pending content of the related amendment will be removed from the Codification and will not become effective for any entity. The Company is currently evaluating the potential impact this standard will have on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses (Subtopic 220-40)* ("ASU 2024-03"). The ASU requires the disaggregated disclosure of specific expense categories, including purchases of inventory, employee compensation, depreciation, and amortization, within relevant income statement captions. This ASU also requires disclosure of the total amount of selling expenses along with the definition of selling expenses. The ASU is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. In January 2025, the FASB issued ASU 2025-01, Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40) - Clarifying the Effective Date to clarify the effective date of ASU 2024-03 for non-calendar year-end entities. ASU 2024-03 is effective for the Company's fiscal year 2028, and interim periods starting in fiscal year 2029. Early adoption is permitted. The amendments in this ASU are to be applied retrospectively to any or all prior periods presented in the consolidated financial statements. Early adoption is also permitted. This ASU will likely result in the required additional disclosures being included in our consolidated financial statements once adopted. The Company is currently assessing the impact of the disclosure requirements on its consolidated financial statements.

In July 2025, the FASB issued ASU 2025-05, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets ("ASU 2025-05"). ASU 2025-05 provides a practical expedient for measuring expected credit losses for current accounts receivable and current contract assets that arise from revenue transactions within the scope of ASC 606, permitting an entity to assume that economic conditions as of the balance sheet date will remain unchanged over the remaining life of the financial assets when developing reasonable and supportable forecasts. ASU 2025-05 is effective for annual reporting periods, including interim periods within those annual reporting periods, beginning after December 15, 2025, with early adoption permitted. The Company has elected not to early adopt ASU 2025-05 and is currently evaluating the potential impact that adoption of this standard will have on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-10, Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities. This ASU provides guidance on the recognition, measurement, presentation and disclosure of government grants received by business entities. The ASU is effective for annual reporting periods beginning after December 15, 2028, and interim reporting periods within those annual periods, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2025-10 will have on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, Interim Reporting (Topic 270): Narrow-Scope Improvements ("ASU 2025-11"). ASU 2025-11 clarifies the applicability of the interim reporting guidance in Topic 270 and improves the navigability and organization of the guidance. The amendments also introduce a principle requiring entities that issue interim financial statements to disclose events and changes occurring after the end of the most recent annual reporting period that are expected to have a material impact on the entity. ASU 2025-11 does not change the recognition or measurement requirements for interim reporting. The ASU is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027 for public business entities, with early adoption permitted. The Company is currently evaluating the potential impact of this guidance on its interim and annual financial statement disclosures.

Subsequent Events

The Company accounts for subsequent events in accordance with ASC 855, *Subsequent Events,* which defines subsequent events as events or transactions that occur after the balance sheet date but before the financial statements are issued. Management has evaluated subsequent events through the date the financial statements were issued and filed with the Securities and Exchange Commission. There were no subsequent events that required recognition or disclosure other than those disclosed in Note 17 — *Subsequent Events*.

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, 2025, 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, 2025 and 2024 (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Financial assets				
Money market funds[(1)]	$ 24,876	$ —	$ —	$ 24,876
Total financial assets	$ 24,876	$ —	$ —	$ 24,876
Financial liabilities				
Warrant liability, noncurrent	—	—	2,961	2,961
Total financial liabilities	$ —	$ —	$ 2,961	$ 2,961

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets				
Money market funds[(1)]	$ 3,300	$ —	$ —	$ 3,300
Receivable from GCBP	—	—	4,961	4,961
Total financial assets	$ 3,300	$ —	$ 4,961	$ 8,261
Financial liabilities				
CVR derivative liability	$ —	$ —	$ 4,961	$ 4,961
Warrant liability, noncurrent	—	—	5,668	5,668
Total financial liabilities	$ —	$ —	$ 10,629	$ 10,629

(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 years ended December 31, 2025 and 2024, 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. As of December 31, 2025, the Company had fully settled the CVR liability and collected all outstanding amounts related to CVR receivables.

Receivable from GCBP and CVR Derivative Liability

The receivable from GCBP and the corresponding CVR derivative liability relate to the asset purchase agreement with GCBP. The fair value of this receivable and derivative liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. These unobservable inputs include the probability of GCBP meeting its contractual payment obligations, the timing of cash flows, and the expected recovery rate of the receivable. The estimation process incorporates GCBP's financial condition and market conditions that could impact its ability to fulfill obligations. Additionally, the selection of the discount rate (which was estimated at 5.05%) may fluctuate over time. The estimated fair value of the receivable from GCBP and CVR derivative liability 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%. In the first quarter of 2025, the Company received a $5.0 million hold-back payment from GCBP and distributed, net of expenses, to the CVR Holders. The change in fair value of the receivable from GCBP and the corresponding CVR derivative liability was recorded in interest and other income, net on the consolidated statement of operations and comprehensive income.

Warrant Liability

In October 2023, Catalyst entered into a Securities Purchase Agreement for a private placement with GNI USA (the "Private Placement"). 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 fair value of the Preferred Stock Warrants is subject to uncertainty due to unobservable inputs, including the expected volatility of the Company's stock price, the likelihood of warrant exercise, and the estimated term of the warrants. Since there is limited market activity for the Preferred Stock Warrants, their fair value is determined using an option pricing model, which incorporates subjective inputs such as the Company's stock price volatility, derived from historical and peer company data, as well as management's expectations regarding future performance. As these assumptions evolve due to market conditions or company specific factors, the warrant liability may experience fluctuations. 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.

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

	December 31, 2025	December 31, 2024
Share price	$ 7.06	$ 12.10
Exercise price	$ 4,915.00	$ 4,915.00
Dividend yield	—%	—%
Risk-free interest	3.93%	4.54%
Term (years)	7.83	8.83
Expected volatility	81.00%	83.00%

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

	Receivable from GCBP	CVR derivative liability	Warrant liability
Balance at December 31, 2023	4,722	4,722	12,835
Additions in the period	—	—	—
Changes in fair value	239	239	(7,167)
Balance at December 31, 2024	4,961	4,961	5,668
Changes in fair value	39	39	(2,707)
Change due to settlements	(5,000)	(5,000)	—
Balance at December 31, 2025	$ —	$ —	$ 2,961

Financial Instruments

Cash equivalents and held-to-maturity debt securities consisted of the following (in thousands):

December 31, 2025	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 24,876	$ —	$ —	$ 24,876
Short-term bank deposits	15,355	—	—	15,355
Long-term certificates of deposit	23,516	—	—	23,516
Total financial assets	$ 63,747	$ —	$ —	$ 63,747
Classified as:				
Cash and cash equivalents				$ 24,876
Short-term bank deposits				15,355
Long-term certificates of deposit				23,516
Total financial assets				$ 63,747

December 31, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Money market funds (cash equivalents)	$ 3,300	$ —	$ —	$ 3,300
Short-term bank deposits	14,858	—	—	14,858
Long-term certificates of deposit	24,568	—	—	24,568
Total financial assets	$ 42,726	$ —	$ —	$ 42,726
Classified as:				
Cash and cash equivalents				$ 3,300
Short-term bank deposits				14,858
Long-term certificates of deposit				24,568
Total financial assets				$ 42,726

The fair value and amortized cost of the Company's held-to-maturity debt securities and redemption date were as follows:

	December 31, 2025	
	Amortized Cost	Fair Value
Due in one year	$ 15,355	$ 15,355
Due in one to five years	23,516	23,516
Total	$ 38,871	$ 38,871

Interest income from the short-term bank deposits is recognized on an accrual basis over the term of the deposits. The accrued interest income for the periods ended December 31, 2025 and 2024 was $0.4 million and $0.4 million, respectively.

Interest income from the long-term certificates of deposit is recognized on an accrual basis over the term of the deposits. The accrued interest income for the periods ended December 31, 2025 and 2024 was $0.5 million and $0.6 million, respectively.

4. Balance Sheet Components

Inventories

Inventories as of December 31, 2025 and 2024, respectively, consisted of the following components (in thousands):

	December 31,	
	2025	2024
Raw materials	$ 970	$ 794
Work in progress	6,307	2,929
Finished goods	2,894	2,614
Inventories	$ 10,171	$ 6,337

Accrued expenses and other current liabilities

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

	December 31,	
	2025	2024
Accrued payroll and welfare	$ 7,621	$ 4,765
Payable to PPE & intangible asset suppliers	2,161	1,219
Accrued sales rebates	1,382	908
Accrued expenses - research and development	1,115	57
Accrued expenses - general and administrative	757	1,005
Accrued professional services	352	667
Payable to selling expense suppliers	270	900
Deferred government grants	97	95
Employee reimbursement	12	737
Other accrued liabilities	578	262
Accrued expenses and other current liabilities	$ 14,345	$ 10,615

Government grants

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, 2025 and 2024, is net of the amount recognized as government grant income. During the years ended December 31, 2025 and 2024, the Company received $0.7 million and $0.9 million government grants, respectively. During the years ended December 31, 2025 and 2024, the Company recognized $0.8 million and $0.1 million of government grant income within other income in the consolidated statements of operations and comprehensive income, respectively.

Summarized below are deferred government grants as of December 31, 2025 and 2024 (in thousands):

	December 31,	
	2025	2024
Government grants for property and equipment, included in accrued expenses and other current liabilities	$ 97	$ 95
Current deferred government grants	97	95
Government grants for property and equipment	852	928
Non-current deferred government grants	852	928
Total deferred government grants	$ 949	$ 1,023

Property and equipment, net

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

	December 31,	
	2025	2024
Buildings	$ 19,569	$ 18,980
Construction in progress	765	222
Machinery and electronic devices	9,895	9,442
Furniture and fixtures	757	653
Motor vehicles	189	182
Property and equipment, gross	31,175	29,479
Less: Accumulated depreciation	(7,576)	(5,599)
Property and equipment, net	$ 23,599	$ 23,880

Depreciation expense was $2.0 million and $1.3 million for each of the years ended December 31, 2025 and 2024, respectively.

Long-Term Investment Measured Under Equity Method

On June 28, 2024, Gyre Pharmaceuticals entered into a partnership agreement as a limited partner with other investors and is obligated to pay $4.2 million for an 18.93% equity interest in the partnership. In April 2025, a new investor joined the partnership agreement, and as a result, Gyre Pharmaceuticals' equity interest was adjusted to 18.35%. Pursuant to the partnership agreement, Gyre Pharmaceuticals, as a limited partner, shall not participate in any activities related to the management of the investment business. However, Gyre Pharmaceuticals may appoint a member to the advisory committee of the partnership.

As of December 31, 2025 and 2024, the Company's total investment into the partnership was $1.7 million and $1.7 million, respectively, and the carrying value of the Company's long-term investment in this affiliate, which was included in "Other assets, noncurrent" on the balance sheet, was $1.6 million and $1.6 million, respectively.

5. Intangible Assets

Intangible assets with finite lives consist primarily of patents, technological know-how, computer software, and technology rights. Technology rights refer to the IP associated with Etorel® (nintedanib, ethanesulfonate soft capsules), which were obtained upon the successful transfer of the marketing authorization holder following approval by the NMPA in March 2025, and the commercial sales of Etorel® commenced in June 2025. As of December 31, 2025, the Company recognized the total consideration for the Etorel® technology rights in the amount of RMB 35.0 million, or approximately $5.0 million, based on the December 31, 2025 spot exchange rate.

The gross carrying amounts and accumulated amortization of the Company's intangible assets with determinable lives as of December 31, 2025 and 2024 were as follows (in thousands):

	December 31, 2025		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	$ 433	$ (328)	$ 105
Computer software	337	(176)	161
Technology rights	4,980	(519)	4,461
Total intangible assets	$ 5,750	$ (1,023)	$ 4,727

	December 31, 2024		
	Gross carrying amount	Accumulated amortization	Intangible assets, net
Intangible assets with finite lives:			
Technological know-how	$ 423	$ (303)	$ 120
Computer software	278	(125)	$ 153
Total intangible assets	$ 701	$ (428)	$ 273

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, 2025 is 7.0 years.

Amortization expense was $576 thousand and $38 thousand for each of the years ended December 31, 2025, and 2024, respectively. Based on finite-lived intangible assets recorded as of December 31, 2025, the estimated future amortization expense is as follows (in thousands):

	Estimated Amortization Expense
2026	$ 694
2027	690
2028	661
2029	659
2030	648
Thereafter	1,375
Total	$ 4,727

6. Revenue

The Company's product revenues were mainly generated from the sale of ETUARY®. The Company launched two new products: Contiva® (avatrombopag maleate tablets), which commenced commercialization in March 2025, and Etorel®, which commenced commercialization in June 2025.

The following table summarizes the composition of product revenues for the years ended December 31, 2025 and 2024:

Product Revenue Composition	Year ended December 31, 2025		Year ended December 31, 2024	
ETUARY®	$ 106,137	91.0%	$ 105,009	99.3%
Contiva®	5,520	4.7%	—	—%
Etorel®	4,619	4.0%	—	—%
Other Products	312	0.3%	748	0.7%
Total	$ 116,588	100.0%	$ 105,757	100.0%

Sales of Pharmaceutical Products

The Company generates revenue mostly through sales of ETUARY®, Contiva®, Etorel® and certain generic drugs. The distributors were the Company's direct customers, and sales to distributors accounted for 100.0% of revenue. The distributors sell pharmaceutical products 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. All sales are generated in mainland China.

7. Leases

Operating leases

As of December 2025, Gyre Pharmaceuticals maintained leases for office spaces in the following locations: in Beijing, comprising approximately 2,130 square meters with a lease expiration in June 2027; in Zhengzhou, comprising approximately 180 square meters with a lease expiration in August 2026; in Shanghai, comprising approximately 224 square meters with a lease expiration in December 2026; in Nanjing, comprising approximately 70 square meters with a lease expiration in February 2027; and in Beijing, for a staff dormitory comprising approximately 249 square meters with a lease expiration in March 2028. The Company also holds a lease for its U.S. headquarters in San Diego, California, which was secured in November 2023 and is set to expire in the first quarter of 2027.

The Company also has multiple short-term leased properties used as offices and employee dormitories. The Company recorded a total of $66 thousand and $68 thousand short-term rent expenses during the years ended December 31, 2025 and 2024, respectively. The short-term rent expense amounts are recorded in operating expenses in the accompanying consolidated statements of operations and comprehensive income.

As of December 31, 2025, the Company recorded an aggregate ROU asset of $1.1 million and an aggregate lease liability of $0.9 million in the accompanying consolidated balance sheets.

Rent expense related to operating leases was $0.9 million and $0.7 million for the years ended December 31, 2025, and 2024, respectively. Variable lease payments for the years ended December 31, 2025 and 2024 were immaterial.

Supplemental cash flow information related to operating leases was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating lease	$ 821	$ 872

The present value assumptions used in calculating the present value of the lease payments were as follows:

	Year Ended December 31,	
	2025	2024
Weighted-average remaining lease term	1.4 years	2.3 years
Weighted-average discount rate	4.76%	4.76%

As of December 31, 2025, undiscounted future minimum payments under the Company's operating leases were as follows (in thousands):

	Amount
2026	$ 668
2027	303
Total undiscounted lease payments	971
Less: imputed interest	(32)
Total lease liabilities	939
Less: current portion of lease liabilities	(636)
Lease liabilities, net of current portion	$ 303

The Company is required to maintain security deposits of $0.3 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, 2025, 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 2070. These parcels, with a combined area of approximately 66,559 square meters, are utilized as manufacturing facilities. As of December 31, 2025, the aggregate recorded land use rights, net assets for these parcels was $1.4 million.

8. 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,			
	2025		2024	
Preferred Stock Warrants issued and outstanding	540,666	[1]	540,666	
Options issued and outstanding	19,483,378		18,077,869	
Total common stock reserved	20,024,044		18,618,535	

[1] Includes 5,587,947 options exercisable for shares of common stock, which underlying shares of common stock were transferred in the name of the Company to Futu Network Technology Limited, the stock plan administrator of the 2023 Omnibus Incentive Sub-Plan for Chinese Participants.

2024 ATM Program

On November 27, 2024, the Company entered into an Open Market Sale Agreement (the "ATM Agreement") with Jefferies LLC (the "Sales Agent") as sales agent, pursuant to which the Company may offer and sell, from time to time, through the Sales Agent, shares of common stock 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 the Sales Agent a commission of up to 3% of the gross proceeds of any shares sold. The Company also agreed to reimburse the Sales Agent for certain expenses incurred in connection with its services under the ATM Agreement, including up to $135,000 for legal expenses in connection with the establishment of the ATM Program. During the year ended December 31, 2024, the Company sold 70,267 shares of common stock under ATM Program and received net proceeds of $0.8 million, after deducting commissions and offering costs of $0.02 million. During the year ended December 31, 2025, the Company sold 54,734 shares of common stock under ATM Program and received net proceeds of $0.5 million, after deducting commissions and offering costs of $0.01 million.

Sales of shares of common stock under the ATM Program may be made pursuant to the registration statement on Form S-3 (File No. 333-283237), which was declared effective by the SEC on November 22, 2024 (the "Shelf Registration Statement"), and a related prospectus supplement filed with the SEC on November 27, 2024.

May 2025 Underwritten Public Offering

On May 22, 2025, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Jefferies LLC, as representative of the several underwriters (the "Underwriters"), pursuant to which the Company agreed to issue and sell 2,222,222 shares of common stock, at a public offering price of $9.00 per share (the "Offering"). In addition, the Company granted the Underwriters an option for a period of 30 days to purchase up to an additional 333,333 shares of common stock at the public offering price, less the underwriting discounts and commissions (the "Greenshoe Option").

The Offering closed on May 27, 2025. On May 29, 2025, the Underwriters exercised the Greenshoe Option in full, and the issuance of the additional 333,333 shares was settled on the same day.

During the year ended December 31, 2025, the Company sold an aggregate of 2,555,555 shares of common stock under the Underwriting Agreement, including the full exercise of the Greenshoe Option, and received gross proceeds of approximately $23.0 million. After deducting the Underwriters' discounts and commissions of $1.4 million and offering costs of $0.3 million, the Company received net proceeds of approximately $21.3 million.

The Offering was made pursuant to the Shelf Registration Statement, as supplemented by a prospectus supplement, dated May 22, 2025, filed with the SEC on May 23, 2025.

Restricted Net Assets

Under PRC laws and regulations, Gyre Pharmaceuticals 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 Gyre Pharmaceuticals to pay dividends to BJContinent Pharmaceuticals Limited ("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 Gyre Pharmaceuticals. 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 $70.1 million and $64.3 million as of December 31, 2025 and 2024, respectively.

As a result of the above restrictions, parent-only financial statements are presented in Schedule I.

Statutory Reserve

Gyre Pharmaceuticals 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.

There were no appropriations to these reserves during the years ended December 31, 2025 and 2024.

Noncontrolling Interest

The noncontrolling interests in the Company's consolidated financial statements represent the economic interests in Gyre Pharmaceuticals held by shareholders other than BJC and four other holding company subsidiaries of the Company.

In the third quarter of 2025, the Company's indirect ownership in Gyre Pharmaceuticals increased from 65.2% to 69.7% as a result of an additional capital contribution of $1.28 million by BJC in exchange for 9,184,910 additional shares of Gyre Pharmaceuticals, which diluted the noncontrolling shareholders' ownership from 34.8% to 30.3%. The transaction was accounted for as an equity transaction and reflected as a reclassification from noncontrolling interests to Gyre stockholders' equity with no gain or loss recognized.

9. Convertible Preferred Stock

In October 2023, the Company issued 811 shares of Convertible Preferred Stock and 811 Preferred Stock Warrants to GNI USA under the Private Placement. For additional information, see Note 3 — *Fair Value Measurements and Financial Instruments.*

In November 2023, GNI USA provided notice to the Company to convert its 13,151 shares of Convertible Preferred Stock. Each share of Convertible Preferred Stock was convertible into approximately 666.67 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 USA upon such conversion.

10. Stock Based Compensation

2023 Omnibus Incentive Plan

The Gyre Therapeutics, Inc. 2023 Omnibus Incentive Plan (the "2023 Omnibus Incentive Plan") was approved by Catalyst's stockholders in August 2023 and ratified by Gyre's board of directors (the "Board") in October 2023. The 2023 Omnibus Incentive Plan became effective on October 30, 2023. The 2023 Omnibus Incentive Plan permits the Company to issue 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. On January 1, 2024, pursuant to the automatic increase in the number of shares reserved, an additional 3,829,780 shares of common stock were reserved and made available for issuance under the 2023 Omnibus Incentive Plan. On January 1, 2025, pursuant to the automatic increase in the number of shares reserved, an additional 4,315,377 shares of common stock were reserved and made available for issuance under the 2023 Omnibus Incentive Plan. During the year ended December 31, 2025, certain members of senior management were granted both awards subject solely to time-based vesting requirements and awards that are subject to the achievement of certain levels of specific performance, in addition to time-based vesting requirements (the "Performance-Based Awards"). These Performance-Based Awards are subject to the achievement of certain sales metrics and approval of Hydronidone for commercialization. The Performance-Based Awards may vest in full after two or three years. The awards become eligible to vest only if the goals are achieved and will vest only if the grantee remains employed by us through each applicable vesting date.

On November 20, 2025, the Company granted non-qualified stock options to employees of Gyre Pharmaceuticals, pursuant to the 2023 Omnibus Incentive Sub-Plan for Chinese Participants under the Company's equity incentive arrangements. The awards covered an aggregate of 2,100,000 shares of the Company's common stock and were granted as part of the Company's employee compensation program.

The stock options were granted with an exercise price of $7.57 per share and have a contractual term of ten years from the grant date, subject to earlier termination upon cessation of employment. The awards generally vest based on a combination of time-based and performance-based vesting conditions. Specifically, 25% of the options vest immediately on the grant date, 35% vest in substantially equal monthly installments over a 24-month service period, and the remaining options are subject to the achievement of specified performance targets related to the Company's consolidated revenue and the employee's individual performance for the 2025 and 2026 calendar years. Performance-Based Awards vest only if the applicable performance conditions are achieved and the employee remains in service through the applicable vesting determination date.

The Company recognizes stock-based compensation expense for these awards based on their grant-date fair value and recognizes compensation cost over the requisite service periods. The Company has elected to account for forfeitures as they occur. Performance-Based Awards are expensed only when achievement of the applicable performance conditions is considered probable.

The following table summarizes stock option activity for year ended December 31, 2025:

	Number of Shares Underlying Outstanding Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (thousands)
Outstanding — December 31, 2024	18,077,869	$ 1.75	6.0	$ 190,377
Options granted	3,854,000	$ 8.50		
Options exercised	(2,396,174)	$ 0.98		
Options forfeited and cancelled	(41,372)	$ 11.70		
Options expired	(10,945)	$ 117.02		
Outstanding — December 31, 2025	19,483,378	$ 3.09	6.0	$ 88,587
Vested and exercisable — December 31, 2025	15,940,772	$ 2.41	5.2	$ 88,551

The weighted-average grant date fair value of options granted was $5.98 per share and $7.25 per share for the years ended December 31, 2025 and 2024, respectively.

The aggregate intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was $17.6 million and $9.6 million, respectively.

The fair value of all equity awards that vested during the periods ended December 31, 2025 and 2024 was $5.4 million and $0.5 million, respectively.

Cash received from the exercise of options was approximately $2.4 million and $1.9 million for the years ended December 31, 2025 and 2024, respectively.

Valuation Assumptions

The Company estimated the fair value of time-based 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 Company also granted performance-based stock options that vest under two types of independent performance conditions. One condition is tied to a certain sales target that is deemed probable as of December 31, 2025. The other condition is tied to the approval in the PRC of a New Drug Application ("NDA") for Hydronidone, which is not considered probable as of December 31, 2025. The grant-date fair value of these awards was determined using the Black-Scholes option-pricing model, which incorporates key inputs such as stock price, exercise price, expected volatility, risk-free interest rate, time to expiration, and a zero-dividend yield.

The following table shows the weighted-average grant date fair value of options and the assumptions used to estimate the fair value for time-based awards, and for Performance-Based Awards during the years ended December 31, 2025 and 2024:

	Year Ended December 31,	
Time-based and performance-based awards	2025	2024
Weighted-average grant-date fair value	$ 5.98	$ 7.25
Risk-free interest rate (%)	3.68% - 4.40%	3.64% - 4.22%
Expected option life (in years)	5.0 - 6.4	5.3 - 6.1
Expected dividend yield (%)	—%	—%
Volatility (%)	81.50% - 84.30%	84.10% - 84.30%

Total stock-based compensation recognized was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Cost of revenues	$ 502	$ —
Selling and marketing	2,250	—
Research and development	245	—
General and administrative	4,160	831
Total	$ 7,157	$ 831

As of December 31, 2025, the Company had an unrecognized stock-based compensation expense of $18.3 million, related to unvested stock option awards, which is expected to be recognized over an estimated weighted-average period of 2.44 years.

11. Commitments and Contingencies

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.

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 $3.9 million as of December 31, 2025 and were expected to be incurred within one year.

Etorel® IP Rights

In May 2024, the Company entered into an IP rights transfer agreement with a third-party, Jiangsu Wangao Pharmaceuticals Co., Ltd., to acquire the IP associated with Etorel® (the "Etorel® IP Rights"). The Etorel® IP Rights are recorded as technology rights in Intangible Assets in Note 5 — Intangible Assets. The commercial sales of Etorel® commenced in June 2025.

According to the agreement, except for RMB 35.0 million, or approximately $5.0 million, based on the December 31, 2025 spot exchange rate, the Company is committed to additional annual payments over eight years following the commencement of commercial sales in June 2025, which will be contingent consideration based on actual annual sales in future years. For each of the first two years starting from June 2025, the minimum annual commission is RMB 10 million, or approximately $1.4 million, based on the December 31, 2025 spot exchange rate, which has already been included in the IP cost. If the sales-based commission calculated at 5% of annual sales in the first year exceeds RMB 10 million (approximately $1.4 million, based on the December 31, 2025 spot exchange rate) or the commission calculated at 4% of annual sales in the second year exceeds RMB 10 million (approximately $1.4 million, based on the December 31, 2025 spot exchange rate), the excess amount for each year will be recognized as contingent consideration. For the third year through the eighth year, the contingent payments will be calculated at 3%, 2%, 2%, 1%, 1%, and 1% of sales in each year, respectively.

As of December 31, 2025, the Company assessed the possibility that annual sales commissions in either of the first two years would exceed RMB 10 million, or approximately $1.4 million, based on the December 31, 2025 spot exchange rate, as remote and did not accrue any contingent consideration.

Hydronidone

In September 2020, Gyre Pharmaceuticals entered into an IP transfer agreement (the "Hydronidone Transfer Agreement") with GNI Japan and certain of its wholly owned subsidiaries (the "GNI Group"). According to the Hydronidone Transfer Agreement, Gyre Pharmaceuticals acquired the exclusive right to use Hydronidone IP rights in mainland China and the right of first offer for the global IP rights (the "Hydronidone IP Rights").

Under the Hydronidone Transfer Agreement, in exchange for the Hydronidone IP Rights, Gyre Pharmaceuticals is obligated to pay GNI Group three payments based on the achievement of the respective milestones: RMB 33.1 million, or approximately $4.7 million, based on the December 31, 2025 spot exchange rate, upon submission of the Hydronidone NDA to the Center for Drug Evaluation of the NMPA of the PRC; RMB 8.3 million, or approximately $1.2 million, based on the December 31, 2025 spot exchange rate, after the NDA passes the NMPA's Center for Food and Drug Review and Inspection's on-site registration inspection for the Hydronidone product; and RMB 49.6 million, or approximately $7.0 million, based on the December 31, 2025 spot exchange rate, upon NMPA's approval of the NDA. As of December 31, 2025, the payment conditions have not been met, and no payments have been made.

Upon Hydronidone product achieving commercialization, the Company will be required to make annual royalty payments based on future product sales. These contingent payments are structured as twelve annual royalties equal to 10%, 14%, 16%, 16%, 16%, 16%, 16%, 15%, 14%, 12%, 10%, and 8% of annual sales. As of December 31, 2025, commercialization has not yet been achieved, and no royalty payments have been incurred or accrued.

SDM Service

In December 2025, the Company entered into a clinical trial service agreement with a third-party CRO in connection with a Phase 3c confirmatory clinical trial for Hydronidone (the "SDM Clinical Trial Agreement"). The Phase 3c trial is designed to evaluate clinical endpoint events and satisfy the safety exposure requirements for the potential conditional approval and subsequent conventional marketing authorization of Hydronidone capsules.

Under the SDM Clinical Trial Agreement, the Company is obligated to make payments based on the achievement of specified clinical and operational milestones and the performance of clinical trial–related services, including trial preparation, patient enrollment and follow-up, site management, interim analyses, data management–related activities, and preparation of the clinical study report. The aggregate contractual amount under the agreement is approximately RMB 114.0 million, or approximately $16.2 million, based on the December 31, 2025 spot exchange rate.

As of December 31, 2025, none of the payment conditions had been met, and no payments had accrued or been made under the agreement. The contractual amount represents a future research and development commitment of the Company as of the end of the fiscal year.

Research and Development Programs

In addition to the $12.9 million commitment to GNI for the Hydronidone program, as of December 31, 2025, the Company has committed to allocate $39.9 million toward future research and development activities for various programs.

Indemnification Agreements

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.

12. Income Taxes

The Company's income before provision for (benefit from) income taxes for the years ended December 31, 2025 and 2024 are as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Income (loss) before income tax expense (benefit):		
United States	$ (5,191)	$ 1,207
Foreign	19,627	22,011
Total income before income taxes	$ 14,436	$ 23,218

The components of the Company's provision for income taxes for the years ended December 31, 2025 and 2024 consist of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Current income tax provision:		
Federal	$ —	$ —
State	2	2
Foreign - PRC	5,662	6,320
Total current income tax provision	$ 5,664	$ 6,322
Deferred income tax provision:		
Federal	$ —	$ —
State	—	—
Foreign - PRC	(1,108)	(1,002)
Total deferred income tax provision	$ (1,108)	$ (1,002)
Total income tax provision	$ 4,556	$ 5,320

Upon adoption of ASU 2023-09, Improvements to Income Tax Disclosures, the reconciliation of the federal statutory income tax rate to the Company's effective tax rate for the years ended December 31, 2025 and 2024 are as follows (in thousands, except for percentages):

	Year Ended December 31, 2025		Year Ended December 31, 2024	
	Amount	Percentage	Amount	Percentage
Tax computed at federal statutory rate	$ 3,032	21.00%	$ 4,876	21.00%
Domestic Federal				
Nontaxable and nondeductible items				
Unrealized Loss – Warrant Liability	(569)	-3.94%	(1,505)	-6.48%
Non-deductible Stock Compensation Expenses	(224)	-1.55%	1,155	4.97%
Other	3	0.02%	270	1.16%
Cross-border tax laws				
GILTI	1,985	13.75%	2,951	12.71%
FTC	(56)	-0.39%	(499)	-2.15%
Changes in valuation allowances	579	4.01%	(2,325)	-10.01%
Other reconciling items	(2)	-0.01%	4	0.02%
Domestic state and local income taxes	(624)	-4.32%	(302)	-1.30%
Foreign Tax Effects				
PRC				
Rate difference due to different jurisdiction	786	5.45%	881	3.79%
Preferential income tax rate for HNTE	(1,965)	-13.61%	(2,201)	-9.48%
R&D Super-deduction	(796)	-5.51%	(789)	-3.40%
Non-deductible Expense – Operating	490	3.39%	287	1.24%
Non-deductible Expense – Other	75	0.52%	37	0.16%
ESOP	(1,937)	-13.42%	(892)	-3.84%
Valuation allowance change	3,693	25.58%	3,139	13.52%
Other	82	0.57%	233	1.00%
Other Foreign Jurisdictions	4	0.03%	—	0.00%
Effective tax rate	$ 4,556	31.57%	$ 5,320	22.91%

Upon adoption of ASU 2023-09, Improvements to Income Tax Disclosures, the cash paid for income taxes, net of refunds, during the year ended December 31, 2025 was as follows (in thousands):

	Year Ended December 31, 2025
US federal	$ —
US state and local	
CA	2
Foreign	
PRC	5,890
Other Foreign Jurisdictions	—
Cash paid for income taxes, net of refunds	$ 5,892

Significant components of the Company's deferred tax assets as of December 31, 2025 and 2024 consist of the following (in thousands):

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Accruals and reserves	$ 1,592	$ 407
Contract liabilities	142	153
Net operating loss carryforwards	42,239	41,714
Tax credit carry forwards	4,463	4,463
Fixed and intangible assets	15,649	15,385
Impact from foreign corporations	12,716	8,754
Capitalized transaction costs	430	430
Lease liabilities	154	288
Lease-prepaid expense	29	—
Deferred income tax assets before valuation allowance	77,414	71,594
Deferred tax liability – ROU assets	(182)	(296)
Deferred tax liability – Fixed assets	(211)	(74)
Less: valuation allowance	(70,148)	(65,605)
Deferred tax assets, net	$ 6,873	$ 5,619

As of December 31, 2025, the Company maintained valuation allowances of $70.1 million for deferred tax assets that are not more likely than not to be realized, which primarily included the Company's U.S. federal and state deferred tax assets and certain limited foreign expenses. The movements of the valuation allowance during the years ended December 31, 2025 and 2024 are as follows (in thousands):

	2025	2024
Balance at the beginning of the year	$ (65,605)	$ (63,773)
Changes of valuation allowances	(4,543)	(1,832)
Balance at the end of the year	$ (70,148)	$ (65,605)

Based on the available objective evidence on December 31, 2025, the Company does not believe it is more likely than not that most of its U.S. federal and state net deferred tax assets will be realizable for U.S. tax purposes. Accordingly, the Company has provided a full valuation allowance against its U.S. federal and state net deferred tax assets on December 31, 2025. The Company's deferred tax assets without a valuation allowance are more likely than not to be realized given the expectation of future earnings in the respective jurisdictions.

As of December 31, 2025, after consideration of certain limitations (see below), the Company had approximately $193.3 million federal and $21.7 million state net operating loss ("NOL") carryforwards 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, 2025, the Company also had tax credit carryforwards available to offset future tax liabilities of approximately $8 thousand 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 is 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 $5.3 million for federal and California state income tax purposes, respectively through the year ended December 31, 2025.

All of the federal R&D credits could expire unutilized, whereas none of the California R&D credits are subject to expiration. Approximately $26.0 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.

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 $1.9 million of unrecognized tax benefits as of December 31, 2025. 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, 2024	$	1,883
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, 2024		1,883
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, 2025	$	1,883

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, 2025 and 2024, 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 2024. 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, 2025 and 2024, the Company had no uncertain tax positions which affected its financial position as its results of operations or its cash flow for US tax purposes, 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.

According to the PRC Tax Administration and Collection Law, the statute of limitations is three years if the underpayment of taxes is due to computational errors made by the taxpayer or the withholding agent. The statute of limitations is extended to five years under special circumstances where the underpayment of taxes is more than approximately $14 thousand (which is RMB 100 thousand translated at the average exchange rate for 2025). In the case of transfer pricing issues, the statute of limitations is 10 years. There is no statute of limitations in the case of tax evasion. The income tax returns of the Company's PRC subsidiaries for the years from 2020 to 2025 are open to examination by the PRC tax authorities.

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 deferred tax liability of approximately $9.6 million as of December 31, 2025 related to PRC withholding taxes on repatriation of Gyre Pharmaceuticals' earnings (i.e., the Company's primary operating subsidiary in the PRC) would need to be recorded.

13. Related Party Transactions

Research and development with GNI Group

No research and development fees were paid to GNI Group during the year ended December 31, 2025. Research and development fees paid to GNI Group during the year ended December 31, 2024 were $0.2 million.

As of December 31, 2025 and December 31, 2024, the Company had $0.2 million related parties payable due to GNI Group.

Other receivables from GNI Group

As of December 31, 2025 and December 31, 2024, the Company had recorded $0.2 million in other receivables from GNI Group, all of which related to Continent Pharmaceuticals Inc.'s ("CPI") restructuring transaction.

14. 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,	
	2025	2024
Numerator:		
Net income	$ 9,880	$ 17,898
Less: Allocation of undistributed earnings to noncontrolling interest	4,853	5,813
Net income attributable to common stockholders - basic	$ 5,027	$ 12,085
Less: Change in fair value of warrant liability	2,707	7,167
Net income attributable to common stockholders - diluted	$ 2,320	$ 4,918
Denominator:		
Basic common shares outstanding:		
Weighted average common shares outstanding	89,344,622	85,094,948
Weighted average shares used in calculating net income per share attributable to common stockholders, basic	89,344,622	85,094,948
Dilutive potential common shares:		
Weighted average of common stock options	13,752,108	16,407,847
Weighted average of Convertible Preferred Stock (as converted)	—	528,442
Weighted average of Preferred Stock Warrants (as converted)	83,307	262,289
Weighted average shares used in calculating net income per share attributable to common stockholders, diluted	103,180,037	102,293,526
Net income per share attributable to common stockholders:		
Basic	$ 0.06	$ 0.14
Diluted	$ 0.02	$ 0.05

Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	December 31,	
	2025	2024
Options to purchase common stock	439,464	896,960
Total	439,464	896,960

15. 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 $5.6 million and $5.1 million for the years ended December 31, 2025, and 2024, 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, 2025 and 2024 were immaterial.

16. Segment Information

The Company is a consolidated entity comprised of two distinct operating segments: Gyre Pharmaceuticals and Gyre. The Company's reportable segments are based upon internal organizational structure, the manner in which operations are managed, the criteria used by the CODM to evaluate segment performance, the availability of separate financial information, and overall materiality considerations. All Gyre's operations are within the United States, while all of Gyre Pharmaceuticals' operations are in mainland China.

Gyre Pharmaceuticals

Gyre Pharmaceuticals has three major commercial drug products, ETUARY®, Etorel®, and Contiva®—as well as several product candidates in preclinical and clinical development. Gyre Pharmaceuticals' product revenues are mainly generated from the sale of ETUARY®, Etorel®, Contiva®, and certain generic drugs. Gyre Pharmaceuticals primarily sells its pharmaceutical products to distributors in mainland China, who ultimately sell the products to hospitals, other medical institutions and pharmacies.

Gyre

Gyre is a biopharmaceutical company focused on the development and commercialization of Hydronidone for the treatment of metabolic dysfunction-associated steatohepatitis ("MASH")-associated liver fibrosis in the United States. Other than the IP associated with Hydronidone in the United States, Gyre has no other product candidates since the Company sold all of its legacy IP assets. Subsequent to October 2023, Gyre has not generated any revenue.

Other

Other represents the financial information from other subsidiaries, consisting of mainly CPI and BJC. As of December 31, 2025, CPI holds a 61.7% indirect ownership interest in Gyre Pharmaceuticals following an additional capital contribution of $1.28 million by BJC in exchange for 9,184,910 additional shares of Gyre Pharmaceuticals.

Segment information for the years ended December 31, 2025 and 2024 is as follows (in thousands):

	Year Ended December 31, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	$ 116,588	$ —	$ —	$ 116,588
Operating expenses:				
Cost of revenues	5,416	—	—	5,416
Selling and marketing	65,179	—	—	65,179
Research and development	12,503	1,195	—	13,698
General and administrative	13,494	7,291	19	20,804
Loss on disposal of property and equipment	4	—	—	4
Total operating expenses	96,596	8,486	19	105,101
Income (Loss) from operations	19,992	(8,486)	(19)	11,487
Interest income, net	1,126	621	—	1,747
Other expense, net	(1,472)	(33)	—	(1,505)
Change in fair value of warrant liability	—	2,707	—	2,707
Income tax expense	(4,554)	(2)	—	(4,556)
Net income (loss)	$ 15,092	$ (5,193)	$ (19)	$ 9,880
Supplemental Disclosure of stock-based compensation expense				
Cost of revenues	$ 502	$ —	$ —	$ 502
Selling and marketing	2,250	—	—	2,250
Research and development	245	—	—	245
General and administrative	1,551	2,609	—	4,160
Stock-based compensation total	$ 4,548	$ 2,609	$ —	$ 7,157

	Year Ended December 31, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Revenues	$ 105,757	$ —	$ —	$ 105,757
Operating expenses:				
Cost of revenues	3,884	—	—	3,884
Selling and marketing	57,511	—	—	57,511
Research and development	11,224	800	—	12,024
General and administrative	11,051	5,056	2	16,109
Loss on disposal of property and equipment	66	—	—	66
Total operating expenses	83,736	5,856	2	89,594
Income (Loss) from operations	22,021	(5,856)	(2)	16,163
Interest income, net	1,321	232	(6)	1,547
Other (expense) income, net	(1,329)	(336)	6	(1,659)
Change in fair value of warrant liability	—	7,167	—	7,167
Income tax expense	(5,318)	(2)	—	(5,320)
Net income (loss)	$ 16,695	$ 1,205	$ (2)	$ 17,898
Supplemental Disclosure of stock-based compensation expense				
Cost of revenues	$ —	$ —	$ —	$ —
Selling and marketing	—	—	—	—
Research and development	—	—	—	—
General and administrative	—	831	—	831
Stock-based compensation total	$ —	$ 831	$ —	$ 831

The table below presents total assets as of December 31, 2025 and 2024.

	December 31, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Total assets	$ 138,407	$ 27,369	$ 356	$ 166,132

	December 31, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Total assets	$ 114,248	$ 10,790	$ 368	$ 125,406

The table below only includes cash outflows for the purchase of property and equipment and excludes non-cash activities.

	Year Ended December 31, 2025			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Purchase of property and equipment	$ (1,190)	$ —	$ —	$ (1,190)

	Year Ended December 31, 2024			
	Gyre Pharmaceuticals	Gyre	Other	Consolidated
Purchase of property and equipment	$ (2,301)	$ (14)	$ —	$ (2,315)

17. Subsequent Events

The Company evaluated subsequent events and transactions that occurred after the balance sheet date through the date that the consolidated financial statements were issued. Other than as set forth below, there were no material subsequent events that required recognition or additional disclosure in the consolidated financial statements presented.

Agreement and Plan of Merger and Reorganization

On March 2, 2026, the Company entered into an Agreement and Plan of Merger and Reorganization (the “Merger Agreement”) with Cullgen Inc., a Delaware corporation (“Cullgen”), and Helix Merger Sub Corp., a Delaware corporation and wholly owned subsidiary of the Company (“Merger Sub”), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Cullgen, with Cullgen continuing as a wholly owned subsidiary of the Company and the surviving corporation of the merger (the “Merger”). The Merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the Internal Revenue Code of 1986, as amended.

Under the terms of the Merger Agreement, the Company will acquire Cullgen in an all-stock transaction that values Cullgen at approximately $300 million. At the effective time of the Merger (the “Effective Time”), each then outstanding share of Cullgen capital stock (the “Cullgen Capital Stock”), excluding shares of Cullgen Capital Stock held as treasury stock immediately prior to the Effective Time and any dissenting shares, will be converted into (1) with respect to shares of Cullgen Capital Stock held by certain designated holders, (i) for each share of Cullgen common stock (“Cullgen Common Stock”) held by such holders, a number of shares of the Company's Series B Convertible Preferred Stock, par value $0.001 per share (the “Company Preferred Stock”), equal to (x) 0.4753 (the “Exchange Ratio”) divided by five, and (ii) for each share of Cullgen preferred stock (“Cullgen Preferred Stock”) held by such designated holders, a number of shares of Company Preferred Stock equal to (x) the number of shares of Cullgen Common Stock issuable upon conversion of each share of Cullgen Preferred Stock, multiplied by the Exchange Ratio, and divided by five, and (2) with respect to shares of Cullgen Capital Stock held by each other holder, (i) for each share of Cullgen Common Stock held by such holders, a number of shares of Company common stock, par value $0.001 per share (the “Company Common Stock”), equal to the Exchange Ratio divided by five, and (ii) for each share of Cullgen Preferred Stock held by such designated holders, a number of shares of Company Common Stock equal to the number of shares of Cullgen Common Stock issuable upon conversion of each share of Cullgen Preferred Stock, multiplied by the Exchange Ratio. Each share of Company Preferred Stock received in the Merger is convertible into five shares of Company Common Stock, subject to certain conditions described below with respect to the Conversion Proposal (as defined below). Notwithstanding anything herein to the contrary, in no event will the Company issue greater than 19.99% of its issued and outstanding Company Common Stock or its voting power prior to the approval of the Conversion Proposal.

In addition, at the Effective Time (1) each then-outstanding in-the-money option to purchase shares of Cullgen Common Stock that is outstanding and unexercised immediately prior to the Effective Time, whether vested or unvested, will cease to represent a right to acquire shares of Cullgen Common Stock and will be converted into and become an option to purchase shares of Company Common Stock on the existing terms and conditions (including with respect to vesting and accelerated vesting), subject to adjustment as set forth in the Merger Agreement, (2) each then-outstanding option to purchase shares of Cullgen Common Stock that is not an in-the-money option and is outstanding and unexercised immediately prior to the Effective Time will be cancelled at the Effective Time for no consideration, and (3) each Cullgen restricted stock unit will vest and be settled for Cullgen Common Stock and the holder thereof will be entitled to receive a number of shares of Company Common Stock calculated in accordance with the Merger Agreement.

The consummation of the Merger is subject to certain closing conditions, including, among other things, (1) approval by the requisite Cullgen stockholders of the adoption and approval of the Merger Agreement and the transactions contemplated thereby, and (2) a filing under The Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

Pursuant to the Merger Agreement, the Company has agreed to convene a meeting of its stockholders to submit to its stockholders for their consideration the approval of the conversion of the Company Preferred Stock into shares of Company Common Stock in accordance with certain of the rules of the Nasdaq Stock Market LLC (the “Conversion Proposal”). In connection with these matters, the Company intends to file with the SEC a proxy statement and other relevant materials.

The closing of the Merger has not yet occurred as of the date these financial statements were issued. Accordingly, no amounts related to the proposed transaction have been recognized in the accompanying consolidated financial statements. The Company will evaluate the impact to the financial statements upon the closing of the Merger.

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, 2025	December 31, 2024
Assets		
Current assets:		
Related party receivables	$ 768	$ 768
Total current assets	768	768
Investment in subsidiaries	107,053	64,313
Total assets	$ 107,821	$ 65,081
Liabilities and stockholders' equity		
Current liabilities:		
Due to related parties	$ 538	$ 538
Accrued expenses and other current liabilities	1,252	1,224
Total current liabilities:	1,790	1,762
Stockholders' equity:		
Common stock, $0.001 par value, 400,000,000 shares authorized; 91,314,007 shares and 86,307,544 shares issued and outstanding at December 31, 2025 and 2024, respectively	91	86
Additional paid-in capital	172,047	136,185
Statutory reserve	3,098	3,098
Accumulated deficit	(68,426)	(73,453)
Accumulated other comprehensive loss	(779)	(2,597)
Total stockholders' equity	106,031	63,319
Total liabilities and stockholders' equity	$ 107,821	$ 65,081

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,	
	2025	**2024**
Operating expenses:		
General and administrative	$ 46	$ 105
Loss before equity in income of subsidiaries	46	105
Income in equity of subsidiaries	5,073	12,190
Net income	$ 5,027	$ 12,085
Other comprehensive loss, net of tax of nil:		
Foreign currency translation adjustments	1,818	(953)
Comprehensive income	$ 6,845	$ 11,132

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,	
	2025	**2024**
Operating Activities		
Net income	$ 5,027	$ 12,085
Adjustments to reconcile net income (loss) to net cash used for operating activities:		
Equity income of subsidiaries	(5,073)	(12,190)
Changes in operating assets and liabilities:		
Due to related parties	—	—
Net cash used in operating activities	(46)	(105)
Effect of exchange rate changes on cash and cash equivalents	46	105
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 previously disclosed business combination agreement pursuant to which the Company acquired an indirect controlling interest in Gyre Pharmaceuticals, considered the “registrant” and presented as the parent company, Gyre Therapeutics, Inc. 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. GAAP have been condensed or omitted.

4. As of December 31, 2025 and 2024, 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.

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. (69.7%) and Beijing Continent Biomedical Technology Co., Ltd (69.7%).

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 reports dated March 13, 2026, with respect to the consolidated financial statements and internal control over financial reporting included in the Annual Report of Gyre Therapeutics, Inc. on Form 10-K for the year ended December 31, 2025. We consent to the incorporation by reference of said reports 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, 333-275222, 333-278291 and 333-285954), and Form S-3 (Nos. 333-273395 and 333-283237).

/s/ Grant Thornton Zhitong Certified Public Accountants LLP

Beijing, China
March 13, 2026

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, Ping Zhang, 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 13, 2026

/s/ Ping Zhang

Ping Zhang
Executive Chairman and Interim Chief Executive Officer
(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 13, 2026

/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 Gyre Therapeutics, Inc. (the "Company") for the period ended December 31, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ping Zhang, 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 13, 2026

/s/ Ping Zhang
Ping Zhang
Executive Chairman and Interim Chief Executive Officer
(Principal Executive 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.

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 Gyre Therapeutics, Inc. (the "Company") for the period ended December 31, 2025, 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 13, 2026

/s/ Ruoyu Chen
Ruoyu Chen
Chief Financial Officer
(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.