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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2024

OR

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

Commission file number: 001-38796

GOSSAMER BIO, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**47-5461709**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3115 Merryfield Row, Suite 120 San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 684-1300

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, $0.0001 par value per share	GOSS	Nasdaq Global Select 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 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 Securities Exchange Act of 1934.

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

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

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

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

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

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

As of June 28, 2024 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $197.4 million, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $0.90 per share.

As of March 6, 2025, the registrant had 227,221,261 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement for the 2025 annual meeting of stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after end of this fiscal year covered by this Form 10-K are incorporated by reference into Part III of this Form 10-K.

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PART I

FORWARD-LOOKING STATEMENTS AND MARKET DATA

This annual report on Form 10-K contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Section 27A of the Securities Act of 1933, as amended, or the Securities Act. All statements other than statements of historical facts contained in this annual report, including statements regarding our future results of operations and financial position, business strategies and plans, research and development plans, the anticipated timing, costs, design and conduct of our ongoing and planned preclinical studies and planned clinical trials for seralutinib, our and Chiesi's performance under our collaboration agreement, the timing and likelihood of regulatory filings and approvals for seralutinib, timing and likelihood of success, plans and objectives of management for future operations and future results of seralutinib, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. This annual report on Form 10-K also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this annual report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this annual report and are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, "Risk Factors." The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

This annual report includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this annual report appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or that the applicable owner will not assert its rights, to these trademarks and tradenames.

This Annual Report also contains industry, market and competitive position data from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information. 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. In addition, while we believe the industry, market and competitive position data included in this report is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in in Part I, Item 1A, "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

We maintain a website at www.gossamerbio.com, to which we regularly post copies of our press releases as well as additional information about us. Our filings with the Securities and Exchange Commission, or SEC, are available free of charge through our website as soon as reasonably practicable after being electronically filed with or furnished to the SEC. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary hypertension, or PH, including pulmonary arterial hypertension, or PAH, and PH

associated with interstitial lung disease, or PH-ILD. Our goal is to be an industry leader in, and to enhance the lives of patients living with, PH. To accomplish this goal, we have assembled a deeply experienced and highly skilled group of industry veterans, scientists, clinicians and key opinion leaders from leading biotechnology and pharmaceutical companies, as well as leading academic centers from around the world. We intend to maintain a scientifically rigorous and inclusive corporate culture where employees strive to bring improved therapeutic options to patients.

Our Team

Our founders and management team have held senior positions at leading biopharmaceutical companies and possess substantial experience and expertise across the spectrum of drug development and commercialization.

Faheem Hasnain is our Co-Founder and has served as our Chief Executive Officer since November 2020 and as our Chairman since our inception. Mr. Hasnain also served as our Chief Executive Officer from our inception through July 2018 and our Executive Chairman from July 2018 through June 2019. Prior to co-founding Gossamer Bio, Mr. Hasnain served as President, CEO and as a Director of Receptos, Inc. from November 2010 to August 2015. Receptos was a public company formed in 2009 focused on developing treatments in immunology and metabolic disorders and was purchased by Celgene Corporation in August 2015. Previously, Mr. Hasnain was the President and Chief Executive Officer and a director of Facet Biotech Corporation, a biology-driven antibody company with a focus in multiple sclerosis and oncology. He held that position from December 2008 until the company's acquisition by Abbott Laboratories in April 2010.

Bryan Giraudo, our Chief Financial Officer and Chief Operating Officer, has extensive biotechnology and medical technology finance experience, having previously served as Senior Managing Director at Leerink Partners and Managing Director at Merrill Lynch, Pierce, Fenner & Smith Incorporated. Richard Aranda, M.D., our Chief Medical Officer, is an experienced clinician and drug developer with previous experience at Bristol Myers Squibb Company, Novo-Nordisk, Inc., Receptos and Celegene Corporation. Bob Smith, our Chief Commercial Officer, has over 30 years of experience in pharmaceuticals, with a strong focus on PAH and rare disease. Prior to Gossamer, Mr. Smith was the National Sales Lead in charge of preparing for the commercial launch of sotatercept for the treatment of PAH in the US at Merck & Co., or Merck. Previously until 2018, Mr. Smith was the Senior Vice President of Sales and an Executive Leadership Team member at Actelion Pharmaceuticals US, Inc., where he spearheaded two successful PAH drug launches, Opsumit (macitentan) and Uptravi (selexipag). Christian Waage, our Executive Vice President, Technical Operations & Administration, has meaningful management biotechnology experience, having previously held various positions at Receptos, most recently as Managing Director after its acquisition by Celgene, and at Ardea Biosciences, Inc. as Vice President, General Counsel. Caryn Peterson, our Executive Vice President, Regulatory Affairs, has considerable experience and regulatory expertise as a Managing Director of Development & Strategic Consulting Associates, as well as management positions leading regulatory affairs at Syndax Pharmaceuticals and FeRx Incorporated.

Our Strategy

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of PH. Our goal is to be an industry leader in, and to enhance the lives of patients living with, PH. Critical components of our business strategy include:

- **Complete the ongoing Phase 3 PROSERA Study of seralutinib in PAH and pursue regulatory approval.** We commenced the registrational Phase 3 PROSERA Study in PAH in the fourth quarter of 2023. We expect to report topline data from the PROSERA study in the fourth quarter of 2025. If the clinical trial is successful, we will seek marketing approval for seralutinib in the United States.

- **Increase the impact of seralutinib by expanding development into PH indications of high unmet need.** We believe that not only does seralutinib offer potential as a therapeutic option for the treatment of PAH but also for the treatment of other rare PH indications of high unmet need, including PH-ILD. To that end, we expect to activate clinical sites for a global registrational Phase 3 for the treatment of PH-ILD in the second half of 2025. Additionally, we will continue to evaluate other potential related indications of high unmet need for further development of seralutinib.

- **Leverage the clinical development and commercialization expertise of our world-class team.** Our executive management team and key scientific leaders have successfully discovered, developed and commercialized pharmaceuticals at both large and small biopharmaceutical companies. Additionally, we have built experienced PH development and commercialization teams, with key team members selected from the leadership of companies such as Actelion, Johnson & Johnson, Merck and United Therapeutics.

- **Build our operational capabilities to successfully commercialize seralutinib for PH, if approved.** If we obtain regulatory approvals for seralutinib, we intend to build in-house sales and marketing capabilities to commercialize seralutinib in the United States, as part of our global collaboration and license agreement, or collaboration agreement, with Chiesi Farmaceutici S.p.A and Chiesi USA, Inc., or collectively, Chiesi. Both PAH and PH-ILD patients are often treated by cardiologists and pulmonologists at national or regional centers of excellence. These concentrations of patients could allow us to commercialize seralutinib with a relatively small commercial footprint, if approved.

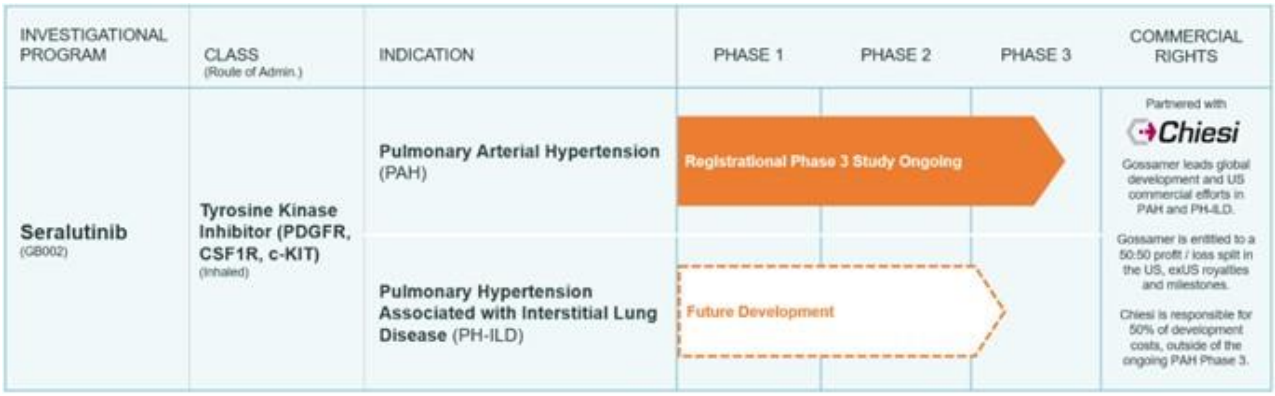
Seralutinib (PDGFR, CSF1R and c-KIT Inhibitor)

Seralutinib, also known as GB002, is an investigational inhaled, small molecule, platelet-derived growth factor receptor, or PDGFR, colony-stimulating factor 1 receptor, or CSF1R, and c-KIT inhibitor, currently being evaluated in a Phase 3 clinical trial for the treatment of PAH. We believe that seralutinib has the potential to reverse pathological remodeling by addressing mechanisms that underlie PAH. Inhaled seralutinib, which is designed to act on both isoforms of the PDGFR, α and β, as well as the CSF1R and c-KIT pathways, inhibited and reversed cellular overgrowth in lung blood vessels in multiple animal PAH models. In December 2022, we announced positive topline results from the 24-week Phase 2 TORREY trial in 86 PAH patients. In this well-treated patient population, the seralutinib arm demonstrated a statistically significant, placebo-adjusted improvement of 14.3% in its primary efficacy endpoint, pulmonary vascular resistance, or PVR. Seralutinib has been generally well tolerated in all completed clinical trials.

We dosed the first patient in our registrational Phase 3 PROSERA Study in PAH in the fourth quarter of 2023. We expect to report topline data from the PROSERA study in the fourth quarter of 2025. In addition to PAH, we believe that seralutinib holds potential as a therapeutic option for the treatment of PH-ILD, and to that end, we expect to activate clinical sites for a global registrational Phase 3 for the treatment of PH-ILD in the second half of 2025.

In May 2024, we entered into a collaboration agreement with Chiesi. Under the collaboration agreement, we will jointly develop seralutinib with Chiesi. We will lead global development of seralutinib in PAH and PH-ILD and will lead potential commercialization for PAH and PH-ILD in the United States, with both parties contributing 50%of commercial efforts, including performing 50% of the commercialization activities. Chiesi will lead global development in any additional indications and will lead potential commercialization in the United States in any additional indications. Chiesi will also have the exclusive right to commercialize seralutinib outside of the United States. We in-licensed seralutinib from Pulmokine, Inc. The United States Food and Drug Administration, or FDA, the European Commission, or EC, and the Pharmaceuticals and Medical Devices Agency, or PMDA, of Japan have granted seralutinib orphan drug designation for the treatment of patients with PAH.

The following table summarizes the current development plan for seralutinib in PH:



Mechanism of Action in PAH

PAH is driven by abnormal cellular proliferation within and around the small blood vessels of the lung that carry blood from the right side of the heart to the lungs. Functional and structural changes in the pulmonary vasculature, known as vascular remodeling, can lead to smooth muscle cell proliferation and migration from the middle layer of the blood vessel into the inner layer. This can result in the development of plexiform and neointimal lesions that can obstruct blood flow. The obstruction of blood flow in the pulmonary vessels can also predispose patients to thrombosis, or blood clots, within these small pulmonary vessels that further blocks blood flow. This progressive obstruction of blood flow from the right side of the heart to the lungs can cause the right ventricle to fail, thus leading to severe breathlessness, reduced exercise tolerance and death.

Seralutinib was designed to inhibit multiple kinases that play a role in the pathology of PAH, including PDGFRα/β, CSF1R and c-KIT.

The PDGFR is a tyrosine kinase receptor which, when activated by its agonist, induces cellular proliferation. PDGF expression is known to be particularly important to stimulating smooth muscle cell proliferation in PAH patients. PDGFRs and their ligands are both upregulated in PAH. Upregulated PDGFR signaling results in endothelial cell and fibroblast dysfunction and the proliferation and migration of smooth muscle cells. This effect results in the overgrowth and occlusion of blood vessels in the lung. Kinase inhibitors with activity against the PDGFR pathway have shown the ability to reverse PAH in animal models.

Inhaled seralutinib is designed to act on both isoforms of the PDGFR, α and β. Data from preclinical animal models and human lung histology from PAH patients suggests that it is important to inhibit both of these isoforms of the PDGF receptor. PDGFRα is highly expressed in pulmonary arteriole vascular smooth muscle cells, or PAVSMCs. Inhibiting PDGFRα may help reduce the abnormal cell proliferation of PAVSMCs that results in blood vessel thickening. PDGFRβ is more highly expressed in fibroblasts and myofibroblasts that are involved with the abnormal cell proliferation within the blood vessel that leads to the obstruction of the pulmonary arterioles. We believe inhibiting PDGFRβ is therefore important in decreasing the abnormal cell proliferation of these cell types.

The c-KIT pathway was also identified as an important growth factor involved in pulmonary vascular remodeling, particularly in the cells implicated in perivascular inflammation. An analysis of lung and pulmonary arteriole samples has also shown increased gene expression of c-KIT in idiopathic PAH. C-KIT positive endothelial cells may also secrete PDGF, and perivascular c-KIT positive mast cells have been shown to secrete pro-inflammatory cytokines and tryptase that further contribute to the inflammatory process in PAH.

Mechanistic validation of a PDGFR and c-KIT kinase inhibitor has been observed in clinical trials of imatinib (Gleevec), an oral tyrosine kinase inhibitor with known activity against the PDGFR and c-KIT pathways, which demonstrated proof-of-concept in humans in a Phase 3 clinical trial in PAH. In preclinical models, as compared to imatinib, seralutinib was a more potent inhibitor of the PDGFRα isoform, and seralutinib was a ten-fold more potent inhibitor of the PDGFRβ isoform and c-KIT.

Macrophages have also been identified as one of the most important inflammatory cells in the development and exacerbation of PAH. Macrophages, which express the CSF1 receptor, are now recognized to play an important role in PAH pathology. Activated CSF1R positive macrophages accumulate around pulmonary arterioles in PAH, which have been shown in vivo in PAH patients with positron emission tomography. Additionally, macrophage activity in PAH is associated with bone morphogenetic protein receptor type II, or BMPR2, levels. The decrease in BMPR2 characteristic of PAH results in induction of granulocyte-macrophage colony-stimulating factor, or GM-CSF, and macrophage recruitment. Notably, in the BMPR2 knock out mouse, there is significant pulmonary inflammation due to activation of tissue macrophages.

Furthermore, inflammatory macrophages secrete PDGF and stimulate pulmonary artery smooth muscle cell migration and proliferation, accelerating the feedback loop of inflammation, hyperproliferation and fibrosis that characterize PAH.

Prior PDGF Pathway Development in PAH - The IMPRES Phase 3 Clinical Trial of Imatinib

The IMPRES trial was a Phase 3 clinical trial conducted by Novartis of imatinib (Gleevec) in patients with PAH. Imatinib has known activity against multiple tyrosine kinases, including the PDGFR, c-KIT receptors and Abelson murine leukemia viral oncogene homolog 1, or c-ABL. The trial met its primary endpoint, improvement in 6-minute walk distance, or 6MWD, versus placebo at week 24.

However, systemic adverse events such as bleeding and poor tolerability and frequent drug discontinuation led to a high drop-out rate within the active arm of the trial. Subdural hematomas occurred in eight patients who were also being administered oral anticoagulants during the trial. Novartis withdrew its supplemental regulatory applications in PAH in 2013 and, to our knowledge, did not pursue further development of imatinib in the indication.

Overview of PAH (WHO Group 1 Pulmonary Hypertension)

PAH, classified as World Health Organization, or WHO, Group 1 Pulmonary Hypertension, is a rare disease that is characterized by abnormally high blood pressure in the blood vessels carrying deoxygenated blood from the right side of the heart to the lungs and is progressive and often fatal. Symptoms include shortness of breath at rest or with minimal exertion.

Other symptoms include fatigue, chest pain, dizzy spells and fainting. The progressive nature of this disease causes the right side of the heart to work much harder and eventually weaken or fail.

Patients are often evaluated by functional class, which categorizes patients by their ability to carry out physical activity and their symptom severity. Worsening symptoms, and thus higher numbered functional classes, are associated with higher mortality. The four functional classes established by the WHO are detailed below in Table 1.

Table 1. PAH Functional Classes

Functional Class	Description
Class I	Patients with PAH, but without resulting limitation of physical activity. Ordinary physical activity does not cause undue dyspnea or fatigue, chest pain or near syncope.
Class II	Patients with PAH resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes undue dyspnea or fatigue, chest pain or near syncope.
Class III	Patients with PAH resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes undue dyspnea or fatigue, chest pain or near syncope.
Class IV	Patients with PAH with inability to carry out any physical activity without symptoms. These patients manifest signs of right heart failure. Dyspnea and/or fatigue may even be present at rest. Discomfort is increased by any physical activity.

Additionally, recent medical society guidelines have identified intermediate and high-risk categories of PAH based on several variables including signs of right heart failure, rate of symptom progression, functional class, 6MWD, maximum oxygen consumption and NT-proBNP, which is a biomarker for heart failure and measures of right heart function. One of these risk categorization tools, the REVEAL 2.0 Risk Score, was utilized in the completed Phase 2 TORREY Study.

Multiple PAH-specific treatments have been introduced in the past two decades, however PAH continues to have a high morbidity and mortality. Based on REVEAL registry data, newly diagnosed functional class III and IV patients have 5-year survival rates of 60% and 44%, respectively, while rates for previously diagnosed patients were even lower at 57% and 27%, respectively.

Overview of PAH Market

PAH most commonly affects women between the ages of 30 and 60. The true incidence and prevalence of PAH are unknown. The estimated PAH patient population in the US is about 50,000 patients, and the estimated patient population in the EU is over 70,000 patients. The number of diagnosed PAH patients continues to increase, and we believe this increase is likely due to enhanced awareness and diagnosis of the disease. Worldwide branded drug sales for PAH and PH-ILD therapies totaled over $7 billion in 2023.

Treatment Paradigm in PAH

Currently approved PAH therapies consist of three classes of vasodilators and one activin ligand trap therapy. The three classes of vasodilatory therapy are PDE5 inhibitors (and guanylate cyclase stimulators), ERAs, and prostanoids (and prostacyclin receptor agonists). PDE5 inhibitors are often used in combination with ERAs as an early treatment strategy. In patients who fail to respond to combination therapy of an ERA and a PDE5 inhibitor, it is common practice to add a prostanoid. Prostanoids are also commonly used to treat patients with evidence of right heart failure. The recent introduction of an activin ligand trap therapy (sotatercept) to the market has provided patients with an additional treatment option. While some existing treatments have led to significant improvements in time to clinical worsening and other composite endpoints in PAH patients, there are no cures. The effects of approved PAH therapies, while capable of improving blood flow through the lungs, may eventually be overtaken by the worsening cellular proliferation and arterial remodeling underlying the condition, given the progressive nature of the disease. We believe an agent with the ability to safely reverse pathological remodeling could provide utility across functional classes and risk categories.

Overview of PH-ILD (WHO Group 3 Pulmonary Hypertension)

We believe that seralutinib has potential as a therapeutic treatment for PH-ILD, a subtype of WHO Group 3 Pulmonary Hypertension. PH-ILD is a collection of progressive and often fatal forms of PH that affect the small airways of the lungs. PH-ILD includes PH related to idiopathic pulmonary fibrosis and PH related connective tissue disease-associated

interstitial lung disease, amongst other diseases. These diseases are characterized by pulmonary vascular pathology associated with PH, in addition to thickening and scarring of the lung interstitium from interstitial lung disease. While the prevalence of PH-ILD is unknown, we believe PH-ILD is at least as prevalent as PAH. Patients living with PH-ILD generally have a poor disease prognosis and have an increased mortality rate, as compared to PAH patients. There is only one FDA-approved treatment for PH-ILD, and there are no approved therapies in the EU.

Seralutinib Product Differentiation

Seralutinib is an inhaled kinase inhibitor designed to build on the evidence of efficacy seen in trials of imatinib while overcoming imatinib's observed systemic safety and tolerability issues and improving on imatinib's kinase inhibitory profile. Seralutinib is designed to have a differentiated selectivity profile as compared to imatinib with increased potency against the PDGFRα isoform, ten-fold higher potency against the PDGFRβ isoform and c-KIT, and no activity against c-ABL or the tyrosine kinase, LCK. Additionally, seralutinib is multiple orders of magnitude more potent against CSF1R, as compared to imatinib. We believe seralutinib has the potential to be a therapeutic option for PH that may provide a:

- differentiated, anti-proliferative mechanism that addresses the underlying mechanisms of both PAH and PH-ILD;
- more tolerable safety profile than systemic imatinib; and
- convenient, simple and portable inhalation delivery system.

Summary of Preclinical Program

Seralutinib inhibits both PGDFR α and β, and it inhibited and reversed cell overgrowth in lung blood vessels in a PAH rat model, which replicates many features of human PAH, including the abnormal cell proliferation that can block the small vessels of the lung. Seralutinib substantially reduced the occlusive lesions in the small lung blood vessels in this model. Additionally, seralutinib demonstrated a statistically significant reduction in right ventricular systolic pressure as compared to placebo. In a separate rat model of PAH, the SU5416 hypoxia model, seralutinib demonstrated a statistically significant reduction in circulating plasma NT-proBNP as compared to placebo, while the difference between imatinib and placebo was not significant for this PAH biomarker. Seralutinib also restored rat lung BMPR2 expression to healthy levels, which was a statistically significant improvement as compared to placebo and imatinib. Irregularities in BMPR2 expression have been linked to PAH. In a separate rat model of PAH, the SU5416 hypoxia model, seralutinib demonstrated a statistically significant reduction in circulating plasma NT-proBNP as compared to placebo, while the difference between imatinib and placebo was not significant for this PAH biomarker. Seralutinib also restored rat lung BMPR2 expression to healthy levels, which was a statistically significant improvement as compared to placebo and imatinib. Irregularities in BMPR2 expression have been linked to PAH.

Clinical Development History of Seralutinib

Summary of Completed Phase 1a Studies

We completed Phase 1a SAD and MAD double-blind, placebo-controlled, randomized studies of orally inhaled seralutinib in 82 healthy adult volunteers. We assessed pharmacokinetics, or PK, parameters and safety. Seralutinib was well-tolerated, and there were no dose-limiting toxicities. No serious adverse events, or SAEs, were reported, and no reported adverse events, or AEs, led to study drug discontinuation. The most common AEs were throat irritation and cough, which were mild in severity and similar in incidence to placebo. Following single and multiple oral inhalations, seralutinib was rapidly absorbed into and cleared from the systemic circulation. Seralutinib exposure increased in a dose-proportional manner following single and multiple dose administration.

Summary of Completed Phase 1b PAH Clinical Trial

In December 2020, we announced topline results from the completed Phase 1b randomized, double-blind, placebo-controlled, multi-center trial of seralutinib in functional class II and III PAH patients. Eight patients completed the two-week blinded portion of the trial. Enrollment for this trial was temporarily paused due to the COVID-19 pandemic but was reopened in the third quarter of 2020. The primary outcome of this 2-week trial was safety and tolerability. Seralutinib was generally well tolerated in PAH patients, and all eight patients completed the 2-week study. There were no SAEs, and the most frequently reported AEs were mild-to-moderate cough and mild headache. Systemic PK was characterized by low systemic exposure and rapid drug clearance in PAH patients, which was consistent with PK data from the Phase 1a studies in healthy

volunteers. Target engagement in PAH patients was demonstrated via whole blood CSF1R stabilization assay across all tested dose levels.

Upon completion of the two-week Phase 1b trial, two PAH patients were able to enroll and complete a six-month open label extension trial of seralutinib. Both patients were able to titrate up to the maximum allowed dose, 90 mg twice daily. No SAEs were reported during the extension trial. Both patients demonstrated a decrease in NT-proBNP levels from baseline, and both patients demonstrated an increase in 6MWD from baseline.

Summary of Completed Phase 2 PAH Clinical Trial (TORREY Study)

In December 2022, we announced positive topline results from the completed Phase 2 TORREY Study, a randomized, double-blind, placebo-controlled, multi-center clinical trial in PAH patients. We enrolled 86 functional class II and III PAH patients who were not meeting treatment goal despite background PAH treatment. 57% of enrolled patients were on triple background PAH therapy, and 40% were on double background PAH therapy. Patients on the active arm received seralutinib at doses starting at 60 mg twice daily, and they titrated up to 90 mg twice daily. While the protocol allowed for down-titration to 45 mg twice daily as necessary, the substantial majority of patients on the seralutinib arm were able to achieve and maintain 90 mg twice daily. Patients remained on their background PAH therapies throughout the trial.

Seralutinib demonstrated a statistically significant improvement on the primary endpoint, change from baseline in PVR over a 24-week treatment period. A mean improvement in PVR between the placebo and seralutinib arms of 96.1 dynes × seconds/cm^5 ($p = 0.0310$), equating to a placebo-adjusted improvement of 14.3%, was observed in the study. The p-value is the probability that the difference between two data sets was due to chance. The smaller the p-value, the more likely the differences are not due to chance alone. In general, if the p-value is less than or equal to 0.05, the outcome is considered statistically significant. Improvements in PVR favored the seralutinib arm across all pre-specified patient sub-groups. The key secondary endpoint in the TORREY Study was change from baseline to week 24 in 6MWD. An observed mean difference in 6MWD between placebo and seralutinib of 6.5 meters numerically favored the seralutinib arm. Changes in 6MWD also favored seralutinib in the majority of pre-specified sub-groups. The trial was neither powered nor designed for statistical significance in 6MWD.

Enhanced effects for both PVR and 6MWD were observed in patients with more severe baseline disease, as defined by WHO functional class, or FC, and REVEAL 2.0 Risk Scores. In FC III patients, a 21% placebo-adjusted reduction in PVR ($p = 0.0427$) and 37-meter placebo-adjusted improvement in 6MWD ($p = 0.0476$) were observed for the seralutinib arm. In patients with a baseline REVEAL 2.0 Risk Score of 6 or greater, seralutinib demonstrated a 23% placebo-adjusted reduction in PVR ($p = 0.0134$) and a placebo-adjusted 22-meter improvement in 6MWD ($p = 0.2482$).

Seralutinib treatment resulted in a statistically significant reduction in NT-proBNP, a biomarker of right heart stress, as early as 12 weeks, increasing to a placebo-adjusted 408.3 ng/L mean difference at Week 24 ($p = 0.0012$). This biomarker change was accompanied by clinically relevant and statistically significant changes for seralutinib vs. placebo in key assessments of right heart structure and function, including right atrium area, right ventricle free wall strain and pulmonary artery compliance.

Seralutinib was generally well tolerated in the TORREY study, with treatment emergent adverse events, or TEAEs, reported in 36 (86%) and 41 (93%) of the patients in the placebo and seralutinib arms, respectively. The vast majority of TEAEs reported in the study were mild to moderate in severity. In the seralutinib arm, there was one SAE related to study drug reported, while no SAEs related to study drug were reported in the placebo arm. The most frequently reported TEAE in the study was cough, reported in 16 (38%) and 19 (43%) of the patients in the placebo and seralutinib arms, respectively. Of the 19 patients reporting cough in the seralutinib arm, 17 experienced mild cough, while 2 experienced moderate cough. The most frequently reported TEAEs in the IMPRES Phase 3 study of imatinib in PAH, including nausea, peripheral edema, diarrhea, and vomiting, were observed at substantially lower frequency in the TORREY study, and reported cases were generally well balanced between the seralutinib and placebo arms. No cases of subdural hematoma were reported in the study.

Summary of Ongoing TORREY Open-Label Extension Clinical Trial in PAH

Upon completion of the 24-week blinded portion of the Phase 2 TORREY Study, 73 of the 80 (91%) completing patients elected to rollover into an ongoing open-label extension trial. In the TORREY open-label continued-seralutinib group treated for 72 weeks continued improvement was noted in PVR and 6MWD, as compared to TORREY baseline. Consistent with completed clinical trials, seralutinib has been generally well tolerated as of December 31, 2024, in the ongoing open-label extension study.

Summary of Ongoing PROSERA Phase 3 PAH Clinical Trial

In the fourth quarter of 2023, we commenced the registrational Phase 3 PROSERA Study, a randomized, double-blind, placebo-controlled, global clinical trial in PAH patients, after receiving input from global regulatory authorities, including the FDA and European Medicines Agency, or EMA. We are enrolling approximately 350 Functional Class II and III PAH patients on stable background therapy. Patients will be randomized in a 1:1 fashion to 90 mg twice daily seralutinib or placebo, and patients will receive blinded therapy for up to 48 weeks. Patients will remain on their background PAH therapies throughout the trial. The primary endpoint of the PROSERA trial is change from baseline in 6MWD at Week 24. A key secondary endpoint is time to first clinical worsening while on blinded therapy, up to 48 weeks. In addition to secondary and exploratory endpoints, safety and tolerability will also be evaluated in the Phase 3 PROSERA Study. We expect to report topline data from the PROSERA study in the fourth quarter of 2025. If the clinical trial is successful, we will seek marketing approval for seralutinib in the United States.

Summary of Planned Phase 3 Clinical Trial in PH-ILD

We expect to activate clinical sites for a global registrational Phase 3 for the treatment of PH-ILD in the second half of 2025. The planned Phase 3 clinical trial will be a registrational, randomized, double-blind, placebo-controlled, global clinical trial in PH-ILD patients. We have discussed the protocol design with global regulatory authorities and this will inform the final design of the Phase 3 clinical trial. The primary endpoint of the trial will be change in 6MWD from baseline.

Competition

The biotechnology and pharmaceutical industries are characterized by rapid technological advancement, significant competition and an emphasis on intellectual property. We face potential competition from many different sources, including major and specialty pharmaceutical and biotechnology companies, academic research institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with current therapies and new therapies that may become available in the future. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects or more convenient than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we do. We believe that the key competitive factors affecting the success of any of our product candidates will include efficacy, safety profile, convenience, cost, level of promotional activity devoted to them and intellectual property protection.

We expect to face competition for seralutinib from existing products and products in development. Seralutinib is a PDGFR, CSF1R and c-KIT inhibitor initially targeted for PAH and PH-ILD patients. We expect competition within the PAH indication will include prostanoids / prostacyclin receptor agonists, including Orenitram (United Therapeutics), Uptravi (Janssen), Tyvaso (United Therapeutics), and Remodulin (United Therapeutics), and activin ligand traps, including Winrevair (Merck). We also may face some competition from products used in Functional Class I and II patients, such as the oral PDE5 inhibitors, including Revatio (Pfizer Inc.) and Adcirca (United Therapeutics); the sGC stimulator Adempas (Bayer AG); and oral ERAs, including Tracleer (Janssen), Letairis (Gilead Sciences, Inc.) and Opsumit (Janssen); and combination PDE5 inhibitor / ERA therapies, such as Opsynvi (Janssen). We believe that, if approved, seralutinib could be used alongside all classes of approved therapies. PAH is also an active indication for investigational drugs, and we may face competition in the future from CS1 (Cereno Scientific), L606 (Liquidia / Pharmosa Biopharm Inc.), treprostinil palmitil (Insmed), ralinepag (United Therapeutics), and REGN13335 (Regeneron Pharmaceuticals, Inc.). Additionally, although not approved for the treatment of PAH, we may face competition from formulations of imatinib, including the one in development from Tenax Therapeutics and Inhibikase Therapeutics.

We expect to face competition from Tyvaso (United Therapeutics) within the PH-ILD indication, as it is the only approved therapy for PH-ILD in the United States. There are no approved therapies for PH-ILD in the EU. PH-ILD is also an active indication for investigational drugs, and we may face competition in the future from L606 (Liquidia / Pharmosa Biopharm Inc.), sirolimus (OrphAI Therapeutics), treprostinil palmitil (Insmed, Inc.), MK-5475 (Merck), and mosliciguat (Pulmovant, Inc.).

There may be other earlier stage clinical programs that, if approved, would compete with seralutinib. Many of our competitors have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

License and Collaboration Agreements

Pulmokine

In October 2017, we entered into a license agreement, or the Pulmokine Agreement, with Pulmokine, Inc., under which we were granted an exclusive worldwide license and sublicense to certain intellectual property rights owned or controlled by Pulmokine, including intellectual property rights co-owned by Pulmokine and Gilead Sciences, to develop and commercialize seralutinib and certain backup compounds for the treatment, prevention and diagnosis of any and all disease or conditions. On November 26, 2024, Pulmokine became a wholly-owned subsidiary of XOMA Royalty Corporation. We also have the right to sublicense our rights under the Pulmokine Agreement, subject to certain conditions. We are required to use commercially reasonable efforts to develop and commercialize at least one licensed product in the United States and in at least two countries in the European Union.

Under the terms of the Pulmokine Agreement, we made an upfront payment of $5.5 million and milestone payments of $5.0 million and are obligated to make future development and regulatory milestone payments of up to $48 million, which includes a payment of $5.0 million due upon the initiation of a Phase 3 clinical trial in a second indication, commercial milestone payments of up to $45 million, and sales milestone payments of up to $190 million. In January 2024, the Company made a payment of $10.0 million in connection with the initiation of the Phase 3 clinical trial of seralutinib. We are also obligated to pay tiered royalties on sales for each licensed product, at percentages ranging from the mid-single digits to the high single-digits. In addition, if we choose to sublicense or assign to any third parties our rights under the Pulmokine Agreement with respect to a licensed product, or our seralutinib operating subsidiary undergoes a change of control, we must pay to Pulmokine a specified percentage of all revenue to be received in connection with such transaction.

Our royalty obligations and the Pulmokine Agreement will expire on a licensed product-by-licensed product and country-by-country basis on the later of ten years from the date of first commercial sale or when there is no longer a valid patent claim covering such licensed product or specified regulatory exclusivity for the licensed product in such country. The Pulmokine Agreement may be terminated in its entirety either by Pulmokine or by us in the event of an uncured material breach by the other party, in the event the other party is subject to specified bankruptcy, insolvency or similar circumstances, or in the event of a force majeure event under certain circumstances. The agreement may be terminated by Pulmokine if we commence a legal action challenging the validity or enforceability of any licensed patents. We may terminate the agreement, either in its entirety or on a product-by-product basis, in the event of potential safety or efficacy concerns affecting a licensed product.

The intellectual property rights co-owned by Pulmokine and Gilead Sciences are subject to a license agreement, or the Gilead Agreement, between Pulmokine and Gilead Sciences. Under the Gilead Agreement, Pulmokine is required to use commercially reasonable efforts to develop and commercialize at least one licensed product, which obligation can be satisfied through our development efforts required under the Pulmokine Agreement, and to pay Gilead Sciences future regulatory milestone payments and royalties. Upon termination of the Gilead Agreement for any reason, our sublicense under the Pulmokine Agreement will survive provided that we did not cause a material breach that was the basis for such termination and we agree to be bound by the terms of the Gilead Agreement.

Upon termination of the Pulmokine Agreement for any reason, all rights and licenses granted to us under the agreement will terminate and revert to Pulmokine, and in the event of certain termination events, we would grant Pulmokine worldwide rights to the terminated program.

Chiesi

On May 3, 2024, we, GB002, Inc., our wholly-owned subsidiary, and Gossamer Bio 002 Ltd., our indirect wholly-owned subsidiary, entered into a collaboration agreement with Chiesi. The collaboration is focused on the development and commercialization of seralutinib and licensed products including seralutinib and related licensed compounds, or Licensed Products, in the United States and the rest of the world, or the ROW Territory, for the treatment of PAH and PH-ILD and other indications, as may be permitted under the collaboration agreement.

Pursuant to the collaboration agreement, we granted exclusive, sublicensable (with our consent required in the United States for third party sublicenses) licenses to Chiesi under intellectual property rights controlled by us relating to Licensed Products, for the worldwide development, manufacture and commercialization of seralutinib and Licensed Products for therapeutic, prophylactic and diagnostic uses in humans and animals. The licenses granted to Chiesi are subject to retained rights of our Company for the worldwide development and manufacture of seralutinib and Licensed Products, commercialization of Licensed Products in the United States, and performance of our obligations and exercise of our rights that may be set forth in the global development plan and U.S. commercialization plan, in each case in accordance with the collaboration agreement.

Chiesi granted us a non-exclusive, sublicensable (with Chiesi's consent required in the US Territory for third party sublicenses) licenses under certain practiced intellectual property rights relating to seralutinib and Licensed Products and arising intellectual property rights, in each case as controlled by Chiesi, for the worldwide development and manufacture of seralutinib and Licensed Product and a co-exclusive license (with Chiesi) to commercialize seralutinib and Licensed Products in the US Territory.

We agreed to use commercially reasonable efforts to conduct development and commercialization activities in relation to seralutinib and Licensed Products, under the global development plan and U.S. commercialization plan in accordance with the timelines therein. We will continue to lead global development of seralutinib in PAH and PH-ILD, and we and Chiesi will equally share the costs for the activities included in the global development plan for all Licensed Products, with the exception of the PROSERA Phase 3 study, which we will be solely responsible for conducting at our own cost and expense. With respect to each country in the ROW Territory, such obligation to equally share such development costs shall end when regulatory approval is received for a Licensed Product in such country. With respect to United States, the development costs incurred following regulatory approval shall continue to be shared equally. We will lead commercialization for PAH and PH-ILD in the United States, with both parties contributing 50 percent of commercial efforts, including performing 50 percent of the commercialization activities. Chiesi will lead commercialization in the United States in additional indications, and Chiesi will have the exclusive right to commercialize Licensed Products in the ROW Territory. Chiesi further agreed to use commercially reasonable efforts to commercialize Licensed Product in certain specified countries in the ROW Territory following receipt of regulatory approvals. Generally, we will have the right to lead in manufacturing commercial supply of seralutinib and Licensed Products for the United States for PAH and PH-ILD, and, subject to any of our existing obligations of to third party manufacturers, Chiesi will have the right to lead in manufacturing commercial supply of seralutinib and Licensed Products in the ROW Territory, in each case in accordance with the collaboration agreement.

Pursuant to the collaboration agreement, neither party nor its affiliates is permitted to develop or commercialize any compound or product throughout the term whose primary mechanism of action is inhibition of a tyrosine kinase for the treatment of PAH or PH-ILD in the United States or ROW Territory, subject to certain restrictions for the EU and UK.

In consideration and as reimbursement for our development costs, Chiesi agreed to pay us $160.0 million. Additionally, we will be eligible to receive up to $146.0 million in regulatory milestones and $180.0 million in sales milestones. In the United States, the parties agreed to share commercial profits and losses equally. In the ROW Territory, Chiesi will pay us an escalating mid-to-high teens percentage royalty, subject to standard deductions, on net sales of Licensed Product for PAH and additional indications on a Licensed Product-by-Licensed Product and country-by-country basis with such payment obligations beginning on the first commercial sale of Licensed Product in such country and expiring on a country-by-country basis on the latest of (a) the expiration of a valid claim to our patent right in such country, (b) the expiration of regulatory exclusivity, and (c) the date that is 10 years after the first commercial sale of such Licensed Product in such country.

In addition, we granted to Chiesi an option to purchase directly from us, on one or more occasions, up to an aggregate number of shares of our common stock such that immediately following such issuance, Chiesi's beneficial ownership of our common stock shall not exceed 9.9% of the total number of issued and outstanding shares of our common stock, or the Equity Option. The Equity Option shall be exercisable by Chiesi, in whole or in part, at any time prior to the earliest to occur of the date on which (a) the last patient is last dosed in either (i) the PROSERA Phase 3 study for PAH or (ii) a Phase 3 clinical trial for the PH-ILD Indication, (b) any third party commences a tender offer or exchange offer for more than 50% of the outstanding shares of our common stock, and (c) we publicly announces our intent to consummate a GB002 change of control. The purchase price of each share of our common stock subject to the Equity Option shall be equal to 107.5% of the daily volume-weighted average per share price of our common stock on The Nasdaq Stock Market over the 30-trading day period ending on and including the last trading day prior to the date on which Chiesi delivers an exercise notice to us; provided that such purchase price shall be no less than $1.63 per share. The shares of our common stock to be issued will be issued in a private placement in reliance on Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions by an issuer not involving any public offering, pursuant to the terms of a stock issuance agreement to be entered into between us and Chiesi in connection with each such exercise of the Equity Option.

Unless earlier terminated, the collaboration agreement will remain in force until no Licensed Products are being developed or commercialized in the United States and in the ROW Territory, on a country-by-country basis, until no royalty terms are in effect for all countries. Either party may terminate the collaboration agreement for the other party's material breach, subject to a specified notice and cure periods, or due to an insolvency event of the other party. In lieu of termination upon a party's material breach due to non-payment of development costs within a specified time the non-breaching party may elect an alternative remedy which may involve modifications to their performance and payment obligations. We have the right to terminate by providing written notice in the event Chiesi or its affiliates or sublicensee brings a patent challenge and Chiesi

does not take certain steps to withdraw from or cease supporting such challenge. Chiesi may terminate the collaboration agreement for any reason upon prior written notice to us, subject to a notice period.

Manufacturing

We currently rely on multiple third-party manufacturers for the manufacture of seralutinib for preclinical and clinical testing. We intend to rely on third-party contract manufacturers for commercial manufacturing if seralutinib receives marketing approval. Typically, there are multiple sources for all of the materials required for the manufacture of seralutinib. Our manufacturing strategy enables us to more efficiently direct financial resources to the research, development and commercialization of seralutinib rather than diverting resources to internally develop manufacturing facilities. As seralutinib advances through development, we expect to enter into longer-term commercial supply agreements with key suppliers and manufacturers to fulfill and secure our production needs.

Intellectual Property

We strive to protect the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates and continuing innovation to develop, strengthen and maintain our proprietary position. We also plan to rely on data exclusivity, market exclusivity and patent term extensions when available. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to defend and enforce our proprietary rights, including any patents that we may own in the future; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties. Intellectual property rights may not address all potential threats to our competitive advantage.

Seralutinib

As of December 31, 2024, with respect to seralutinib, we have exclusively licensed two issued U.S. patents owned by Pulmokine, which are not due to expire before 2037, excluding any additional term for patent term extension; one pending U.S. Patent application, which, if issued, is not due to expire before 2037, excluding any additional term for patent term extension; and a number of patents and pending applications in other jurisdictions, including issued patents in Mexico, Russia, Australia, India, Japan, South Korea, and New Zealand, and pending applications in, Brazil, Canada, China, the European Patent Convention, and New Zealand, which, if issued, are not due to expire before 2037, excluding any additional term for patent term extension. These patents and patent applications are directed to method of use claims. We have also exclusively licensed four issued U.S. patents co-owned by Pulmokine and Gilead Sciences, Inc., which are not due to expire before 2034, excluding any additional term for patent term extension; two pending U.S. patent applications which, if issued, are not due to expire before 2034, excluding any additional term for patent term extension; and a number of patents and pending patent applications in other jurisdictions, including issued patents in Australia, Canada, China, the European Patent Convention, Japan, and Hong Kong. These patents and patent applications are directed to seralutinib compound, formulation and method of use claims. We also own a pending patent application, which, if issued, is not due to expire before 2042, directed to forms of seralutinib, and a pending application, which, if issued, is not due to expire before 2043, directed to combination treatment with seralutinib.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing and export and import of products such as those we are developing. A new drug must be approved by the FDA through the new drug application, or NDA, process before it may be legally marketed in the United States.

Seralutinib is subject to regulation as a combination product, which means that it is composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a Center that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of seralutinib, the primary mode of action is attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research has primary jurisdiction over the premarket development, review and approval. Accordingly, we plan to investigate seralutinib through the Investigational New Drug, or IND, framework and seek approval through the NDA pathway. We do not anticipate

that the FDA will require a separate medical device authorization for the device, but this could change during the course of its review of any marketing application that we may submit.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of certain preclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice, or GLP, regulations and other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice, or GCP, regulations to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current GMP, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity, and potential inspection of selected clinical investigation sites to assess compliance with GCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States.

Once a pharmaceutical candidate is identified for development, it enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. An IND is a request for allowance from the FDA to administer an investigational drug product to humans. The sponsor will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the clinical trial lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns about on-going or proposed clinical trials or non-compliance with specific FDA requirements, and trials may not begin or continue under the IND until the FDA notifies the sponsor that the hold has been lifted. Submission of an IND therefore may or may not result in FDA allowance to begin a clinical trial.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations, which among other things, include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Clinical Trials must be conducted under protocols

detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND as well as any subsequent protocol amendments. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Furthermore, an independent IRB at each institution participating in the clinical trial must review and approve each protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each trial subject or his or her legal representative, monitor the study until completed and otherwise comply with IRB regulations. The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial. There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

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

- *Phase 1*: The product candidate is initially introduced into healthy human volunteers and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain an early indication of its effectiveness. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

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

- *Phase 3*: The product candidate is further evaluated for dosage, clinical efficacy and safety in an expanded patient population, generally at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and/or for the sponsor and the FDA to reach agreement on the next phase of development.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug. In addition, 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.

Regulation of Combination Products in the United States

Certain products may be comprised of components, such as drug components and device components that would normally be regulated under different types of regulatory authorities, and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- a product comprised of two or more regulated components that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
- two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- a drug, or device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, or device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
- any investigational drug, or device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Under the FDCA and its implementing regulations, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. The designation of a lead center generally eliminates the need to receive approvals from more than one FDA component for combination products, although it does not preclude consultations by the lead center with other components of FDA. The determination of which center will be the lead center is based on the "primary mode of action" of the combination product. Thus, if the primary mode of action of a drug-device combination product is attributable to the drug product, the FDA center responsible for premarket review of the drug product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

A combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes under the FDCA. In reviewing the NDA application for such a product, however, FDA reviewers in the drug center could consult with their counterparts in the device center to ensure that the device component of the combination product met applicable requirements regarding safety, effectiveness, durability and performance. In addition, under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System, regulations applicable to medical devices.

NDA Review and Approval Process

The results of product development, including results from preclinical and other non-clinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. The FDA conducts a preliminary review of an NDA within the first 60 days after submission, before accepting the application for filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once filed, the FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity,

strength, quality and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes twelve months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after it the application is submitted.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. 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 assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data or other significant and time consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA or, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require a sponsor to conduct additional clinical or non-clinical testing, including Phase 4 testing, to further assess a drug's safety and effectiveness after NDA approval, and may require additional testing and surveillance programs to monitor the safety of approved products. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS, and the FDA will not approve the application without an approved REMS. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric clinical trials for most drugs, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or fails to submit a request for approval of a pediatric formulation.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making a drug product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or inability to manufacture the product in sufficient quantities. The designation of such drug also entitles a party to financial incentives such

as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. However, competitors, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity.

In addition, if an orphan designated product receives marketing approval for a disease or condition broader than what is designated, it may not be entitled to orphan exclusivity. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Expedited Development and Review Programs

A sponsor may seek approval of its product candidate under programs designed to expedite FDA's review and approval of new drugs and biological products that meet certain criteria. For example, the FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, a product candidate is eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during development. With regard to a fast track product, the FDA may also 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.

A product candidate 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 candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, 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 candidate, including involvement of senior managers.

Any NDA for a product candidate submitted to the FDA for approval, including for a product candidate with a fast track designation or breakthrough designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review. An NDA is eligible for priority review if the product candidate is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, depending on the design of the applicable clinical trials, a product candidate may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for 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 approval, the FDA will generally require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled confirmatory clinical trials and may require that such confirmatory trials be underway prior to granting accelerated approval. 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. FDA may withdraw approval of a drug or indication approved under accelerated approval on an expedited basis if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product or if the sponsor fails to conduct such trials in a timely manner.

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

Post-Approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP regulations and other laws and regulations. In addition, the FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

Any drug products manufactured or distributed pursuant to FDA approvals will be subject to pervasive and continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements, complying with certain electronic records and signature requirements, and complying with FDA promotion and advertising requirements. The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market and imposes requirements and restrictions on drug manufacturers, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet.

Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds on post-approval clinical trials, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Marketing Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of non-patent exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to an existing period of regulatory exclusivity or patent term if a sponsor conducts clinical trials in children in response to a written request from the FDA. The

issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

U.S. Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidate for which we may seek regulatory approval. Sales in the United States will depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs such as Medicare, Medicaid, TRICARE and the Veterans Administration, as well as managed care organizations and private health insurers. Prices at which we or our customers seek reimbursement for seralutinib can be subject to challenge, reduction or denial by third-party payors.

The process for determining whether a third-party payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payors for coverage or reimbursement. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider seralutinib to be medically necessary or cost-effective compared to other available therapies, or the rebate percentages required to secure favorable coverage may not yield an adequate margin over cost or may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development.

U.S. Healthcare Reform

In the United States, there has been, and continues to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the profitable sale of product candidates.

Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the Patient Protection and Affordable Care Act, or ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (1) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; (2) created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected; (3) established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in certain government healthcare programs; (4) expanded the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; (5) expanded the eligibility criteria for Medicaid programs; (6) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; (7) established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and (8) established a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drugs. Since its enactment, there have been judicial and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

Other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in aggregate reductions of Medicare payments to providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute,

will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

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 legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Most recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new manufacturer discounting program (which began in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and has published the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Healthcare Fraud and Abuse Laws and Compliance Requirements

Federal, state and foreign healthcare laws and regulations restrict business practices in the biopharmaceutical industry. These laws include anti-kickback and false claims laws and regulations, and transparency laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. Similar to the federal Anti-Kickback Statute, A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

The 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 report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers including physician assistants and nurse practitioners, and teaching hospitals, and applicable manufacturers and applicable group

purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined by statute) and their immediate family members.

Similar state, local and foreign laws and regulations may also restrict business practices in the biopharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Foreign laws and regulations may be broader in scope than the provisions described above and may apply regardless of payor. These laws and regulations may differ from one another in significant ways, thus further complicating compliance efforts. For instance, in the EU, many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medicinal products, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on pharmaceutical companies. Certain countries also mandate implementation of commercial compliance programs, or require disclosure of marketing expenditures and pricing information.

Efforts to ensure compliance with applicable healthcare laws and regulations can involve substantial costs. Violations of healthcare laws can result in significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other U.S. and foreign healthcare programs, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of operations.

U.S. Data Privacy and Security Laws

Numerous state and federal laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. 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 make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

Foreign Regulation

In order to market any product outside of the United States, we need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, or MA, commercial sales and distribution of our products.

Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, or EU, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

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

Non-clinical studies and clinical trials

Similar to the U.S., the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products, e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, guidelines on GCP as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If the sponsor of the clinical trial is not established within the EU, it must appoint an EU entity to act as its legal representative. The sponsor must take out a clinical trial insurance policy, and in most EU countries, the sponsor is liable to provide ‘no fault’ compensation to any study subject injured in the clinical trial.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the EU Clinical Trials Directive required a separate CTA to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state’s decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical trial development may proceed.

The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR.

Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practices , or GMP. Other national and EU-wide regulatory requirements may also apply.

Marketing Authorization

To market a medicinal product in the EU, we must obtain a MA. To obtain regulatory approval of an investigational medicinal product under EU regulatory systems, we must submit a MA application, or MAA. The process for doing this depends, among other things, on the nature of the medicinal product. There are two types of MAs:

- “Centralized MAs” are issued by the EC through the centralized procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and are valid throughout the EU. The centralized procedure is mandatory for certain types of products, such as: (i) medicinal products derived from biotechnology medicinal

products, (ii) designated orphan medicinal products, (iii) advanced therapy medicinal products, or ATMPs, and (iv) medicinal products containing a new active substance indicated for the treatment certain diseases, such as HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

- "National MAs" are issued by the competent authorities of the EU member states, only cover their respective territory, and are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EU member state, this national MA can be recognized in another member state through the mutual recognition procedure. If the product has not received a national MA in any member state at the time of application, it can be approved simultaneously in various member states through the decentralized procedure. Under the decentralized procedure an identical dossier is submitted to the competent authorities of each of the member states in which the MA is sought, one of which is selected by the applicant as the reference member state.

Under the above described procedures, before granting the MA, the regulatory authorities make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Under the centralized procedure the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. In exceptional cases, the CHMP might perform an accelerated review of a MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIority MEdicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. In March 2016, the EMA launched an initiative, the PRIME scheme, a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is not guaranteed. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated MAA assessment once a dossier has been submitted. Importantly, a dedicated contact and rapporteur from the CHMP is appointed early in the PRIME scheme facilitating increased understanding of the product at EMA's committee level. An initial meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Moreover, in the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and has to be renewed annually until fulfillment of all the conditions. Once the pending studies are provided, it can become a "standard" MA. However, if the conditions are not fulfilled within the timeframe set by the EMA, the MA ceases to be renewed. Furthermore, MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable.

MAs have an initial duration of five years. After these five years, the authorization may be renewed for an unlimited period on the basis of a reevaluation of the risk-benefit balance.

Data and marketing exclusivity

In the EU, new products authorized for marketing, or reference products, generally receive eight years of data exclusivity and an additional two years of market exclusivity upon MA. If granted, the data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference

product was first authorized in the EU. During the additional two-year period of market exclusivity, a generic or biosimilar MAA can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until 10 years have elapsed from the initial MA of the reference product in the EU. The overall 10-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those 10 years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Pediatric development

In the EU, MAAs for new medicinal products have to include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan, or PIP, agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the product candidate for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data is not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU member states and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension (if any is in effect at the time of approval) or, in the case of orphan medicinal products, a two year extension of the orphan market exclusivity is granted.

Orphan designation

The criteria for designating an "orphan medicinal product" in the EU are similar in principle to those in the United States. A medicinal product may be designated as orphan if its sponsor can establish that (1) the product is intended for the diagnosis, prevention or treatment of a life threatening or chronically debilitating condition (2) either (a) such condition affects not more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from the orphan status, would not generate sufficient return in the EU to justify the necessary investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized for marketing in the EU or, if such method exists, the product will be of significant benefit to those affected by that condition.

In the EU, an application for designation as an orphan product can be made any time prior to the filing of an MAA. Orphan designation entitles a party to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the regulatory authorities cannot accept another MAA, or grant a MA, or accept an application to extend a MA for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The orphan exclusivity period may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example because the product is sufficiently profitable not to justify market exclusivity, or where the prevalence of the condition has increased above the threshold. Granting of an authorization for another similar orphan medicinal product can happen at any time if: (i) the second applicant can establish that its product, although similar to the authorized product, is safer, more effective or otherwise clinically superior, (ii) inability of the applicant to supply sufficient quantities of the orphan medicinal product or (iii) where the applicant consents to a second orphan medicinal product application. A company may voluntarily remove a product from the orphan register.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC and/or the competent regulatory authorities of the member states. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAA must include a risk management plan, or RMP describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Regulation of Combination Products in the EU

The EU regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug-device combination product. EU guidance has been published to help manufacturers select the right regulatory framework.

Drug-delivery products intended to administer a medicinal product where the medicinal product and the device form a single integral product are regulated as medicinal products in the EU. The EMA is responsible for evaluating the quality, safety and efficacy of MAAs submitted through the centralized procedure, including the safety and performance of the medical device in relation to its use with the medicinal product. The EMA or the EU member state national competent authority will assess the product in accordance with the rules for medicinal products described above but the device part must comply with the Medical Devices Regulation (including the general safety and performance requirements provided in Annex I). MAA must include – where available – the results of the assessment of the conformity of the device part with the Medical Devices Regulation contained in the manufacturer's EU declaration of conformity of the device or the relevant certificate issued by a notified body. If the MAA does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required, the competent authority must require the applicant to provide a notified body opinion on the conformity of the device.

By contrast, in case of drug-delivery products intended to administer a medicinal product where the device and the medicinal product do not form a single integral product (but are e.g. co-packaged), the medicinal product is regulated in accordance with the rules for medicinal products described above while the device part is regulated as a medical device and will have to comply with all the requirements set forth by the Medical Devices Regulation.

The characteristics of non-integral devices used for the administration of medicinal products may impact the quality, safety and efficacy profile of the medicinal products. To the extent that administration devices are co-packaged with the medicinal product or, in exceptional cases, where the use of a specific type of administration device is specifically provided for in the product information of the medicinal product, additional information may need to be provided in the MAA for the

medicinal product on the characteristics of the medical device(s) that may impact on the quality, safety and/or efficacy of the medicinal product.

The requirements regarding quality documentation for medicinal products when used with a medical device, including single integral products, co-packaged and referenced products, are outlined in the EMA guideline of July 22, 2021, which became applicable as of January 1, 2022.

The aforementioned EU rules are generally applicable in the EEA.

Brexit and the Regulatory Framework in the United Kingdom

Since the end of the Brexit transition period on January 1, 2021, and the implementation of the Windsor Framework on January 1, 2025, the United Kingdom, or UK, has not generally been directly subject to EU laws with respect to medicinal products. It is currently unclear to what extent the government of the UK will seek to align its regulations with the EU. The EU laws that have been transposed into UK law through secondary legislation remain applicable in Great Britain (England, Scotland and Wales), or GB, however, new legislation such as the (EU) CTR is not applicable in GB. Whilst the EU-UK Trade and Cooperation Agreement, or TCA, includes the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, it does not contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards.

The UK Medicines and Medical Devices Act 2021 has introduced delegated powers in favor of the Secretary of State or an 'appropriate authority' to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

Since January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, has been the UK's standalone medicines and medical devices regulator. As a result of the Northern Ireland Protocol, different rules applied in Northern Ireland than in GB; broadly, Northern Ireland continued to follow the EU regulatory regime. However, on January 1, 2025, a new arrangement called the "Windsor Framework" came into effect and reintegrated Northern Ireland under the regulatory authority of the MHRA with respect to medicinal products. The Windsor Framework removes EU licensing processes, and EU labelling and serialization requirements in relation to Northern Ireland, and introduces a UK-wide licensing process for medicinal products.

MAs in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. All existing EU MAs for centrally authorized products were automatically converted or grandfathered into UK MAs, effective in GB (only), free of charge on January 1, 2021, unless the MA holder opted-out. Under the terms of the Windsor Framework, these MAs became valid for the whole of the UK from January 1, 2025. In order to use the centralized procedure to obtain an MA that will be valid throughout the EEA, companies must be established in the EEA. Therefore, since Brexit, companies established in the UK can no longer use the EU centralized procedure and instead an EEA entity must hold any centralized MAs. In order to obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures. Applications are governed by the Human Medicines Regulations (SI 2012/1916), as amended, and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicinal products that will benefit patients, including a 150-day assessment (subject to clock-stops) and a rolling review procedure. In addition, an international recognition procedure, or IRP, has been in place since January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new UK MA. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (i.e. the regulators in Australia, Canada, Switzerland, Singapore, Japan, the U.S. and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update an MA in the UK. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60-day period and the approval from the trusted regulatory partner selected has been granted within the previous 2 years or if there are such major objections identified or such approval has not been granted within the previous 2 years within 110 days. Applicants can submit initial MAAs to the IRP but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals. In the UK, the initial duration of an MA is five years and following renewal will be valid for an unlimited period unless the MHRA decides on justified grounds relating to pharmacovigilance, to proceed with only one additional 5-year renewal. Any authorization which is not followed by the actual placing of the medicinal product on the market in the UK within 3 years shall cease to be in force.

There is no pre-MA orphan designation in the UK. Instead, the MHRA reviews applications for orphan designation in parallel to the corresponding MA application. The criteria are essentially the same, but have been tailored for the market, i.e., the prevalence of the condition in the UK, rather than the EU, must not be more than five in 10,000. Should an orphan designation be granted, the period or market exclusivity will be set from the date of first approval of the product in the UK.

The UK regulatory framework in relation to clinical trials is derived from the now-repealed EU Clinical Trials Directive (as implemented into UK law, through the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended). The extent to which the regulation of clinical trials in the UK will mirror the (EU) CTR in the long term is not yet certain, however, on December 12, 2024, the UK government introduced a legislative proposal - the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 - that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The UK government has provided the legislative proposal to the UK Parliament for its review and approval. Once the legislative proposal is approved (with or without amendment), it will be adopted into UK law which is expected in early 2026.

Foreign Data Privacy and Security Laws

We are also subject to laws and regulations in non-U.S. countries governing data privacy and the protection of personal data, including health-related data. Laws and regulations in the EU and other jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal data, and have generally become more stringent over time. 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.

Human Capital

We have assembled a deeply experienced and highly skilled group of industry veterans, scientists, clinicians and key opinion leaders from leading biotechnology and pharmaceutical companies, as well as leading academic centers from around the world. Our employees are a team of highly dedicated, passionate individuals who pride themselves on a culture of respect, humility, transparency, inclusion, dedication, collaboration and fun. Our ultimate goal is to enhance and extend the lives of patients.

Our philosophy is to offer a comprehensive compensation and benefits package to support our greatest assets, our people, and our human capital resources objectives include, as applicable, identifying, attracting, retaining and motivating our highly qualified management and our clinical, scientific and other employees and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and motivate personnel through the granting of stock-based and cash-based compensation awards, in order to align our interests and the interests of our stockholders with those of our employees and consultants.

As of March 6, 2025, we had 144 full-time employees and 1 part-time employee. Of those 145 employees, 30, or 21%, have a Ph.D. or M.D., and 84, or 58%, are women. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated under the laws of the state of Delaware on October 26, 2015 under the name FSG, Bio, Inc. and changed our name to Gossamer Bio, Inc. in 2017. Our principal executive offices are located at 3115 Merryfield Row, Suite 120, San Diego, California 92121, and our telephone number is (858) 684-1300.

Available Information

Our internet address is www.gossamerbio.com. Our investor relations website is located at http://ir.gossamerbio.com. We make available free of charge on our investor relations website under “filings” our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, our directors’ and officers’ Section 16 reports and any amendments to those reports as soon as reasonably practicable after filing or furnishing such materials to the US Securities and Exchange Commission, or SEC. They are also available for free on the SEC’s website at www.sec.gov. We use our investor relations website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor such website, in addition to following our press releases, SEC filings and public conference calls and webcasts. Information relating to our corporate governance is also included on our investor relations

website. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, together with the other information contained in this annual report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making a decision to purchase or sell shares of our common stock. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects. If that were to happen, the trading price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations or financial condition.

Summary Risk Factors

The risk factors described below are a summary of the principal risk factors associated with an investment in us. These are not the only risks we face. You should carefully consider these risk factors, together with the risk factors set forth in this Item 1A.

- We have a limited operating history, a history of losses and expect to incur additional losses in the future.
- We will require substantial additional financing to achieve our goals.
- We depend heavily on the ability to successfully advance seralutinib through clinical development.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results.
- Our business may be adversely affected by difficulties or delays in enrolling patients in our current or planned clinical trials or the commencement or completion, or termination or suspension, of our current or planned clinical trials.
- We operate in a highly regulated industry and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize seralutinib.
- We are dependent on third parties to conduct our pre-clinical and clinical trials.
- Our business activities could be adversely affected by a global pandemic and other epidemic diseases.
- We are dependent on third parties to manufacture seralutinib.
- We may not be successful in entering into or maintaining collaborations, licenses and other similar arrangements, including the maintenance of our collaboration with Chiesi.
- If approved, the success of seralutinib will depend on meeting ongoing regulatory obligations, market acceptance and adequate coverage by governmental authorities and insurers.
- We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- Our results of operations may fluctuate significantly.
- Our business relies on our ability to attract, retain and motivate highly qualified management, clinical and scientific personnel.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of seralutinib.

- Our business relies on our ability to protect our intellectual property and our proprietary technologies.
- We must comply with our license agreements or we could lose our license rights to seralutinib.
- Our stock price is volatile, and investors may incur substantial losses.
- We have been involved in securities class action litigation and could be subject in the future to securities class action litigation.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We have a relatively limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a clinical-stage biopharmaceutical company with a relatively limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2017, and to date, we have focused primarily on organizing and staffing our company, business planning, raising capital, identifying, acquiring and in-licensing product candidates and conducting preclinical studies and clinical trials. Seralutinib is in active clinical development. We have not yet demonstrated an ability to successfully complete any clinical trials beyond Phase 2, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception. If seralutinib is not successfully developed and approved, we may never generate any revenue. Our net losses were $56.5 million and $179.8 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $1,268.6 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Seralutinib will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize seralutinib and seek to identify, assess, acquire, in-license or develop additional product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of seralutinib, obtaining regulatory approval for seralutinib and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates beyond seralutinib or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our seralutinib development program, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to remain high in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials of seralutinib, continue research and development, and seek regulatory approval for seralutinib. In addition, as seralutinib progresses through development and toward commercialization, we will need to make milestone payments to Pulmokine from whom we have in-licensed seralutinib. Furthermore, if and to the extent we seek to acquire or in-license additional product candidates in the future, we may be required to make significant upfront payments, milestone payments, and/or licensing

payments. If we obtain regulatory approval for seralutinib, we also expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Because the outcome of any clinical trial or preclinical study is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of seralutinib. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operations for at least the next 12 months from the date this annual report is filed with the SEC. In particular, we expect that these funds will allow us to complete our registrational Phase 3 clinical trial in PAH for seralutinib. We have based these estimates on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop seralutinib.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, expansions, results, costs and timing of, our clinical trials and preclinical studies of seralutinib or product candidates we may choose to pursue in the future;
- the costs and timing of manufacturing for seralutinib, including commercial manufacturing if seralutinib is approved;
- the costs, timing and outcome of regulatory review of seralutinib;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants as our clinical activities increase;
- the timing and amount of the milestone or other payments we must make to Pulmokine from whom we have in-licensed seralutinib;
- the costs and timing of establishing or securing sales and marketing capabilities if seralutinib is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for seralutinib, if approved;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements; and
- costs associated with any products or technologies that we may in-license or acquire.

Conducting clinical trials and preclinical studies is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, seralutinib, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, including as a result of financial and credit market deterioration or instability, market-wide liquidity shortages, geopolitical events or otherwise. In addition, we may seek additional capital due to favorable market conditions or liquidity or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Our indebtedness and liabilities could limit the cash flow available for our operations, expose us to risks that could adversely affect our business, financial condition and results of operations and impair our ability to satisfy our obligations under the notes.

As of December 31, 2024, we have sold $200.0 million in aggregate principal amount of 5.00% convertible senior notes due 2027 and have approximately $88.3 million of other liabilities, including trade payables. We may also incur additional indebtedness or liabilities to meet our future financing needs. Our indebtedness and liabilities could have significant negative consequences for our stockholders and our business, results of operations and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- making it more difficult or expensive for a third party to acquire us;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of the notes; and
- placing us at a possible competitive disadvantage with competitors that are less leveraged than us or have better access to capital.

Our business may not generate sufficient funds, and we may otherwise be unable to maintain sufficient cash reserves, to pay amounts due under our indebtedness, including the notes, and our cash needs may increase in the future. In addition, any future indebtedness that we may incur may contain, financial and other restrictive covenants that limit our ability to operate our business, raise capital or make payments under our other indebtedness. If we fail to comply with these covenants or to make payments under our indebtedness when due, then we would be in default under that indebtedness, which could, in turn, result in that and our other indebtedness becoming immediately payable in full.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or seralutinib.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity offerings, debt financings or other capital sources including potentially collaborations, licenses and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through future collaborations, licenses and other similar arrangements, we may have to relinquish valuable rights to our future revenue streams or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock.

Risks Related to the Development and Regulatory Approval of Seralutinib

We depend entirely on the success of seralutinib, which is currently in Phase 3 clinical development. If we are unable to advance seralutinib in clinical development, obtain regulatory approval and ultimately commercialize seralutinib, or experience significant delays in doing so, our business will be materially harmed.

Our only product candidate is currently in Phase 3 clinical development. We are conducting an open-label extension of our Phase 2 clinical trial of seralutinib in PAH which commenced in 2020, and we commenced a registrational Phase 3 clinical trial of seralutinib in PAH in the fourth quarter of 2023. We expect to activate clinical sites for a global registrational Phase 3 for the treatment of PH-ILD in the second half of 2025.

Our assumptions about why seralutinib is worthy of future development and potential approval in PAH, or any additional indications including PH-ILD, are based in part on data collected by other companies. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of seralutinib. The success of seralutinib will depend on several factors, including the following:

- successful enrollment in clinical trials and completion of clinical trials and preclinical studies with favorable results;
- regulatory authority acceptance of our proposed design of future clinical trials and allowance to proceed with such clinical trials under INDs by the FDA or under similar applications by comparable regulatory authorities;
- demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including NDAs from the FDA and maintaining such approvals;
- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and launching commercial sales of seralutinib, if and when approved, whether alone or in collaboration with others;
- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for seralutinib;
- maintaining an acceptable safety profile of seralutinib following any approval; and
- maintaining and growing an organization of people who can develop seralutinib and our technology.

Seralutinib is subject to regulation as a combination product, which means that it is composed of both a drug product and device product. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. Seralutinib, will therefore require review and coordination by FDA's drug and device centers prior to approval, which may delay approval. Under FDA regulations, combination products are subject to current good manufacturing practice, or cGMP, requirements applicable to both drugs and devices, including the Quality System regulation currently applicable to medical devices in the United States. The EU regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug-device combination product. Problems associated with the device component of seralutinib may delay or prevent approval. If the manufacturer of the device products make modifications, or if we elect to change a device component or develop our own proprietary device component, we will need to perform validation testing and obtain FDA and other regulatory authorization or certification prior to using the modified device component. If the FDA, any other regulatory authority or notified body fails to authorize or certify use of those modified devices in combination with seralutinib or take significant enforcement action against the manufacturer of the device component, we would not be able to market or may have to suspend marketing seralutinib in certain jurisdictions.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of seralutinib, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for seralutinib in clinical trials or in obtaining marketing approval thereafter. Given our current stage of development, it may be several years, if at all, before we have demonstrated the safety and efficacy of a treatment sufficient to warrant approval for commercialization. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize seralutinib, we may not be able to generate sufficient revenue to continue our business.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. In addition, some of our assumptions about why seralutinib is worthy of future development and potential approval are based on data collected by other companies. Seralutinib may not have favorable results in its Phase 3 clinical trial in PAH or the anticipated Phase 3 clinical trial in PH-ILD, or receive regulatory approval on a timely basis, if at all.

Clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical study or clinical trial process. Despite promising preclinical or clinical results, seralutinib may unexpectedly fail. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of seralutinib or a competitor's product candidate in the same class may not predict the results of later clinical trials of seralutinib, and interim, topline or preliminary results of a clinical trial are not necessarily indicative of final results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies and initial clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. For example, our decision to advance seralutinib as a potential treatment for PAH is based in part on the efficacy of imatinib (Gleevec), a tyrosine kinase inhibitor with known activity against PDGF and marketed for oncology indications, observed by Novartis in a Phase 3 clinical trial; however, we may not observe similar efficacy in our Phase 3 clinical trial of seralutinib. Moreover, these and any future preclinical and clinical data may be susceptible to varying interpretations and analyses. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of seralutinib in PAH and other indications including PH-ILD, which could have a material adverse effect on our business, financial condition and results of operations.

Any difficulties or delays in the commencement or completion, or termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of seralutinib, we must conduct extensive clinical studies to demonstrate the safety and efficacy of seralutinib in humans. For example, we are currently conducting a registrational Phase 3 clinical trial of seralutinib in PAH patients. In addition, before we can initiate clinical development for our product candidates, and in some cases, before we can pursue clinical development of a product candidate for a new potential indication, we must submit the results of preclinical studies to the FDA along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND, and we are also required to submit regulatory filings to foreign regulatory authorities for clinical trials outside of the United States.

We do not know whether our ongoing or planned trials will begin on time or be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials can be delayed for a number of reasons including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies, including the doses and endpoints of our ongoing and planned Phase 3 clinical trial of seralutinib;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with contract research organizations, or 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 or positive opinion from one or more institutional review boards, or IRBs or ethics committees;

- IRBs refusing to approve, suspending or terminating a trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of a trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of seralutinib or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- subjects choosing an alternative treatment for PAH or other indications including PH-ILD for which we are developing seralutinib, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing seralutinib or any of its components, including the device component of orally inhaled seralutinib, being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP or similar foreign regulations or other applicable requirements, or infections or cross-contaminations of seralutinib in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- 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, good clinical practices, or GCP, or other regulatory requirements; third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

Such delays or regulatory feedback on our trial designs could also significantly increase the costs of our clinical trials, including our Phase 3 clinical trial of seralutinib. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign 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 drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs or ethics committees for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national

health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application concerned for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations, or CROs, may impact our developments plans.

It is currently unclear to what extent UK will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from the now-repealed EU Clinical Trials Directive (as implemented into UK law, through the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended). The extent to which the regulation of clinical trials in the UK will mirror the (EU) CTR in the long term is not yet certain, however, on December 12, 2024, the UK government introduced a legislative proposal - the Medicines for Human Use (Clinical Trials) Amendment Regulations 2024 - that, if implemented, will replace the current regulatory framework for clinical trials in the UK. The legislative proposal aims to provide a more flexible regime to make it easier to conduct clinical trials in the UK, increase the transparency of clinical trials conducted in the UK and make clinical trials more patient centered. The UK government has provided the legislative proposal to the UK Parliament for its review and approval. Once the legislative proposal is approved (with or without amendment), it will be adopted into UK law which is expected in early 2026. Under the terms of the Protocol on Ireland/Northern Ireland, provisions of the (EU) CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. A decision by the UK government not to closely align its regulations with the new approach that has been adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries. Clinical trial submissions in the UK will not be able to be bundled with those of EU member states within the EMA CTIS, adding further complexity, cost and potential risk to future clinical and development activity in the UK.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may also be impacted.

Further, conducting clinical trials in foreign countries, as we currently and may continue to do for seralutinib, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks, including war, relevant to such foreign countries. For example, we are currently conducting our registrational Phase 3 study of seralutinib in PAH at sites outside the United States.

If we experience delays in the completion of, or termination of, any clinical trial of seralutinib, the commercial prospects of seralutinib will be harmed, and our ability to generate product revenues from seralutinib will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down development and approval process for seralutinib and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of seralutinib. We may make formulation or manufacturing changes to seralutinib, in which case we may need to conduct additional preclinical studies to bridge our modified seralutinib to an earlier version. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize seralutinib and our competitors may be able to bring products to market before we do, and the commercial viability of seralutinib could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling subjects in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may not be able to initiate or continue clinical trials for seralutinib if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as may be required by the FDA or similar regulatory authorities outside the United States. Subject enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators and associated staff with the appropriate competencies and experience, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being

studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating as well as any drugs under development. We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials. Potential subjects for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for such trials. For example, a limited number of patients are affected by PAH and other indications including PH-ILD, which are our target indication for seralutinib, and we have encountered difficulties enrolling patients in our previous clinical trials of seralutinib in PAH patients. We also may encounter difficulties in identifying and enrolling subjects with a stage of disease appropriate for our Phase 3 trial of seralutinib and monitoring such subjects adequately during and after treatment. We may not be able to initiate or continue clinical trials if we are unable to locate a sufficient number of eligible subjects to participate in the clinical trials required by the FDA or comparable foreign regulatory authorities. In addition, the process of finding and diagnosing subjects may prove costly.

The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. The eligibility criteria of our clinical trials, once established, will further limit the pool of available trial participants. For example, PAH is a rare disease with limited patient pools from which to draw for our registrational Phase 3 trial. If patients are unwilling to participate in our trials for any reason, including the existence of concurrent clinical trials for similar patient populations in PAH, if they are unwilling to enroll in a clinical trial with a placebo-controlled design or the availability of approved therapies, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting subjects, conducting studies and obtaining regulatory approval of seralutinib may be delayed. Our inability to enroll a sufficient number of subjects for our Phase 3 trial of seralutinib or any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we expect to rely on CROs and clinical trial sites to ensure proper and timely conduct of our future clinical trials and, while we intend to enter into agreements governing their services, we will have limited influence over their actual performance.

We cannot assure you that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays in enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of seralutinib could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon seralutinib, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, prospects, results of operations and financial condition.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with seralutinib's use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by seralutinib could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, based upon the benefit / risk profile and in response to serious adverse events observed, we decided to terminate the Phase 1b/2 study for GB5121. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Moreover, if seralutinib is associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon its development or limit its 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, which may limit the commercial expectations for seralutinib if approved. We may also be required to modify our study plans based on findings in our ongoing clinical trials. For example, although we believe seralutinib has been generally well tolerated in completed clinical trials, future clinical trials, including our Phase 3 trial of seralutinib in PAH patients may reveal adverse events inconsistent with the safety findings observed to date. For example, in 2013, results from a Phase 3 clinical trial in PAH of imatinib (Gleevec) showed statistically significant improvement in its primary efficacy endpoint, but systemic toxicities were also observed. Although we have not observed the systemic toxicities associated with imatinib, we cannot be certain that seralutinib will not exhibit similar or other toxicities in a larger Phase 3 clinical trial. Many compounds that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the compound. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test seralutinib in our Phase 3 trial in PAH, or as the use of seralutinib becomes more widespread if it receives regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by subjects. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition and prospects significantly.

In addition, if seralutinib receives marketing approval, and we or others later identify undesirable side effects caused by seralutinib, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of seralutinib;
- we may be required to recall a product or change the way seralutinib is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a "black box" warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients, or similar risk management measures;
- we may be required to change the way seralutinib is distributed or administered, conduct additional clinical trials or change the labeling of seralutinib or be required to conduct additional post-marketing studies or surveillance;
- we could be sued and held liable for harm caused to patients;
- sales of seralutinib may decrease significantly or seralutinib could become less competitive; and
- our reputation may suffer.

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

Although we have completed Phase 2 clinical trials for multiple product candidates including seralutinib, we have not, as an organization, completed later-stage clinical trials or submitted an NDA, and we may be unable to do so for seralutinib.

We will need to successfully complete a pivotal clinical trial in order to obtain FDA or comparable foreign regulatory approval to market seralutinib. Carrying out later-stage clinical trials and the submission of a successful NDA or other comparable foreign regulatory submission is a complicated process. As an organization, we have completed four Phase 2 clinical trials, including a Phase 2 clinical trial of seralutinib, and are conducting a Phase 3 clinical trial of seralutinib in PAH. We have not yet completed any pivotal clinical trials for seralutinib or previous product candidates. We also have limited experience as a company in preparing, submitting marketing applications and have not previously submitted an NDA or other comparable foreign application for any product candidate. We may also conduct a number of clinical trials for seralutinib in parallel over the next several years, which may be a difficult process to manage with our limited resources and which may divert the attention of management. In addition, we have had limited interactions with the FDA and cannot be certain our Phase 3 clinical trial of seralutinib will be sufficient to support an NDA submission, even if we believe the results are sufficiently positive. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to regulatory submission and approval of seralutinib. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of seralutinib. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs or other comparable foreign regulatory submissions for and commercializing seralutinib.

Seralutinib is subject to extensive regulation and compliance, which is costly and time consuming, and such regulation may cause unanticipated delays or prevent the receipt of the required approvals to commercialize seralutinib.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of seralutinib are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market seralutinib in foreign jurisdictions until we receive regulatory approval from the FDA and similarly, we are not permitted to market seralutinib until we receive foreign regulatory authorities' approval. The process of obtaining regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and foreign regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

Prior to obtaining approval to commercialize seralutinib in the United States or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that seralutinib is safe and effective for its intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for seralutinib are promising, such data may not be sufficient to support approval by the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for seralutinib either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities could delay, limit or deny approval of seralutinib for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies 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 seralutinib;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- we may be unable to demonstrate that seralutinib's clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of seralutinib are acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials
- such authorities may disagree regarding the formulation, labeling and/or the specifications of seralutinib;
- approval may be granted only for indications that are significantly more limited than what we apply for and/or with other significant restrictions on distribution and use;
- such authorities may find deficiencies in the manufacturing processes or facilities of our third-party manufacturers with which we contract for clinical and commercial supplies; or the approval policies;
- regulations of such authorities may significantly change in a manner rendering our or any of our potential future collaborators' clinical data insufficient for approval; or
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities. In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and comparable foreign regulatory authorities in reviewing new drugs based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us or any of our potential future collaborators from commercializing seralutinib.

Of the large number of drugs in development, only a small percentage successfully complete the 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 seralutinib, which would significantly harm our business, financial condition, results of operations and prospects.

Even if we eventually complete clinical trials and receive approval of an NDA or foreign marketing application for seralutinib, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS or similar risk management measures, which may be required to ensure safe use of the drug after approval. The FDA or the comparable foreign regulatory authority also may approve seralutinib for a more limited indication or patient population than we originally requested, and the FDA or comparable foreign regulatory authority may not approve the labeling that we believe is necessary or desirable for the successful commercialization of a product. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of seralutinib and would materially adversely impact our business and prospects.

We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

We may in the future seek an accelerated approval for seralutinib. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that seralutinib has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, confirmatory studies to verity and describe the drug's predicted clinical benefit. If such confirmatory studies fail to verify the drug's predicted clinical benefit or of the sponsor fails to conduct such studies in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, the Food and Drug Omnibus Reform Act of 2022, among other things, provided FDA statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted.

If we decide to submit an application seeking accelerated approval, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for seralutinib would result in a longer time period to commercialization of seralutinib, if any, could increase the cost of development of seralutinib and could harm our competitive position in the marketplace.

Moreover, in the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Furthermore, marketing authorizations may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to the introduction of specific procedures. This may arise when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive

information, or when generating data may be contrary to generally accepted ethical principles. This type of marketing authorization is close to a conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike a conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although a marketing authorization "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the marketing authorization may be withdrawn where the risk-benefit ratio is no longer favorable.

We may not be able to obtain or maintain orphan drug designations for seralutinib, and we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EC grants orphan designation based on the EMA's Committee for Orphan Medicinal Products' opinion to promote the development of products (1) that are intended for the diagnosis, prevention or treatment that is life-threatening or chronically debilitating, and (2) either (a) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (b) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the EU to justify the necessary investment, and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition. We have received orphan drug designation in the United States and the EU for seralutinib for treatment of PAH and may seek additional orphan designations for seralutinib in the future. There can be no assurance that we will be able to maintain or obtain such designations.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding toward clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has orphan 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 exclusivity, which means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same disease or condition for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. Upon grant of a marketing authorization in the EU, orphan medicinal products are entitled to ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. This period may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the orphan designation criteria, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA or comparable foreign regulatory authority can subsequently approve the same drug for the same condition if such regulatory authority concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We are currently conducting, and may in the future conduct, certain of our clinical trials for seralutinib outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

We are currently conducting, and may in the future conduct, one or more of our clinical trials for seralutinib outside the United States. The acceptance of study data from clinical trials conducted outside the U.S. or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, for such clinical trials not subject to an IND, the FDA will not accept the data as support for an application for marketing approval unless the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have

similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the U.S. or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in seralutinib not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data or cause us not to proceed into further clinical development.

From time to time, we may publicly disclose preliminary or topline or data from our clinical studies, which is 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 related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the preliminary or topline 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. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete 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. Adverse differences between topline, preliminary or interim data and final data could significantly harm our business prospects.

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 seralutinib, the approvability or commercialization of seralutinib and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding seralutinib or our business. If the topline, preliminary 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, seralutinib may be harmed, which could harm our business, results of operations, prospects or financial condition.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or if staffing or funding shortages or renewed global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Our business is subject to risks arising from pandemic and epidemic diseases.

Any future pandemic or epidemic disease outbreaks, and any supply chain disruptions or staffing shortages, could disrupt the manufacture or shipment of supplies of seralutinib for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing or timely advancing research and development activities, impede our clinical trial initiation and recruitment and the ability of subjects to continue in clinical trials, impact the results of the clinical trial based on participants contracting the disease or otherwise increasing the number of observed adverse events, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future pandemic or future epidemic disease outbreaks could also potentially further affect the business of the FDA or other regulatory authorities, which could result in delays in meetings related to planned clinical trials or other regulatory matters.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct many of our clinical trials and preclinical studies. Any failure by a third party to conduct the clinical trials according to GCPs and other requirements and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize seralutinib.

We are dependent on third parties to conduct our clinical trials and preclinical studies, including our ongoing and potential future clinical trials for seralutinib. Specifically, we have used and relied on, and intend to continue to use and rely on, medical institutions, clinical investigators, CROs and consultants to conduct our clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for seralutinib. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP or similar regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any such CROs, investigators or other third parties will devote adequate time and resources to such trials or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise performs in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or foreign regulatory authorities conclude that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA or similar foreign applications we submit by the FDA or foreign regulatory authorities. Any such delay or rejection could prevent us from commercializing seralutinib.

If any of our relationships with these third parties terminate or their services are delayed, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical and preclinical development timelines. Though we carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties for the manufacture of seralutinib for clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of seralutinib or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities and have no plans to build our own clinical or commercial scale manufacturing capabilities. We rely, and expect to continue to rely, on third parties for the manufacture of seralutinib and related raw materials for clinical and preclinical development, as well as for commercial manufacture if seralutinib receives marketing approval. The facilities used by third-party manufacturers to manufacture seralutinib must be approved by the FDA or foreign regulatory authorities for the manufacture of seralutinib pursuant to inspections that will be conducted after we submit an NDA to the FDA or similar applications to foreign regulatory authorities. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP or similar requirements for manufacture of drug products. If these third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, including requirements related to the manufacturing of high potency compounds, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of seralutinib or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market seralutinib, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of seralutinib, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of seralutinib.

Our or a third party's failure to execute on our manufacturing requirements, to do so on commercially reasonable terms and comply with cGMP or similar requirements outside of the United States could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of seralutinib, or any future product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for seralutinib;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of seralutinib; and
- in the event of approval to market and commercialize seralutinib, an inability to meet commercial demands for seralutinib.

In addition, we do not have long-term commitments or supply agreements with all of our third-party manufacturers. We may be unable to establish any supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of timely obtaining sufficient quantities of seralutinib or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture seralutinib according to our specifications;

- failure to manufacture seralutinib according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Seralutinib and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP or similar foreign regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of seralutinib. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, or public health epidemics. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers, and we may be unable to replace them on a timely basis or at all.

Our current and anticipated future dependence upon others for the manufacture of seralutinib may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We have entered into, and may in the future seek to enter into, collaborations, licenses and other similar arrangements and we may not realize the benefits of such relationships, or may not be successful in entering into such relationships

On May 3, 2024, we entered into the collaboration agreement with Chiesi for the development and commercialization of seralutinib around the world, and we may in the future seek to enter into other collaborations, joint ventures, licenses and other similar arrangements for the development or commercialization of our product candidates, due to capital costs required to develop or commercialize such product candidates or manufacturing constraints. For additional information regarding our collaboration with Chiesi, see the section titled “Business—License and Collaboration Agreements” included in this Form 10-K.

We may not be successful in our efforts to establish or maintain collaborations, including our collaboration with Chiesi, because third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time consuming and complex. Further, in connection with any such collaborations, we may have to relinquish valuable rights to our future revenue streams, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following the entry into our collaboration with Chiesi or any other strategic transaction or license, we will achieve an economic benefit that justifies such transaction. If we are successful in our efforts to establish any additional collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development or approval of seralutinib is delayed, the safety of seralutinib is questioned or sales of seralutinib, if approved, are unsatisfactory. In addition, our collaboration with Chiesi and any potential future collaborations may be terminable by Chiesi or our other strategic partners in certain circumstances, and we may not be able to adequately protect our rights under these agreements. Furthermore, our strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of seralutinib. For example, under the Chiesi collaboration, Chiesi received such rights and may not conduct development and commercialization activities in the same manner as we do. Any termination of the collaboration with Chiesi or of any other collaborations we enter into in the future, or any delay in entering into collaborations related to seralutinib, could delay the development and commercialization of seralutinib and reduce its competitiveness if it reaches the market, which could have a material adverse effect on our business, financial condition and results of operations.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on other third parties to manufacture seralutinib and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, consulting agreements or other similar agreements with our advisors, employees and consultants prior to beginning research or disclosing proprietary information.

These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are intentionally or inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Commercialization of Seralutinib

Even if we receive regulatory approval for seralutinib, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, seralutinib, if approved, could be subject to labeling and other restrictions on marketing or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with seralutinib, when and if it is approved.

Following potential approval of seralutinib, the FDA or foreign regulatory authorities may impose significant restrictions on its indicated uses or marketing or impose ongoing requirements for potentially costly and time-consuming post-approval studies, post-market surveillance or clinical trials to monitor the safety and efficacy of the product. The FDA or foreign regulatory authorities may also require a REMS or similar risk management measures as a condition of approval of seralutinib, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves seralutinib, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for seralutinib will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs or similar requirements and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with seralutinib, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of seralutinib, withdrawal of seralutinib from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA or foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of seralutinib; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize seralutinib and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of seralutinib. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before 2026. The revisions may however have a significant impact on the biopharmaceutical industry in the long term. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt

to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action, and we may not achieve or sustain profitability.

The commercial success of seralutinib will depend upon the degree of its market acceptance by physicians, patients, healthcare payors and others in the medical community.

Seralutinib may not be commercially successful. Even if seralutinib receives regulatory approval, it may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of seralutinib will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. The degree of market acceptance of seralutinib will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which seralutinib is approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA- or foreign regulatory authorities- approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of seralutinib, as well as the cost of treatment with seralutinib in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with seralutinib in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of seralutinib, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of seralutinib as well as competitive drugs;
- the effectiveness of our or any of our potential future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to seralutinib.

If seralutinib is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from seralutinib and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of seralutinib may require significant resources and may never be successful.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found or alleged to have improperly promoted off-label uses, we may become subject to significant liability.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, as seralutinib would be, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of seralutinib, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The successful commercialization of seralutinib, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for seralutinib could limit our ability to market seralutinib and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as seralutinib, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for seralutinib by third-party payors will have an effect on our ability to successfully commercialize seralutinib. Even if we obtain coverage for seralutinib by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for seralutinib, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider seralutinib as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with seralutinib, pricing of existing drugs may limit the amount we will be able to charge for seralutinib. These payors may deny or revoke the reimbursement status of seralutinib or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize seralutinib and may not be able to obtain a satisfactory financial return on seralutinib.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for seralutinib.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. 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 seralutinib to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for seralutinib. Accordingly, in markets outside the United States, the reimbursement for seralutinib may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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 the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for seralutinib. We expect to experience pricing pressures in connection with the sale of seralutinib 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, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We face significant competition, and if our competitors develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize seralutinib may be adversely affected.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with seralutinib. Seralutinib, if approved, will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In particular, there is intense competition in the fields of PAH and other PH indications including PH-ILD. Our competitors include larger and better funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions who may be active in the indications we are targeting and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect to face competition for seralutinib from existing products and products in development. Seralutinib is a PDGFR, CSF1R and c-KIT inhibitor initially targeted for PAH and PH-ILD patients. We expect competition within the PAH indication will include prostanoids / prostacyclin receptor agonists, including Orenitram (United Therapeutics), Uptravi (Janssen), Tyvaso (United Therapeutics), and Remodulin (United Therapeutics), and activin ligand traps, including Winrevair (Merck). We also may face some competition from products used in Functional Class I and II patients, such as the oral PDE5 inhibitors, including Revatio (Pfizer Inc.) and Adcirca (United Therapeutics); the sGC stimulator Adempas (Bayer AG); and oral ERAs, including Tracleer (Janssen), Letairis (Gilead Sciences, Inc.) and Opsumit (Janssen); and combination PDE5 inhibitor / ERA therapies, such as Opsynvi (Janssen). We believe that, if approved, seralutinib could be used alongside all classes of approved therapies. PAH is also an active indication for investigational drugs, and we may face competition in the future from CS1 (Cereno Scientific), L606 (Liquidia / Pharmosa Biopharm Inc.), treprostinil palmitil (Insmed), ralinepag (United Therapeutics), and REGN13335 (Regeneron Pharmaceuticals, Inc.). Additionally, although not approved for the treatment of PAH, we may face competition from formulations of imatinib, including the one in development from Tenax Therapeutics and Inhibikase Therapeutics.

We expect to face competition from Tyvaso (United Therapeutics) within the PH-ILD indication, as it is the only approved therapy for PH-ILD in the United States. There are no approved therapies for PH-ILD in the EU. PH-ILD is also an active indication for investigational drugs, and we may face competition in the future from L606 (Liquidia / Pharmosa Biopharm Inc.), sirolimus (OrphAI Therapeutics), treprostinil palmitil (Insmed, Inc.), MK-5475 (Merck), and mosliciguat (Pulmovant, Inc.).

There may be other earlier stage clinical programs that, if approved, would compete with seralutinib. Many of our competitors have substantially greater financial, technical and human resources than we have. Additional mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances made in the commercial applicability of technologies and greater availability of capital for investment in these fields. Our success will be based in part on our ability to build and actively manage a portfolio of drugs that addresses unmet medical needs and creates value in patient therapy.

If the market opportunities for seralutinib are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

The precise incidence and prevalence for all the conditions we aim to address with seralutinib are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with seralutinib, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market of seralutinib will ultimately depend upon, among other things, the diagnosis criteria included in the final label for seralutinib, the availability of alternative treatments and the safety, convenience, cost and efficacy of seralutinib relative to such alternative treatments, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with seralutinib or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Further,

even if we obtain significant market share for seralutinib, because our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell seralutinib, we may not be able to generate product revenue.

Although we have started to build a commercial infrastructure, we have no formal internal sales, marketing or distribution capabilities, nor have we commercialized a product. If seralutinib ultimately receives regulatory approval, we, in collaboration with Chiesi, must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize seralutinib in the United States, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of seralutinib. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute seralutinib. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market seralutinib effectively. If we are not successful in commercializing seralutinib, either on our own in partnership with Chiesi or through arrangements with one or more third parties, we may not be able to generate any future product revenue, and we would incur significant additional losses.

Our future profitability may depend, in part, on Chiesi's ability to operate in foreign markets, where they would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on Chiesi's ability to develop and commercialize seralutinib in foreign markets and pay us royalties on commercial sales. Chiesi is not permitted to market or promote seralutinib before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for seralutinib. To obtain separate regulatory approval in many other countries, Chiesi must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of seralutinib. If we obtain regulatory approval of seralutinib and Chiesi ultimately commercializes seralutinib in foreign markets, we and Chiesi would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- new or unexpected changes in tariffs (including recent U.S. tariffs imposed or threatened to be imposed on other countries and any retaliatory actions taken by such countries), trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geopolitical actions, including war and terrorism, health epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

Risks Related to Our Business Operations and Industry

Our results of operations may fluctuate significantly, which makes our future results of operations difficult to predict and could cause our results of operations to fall below expectations or any guidance we may provide.

Our quarterly and annual results of operations may fluctuate significantly, which makes it difficult for us to predict our future results of operations. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the timing and cost of, and level of investment in, research, development, regulatory approval and commercialization activities relating to seralutinib, which may change from time to time;
- coverage and reimbursement policies with respect to seralutinib, if approved, and potential future drugs that compete with seralutinib;
- the cost of manufacturing seralutinib, which may vary depending on the quantity of production and the terms of our agreements with third-party manufacturers;
- the timing and amount of the milestone or other payments we must make to Pulmokine and other third parties from whom we have in-licensed seralutinib, including payments due upon a change in control of our subsidiaries as well as timing and amount of the milestone or other payments we receive from Chiesi;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for any approved products, which may vary significantly;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of preclinical studies or clinical trials for seralutinib or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual results of operations. As a result, comparing our results of operations on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or results of operations fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

We are dependent on the services of our management and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. The loss of services of any of these personnel could delay or prevent the successful development of seralutinib, initiation or completion of our clinical trials or the commercialization of seralutinib. Executive leadership transitions can be inherently difficult to manage and, as a result, we may experience disruption or have difficulty in maintaining or developing our business. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the increasingly intense competition for qualified personnel among pharmaceutical, biotechnology and other businesses, particularly in the San Diego area. Our industry has experienced a high rate of turnover for all personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

We may encounter difficulties in managing our growth and expanding our operations successfully.

We had 144 full-time employees as of March 6, 2025. As we continue development and pursue the potential commercialization of seralutinib, as well as function as a public company, we may need to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. If our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to develop and commercialize seralutinib and to compete effectively will depend, in part, on our ability to manage any future growth effectively.

We are subject to various federal, state and foreign healthcare laws and regulations, and our failure to comply with these laws and regulations could harm our results of operations and financial condition.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers expose us to broadly applicable federal, state and foreign fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation.

- the federal false claims laws, including the civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, 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 federal Physician Payments Sunshine Act, which 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 certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-

midwives), and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by the patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives.

Ensuring that our internal operations and business arrangements with third-parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our consulting and advisory board arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other 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 exclusion from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

We are subject to governmental regulation and other legal obligations related to privacy, data protection and information security. Actual or perceived failures to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.

The global data protection landscape is rapidly evolving, and we are or may become subject to numerous state, federal and foreign laws, requirements and regulations governing the collection, use, disclosure, retention, and security of personal information, such as information that we may collect in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business. This evolution may create uncertainty in our business, affect our ability to operate in certain jurisdictions or to collect, store, transfer use and share personal information, necessitate the acceptance of more onerous obligations in our contracts, result in liability or impose additional costs on us. Compliance with these data privacy and security requirements is rigorous and time-intensive and may increase our cost of doing business. Despite our efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm for actual or perceived failures to comply with such requirements, which could materially and adversely affect our business, financial condition and results of operations.

As our operations and business grow, we may be subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and regulations promulgated thereunder, or collectively, HIPAA, imposes requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. Further, we may also be subject to other state laws governing the privacy, processing and protection of personal information. By way of example, California enacted the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively, the CCPA, requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may also be required.

Our operations abroad may also be subject to increased scrutiny or attention from data protection authorities. For example, in Europe, the General Data Protection Regulation, or GDPR, went into effect in May 2018, and imposes stringent requirements for controllers and processors of personal data. The GDPR allows EU and EEA member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union, or CJEU, states that reliance on the standard contractual clauses, or SCCs - a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism - alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. On July 10, 2023, the European Commission adopted its Adequacy Decision in relation to the new EU-US Data Privacy Framework, or DPF, rendering the DPF effective as a GDPR transfer mechanism to U.S. entities self-certified under the DPF. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Since the beginning of 2021, we have also been subject to the United Kingdom's data protection regime, which imposes separate but similar obligations to those under the GDPR and comparable penalties, including fines of up to £17.5 million or 4% of a noncompliant company's global annual revenue for the preceding financial year, whichever is greater. On October 12, 2023, the UK Extension to the DPF came into effect (as approved by the United Kingdom Government), as a data transfer mechanism from the United Kingdom to U.S. entities self-certified under the DPF. Other foreign jurisdictions, such as China and Russia, are increasingly implementing or developing their own privacy regimes with complex and onerous compliance obligations and robust regulatory enforcement powers. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize seralutinib and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. Among the provisions of the ACA of importance to seralutinib, the ACA: established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the Public Health program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been judicial and political challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020, through March 31, 2022, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory Medicaid drug rebate cap, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was enacted into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a new discounting program (which began in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS has published the negotiated prices for the initial ten drugs, which will first be effective in 2026, and the list of the subsequent 15 drugs that will be subject to negotiation, although the Medicare drug price negotiation program is currently subject to legal challenges. For that and other reasons, it is currently unclear how the IRA will be effectuated.

We expect that new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize seralutinib, if approved.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards, which ultimately may attempt to impose price limits on certain drugs in these states. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition 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 seralutinib, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In the EU, similar political, economic and regulatory developments may affect our or Chiesi's ability to profitably commercialize, or co-commercialize, seralutinib, if approved. For instance, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in

other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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

We face an inherent risk of product liability as a result of the clinical trials of seralutinib and will face an even greater risk if we commercialize seralutinib. For example, we may be sued if seralutinib allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in seralutinib, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the commercialization of seralutinib. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for seralutinib;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact;
- the inability to commercialize seralutinib; and
- a decline in our stock price.

We currently hold approximately $10 million in aggregate product liability insurance coverage. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of seralutinib. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of seralutinib. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We, Chiesi and any of our potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we, Chiesi and any of our potential future collaborators are successful in commercializing seralutinib, the FDA and foreign regulatory authorities would require that we, Chiesi and any of our potential future collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We, Chiesi and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we, Chiesi or any of our potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of seralutinib or delay in approval or clearance of future products.

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

We are exposed to the risk that our employees and independent contractors, including principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (1) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, including cGMP and similar requirements, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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 and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, individual imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies, similar to our approach in in-licensing seralutinib. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for seralutinib, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or seralutinib, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to seralutinib, proprietary technologies and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, designed around or invalidated by third parties. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties

and/or limitations in our ability to properly protect the intellectual property rights relating to seralutinib could have a material adverse effect on our financial condition and results of operations.

Although we own issued patents in the United States and foreign countries, we cannot be certain that the claims in our U.S. pending patent applications and patent applications in foreign countries and jurisdictions will be considered patentable by the United States Patent and Trademark Office, or USPTO, courts in the United States or by the patent offices and courts in foreign countries and jurisdictions, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting seralutinib by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell seralutinib;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries and jurisdictions other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license from third parties. We may also require the cooperation of our licensor in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize seralutinib may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights for seralutinib from third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights for seralutinib. Additionally, our license agreement for seralutinib includes sublicenses from a third party, and we must rely on Pulmokine's compliance with its obligations under its original license agreement.

In October 2017, we entered into an exclusive license agreement with Pulmokine, Inc. to obtain an exclusive license to certain intellectual property rights to develop and commercialize seralutinib. This license agreement imposes, and we

expect that any future license agreements where we in-license intellectual property, will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to bankruptcy-related proceedings, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Additionally, our existing license agreement with Pulmokine includes sublicenses from a third party who is not the original licensor of the seralutinib intellectual property. Under this agreement, we must rely on Pulmokine to comply with its obligations under the primary license agreements under which it obtained rights in the applicable intellectual property, where we do not have a relationship with the original licensor of such rights. If Pulmokine fails to comply with its obligations under the upstream license agreement, the original third-party licensor may have the right to terminate the original license, which may terminate our license. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize seralutinib.

We may need to obtain licenses from third parties to advance our research or allow commercialization of seralutinib, and we cannot provide any assurances that third-party patents do not exist which might be enforced against seralutinib in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the seralutinib, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of seralutinib, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize seralutinib, which would have a material adverse effect on our business.

In addition, our license agreement with Pulmokine may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, if we choose to sublicense or assign to any third parties our rights under our existing license agreement with Pulmokine with respect to any licensed product, we may be required to pay to Pulmokine, as applicable, a specified percentage of all revenue to be received in connection with such transaction.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical 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 pending and future patent applications may not result in patents being issued which protect seralutinib or which effectively prevent others from commercializing competitive product candidates.

Moreover, 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 own or license currently or in the future issue as patents, they may not issue 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. Any patents that we own or license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether seralutinib will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may not cover seralutinib or may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter parties review, or IPR, or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we or our predecessors and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications or those of our licensors has been found. There is also no assurance that there is not prior art of which we, our predecessors or licensors are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or those of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize seralutinib and compete directly with us, without payment to us. Such loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of seralutinib. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize seralutinib.

The patent protection and patent prosecution for seralutinib may be dependent on third parties.

We or our licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position with respect to seralutinib. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Pursuant to the terms of the license agreement with Pulmokine, Gilead Sciences and Rensselaer the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our licensors or any of our future licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents covering seralutinib, our ability to develop and commercialize seralutinib may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed from various third parties may be subject to retained rights. Our predecessors or licensors often retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

If we are limited in our ability to utilize acquired or licensed technologies, or if we lose our rights to critical in-licensed technology, we may be unable to successfully develop, out-license, market and sell seralutinib, which could prevent or delay new product introductions. Our business strategy depends on the successful development of seralutinib, which is a licensed technologies, into a commercial product. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell seralutinib.

Some of our intellectual property has been discovered through government-funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have licensed or may acquire or license in the future may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. For example, some of the research and development work on seralutinib was funded by government research grants. As a result, the U.S. government may have certain rights to intellectual property embodied in seralutinib pursuant to the Bayh-Dole Act of 1980, or Bayh-Dole Act. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our future intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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

- others may be able to develop products that are similar to seralutinib but that are not covered by the claims of the patents that we own or license;
- we or our licensors or predecessors might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our licensors or predecessors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;

- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import seralutinib and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing seralutinib. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of seralutinib.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that seralutinib may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of seralutinib, and we cannot be certain that we were the first to file a patent application related to seralutinib or related technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that seralutinib may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing seralutinib until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this annual report on Form 10-K, others may hold proprietary rights that could prevent seralutinib from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to seralutinib or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop seralutinib. Defense of these claims, regardless of their merit, would involve substantial

litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign seralutinib or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing seralutinib, which could harm our business, financial condition and results of operations.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can, because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our intellectual property rights or those of our licensors. To prevent infringement or unauthorized use, we and/or our licensors may be required to file infringement claims, which can be expensive and time consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our licensors or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at seralutinib, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on seralutinib. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize seralutinib or future product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. 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. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation or interference proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation or interference proceedings provoked by third parties or brought by us or declared by the USPTO or similar proceedings in foreign patent offices may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring seralutinib to market.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first inventor to file" system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to seralutinib or (2) invent any of the inventions claimed in our patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, a Unitary Patent and Unified Patent Court (UPC) system were implemented in Europe on June 1, 2023. This new regime may present uncertainties for our ability to protect and enforce our patent rights against competitors in Europe. Under the UPC, all European patents, including those issued prior to ratification of the European Patent Package, by default automatically fall under the jurisdiction of the UPC. The UPC provides our competitors with a new forum to centrally revoke our European patents, and allows for the possibility of a competitor to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the EU Patent Package, we will have the right to opt our patents out of the UPC over the first seven years of the court's existence, but doing so may preclude us from realizing the benefits of the new unified court.

Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect seralutinib.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the

prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

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

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on seralutinib for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering seralutinib are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of seralutinib, patents protecting seralutinib might expire before or shortly after seralutinib is commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for seralutinib, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of seralutinib, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch- Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of seralutinib. However, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Although we have issued patents pending patent applications in the United States and certain other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have

patent protection but enforcement is not as strong as that in the United States. These products may compete with seralutinib, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

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

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biopharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of seralutinib. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other biopharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we,

our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Risks Related to Our Common Stock

An active, liquid and orderly market for our common stock may not be maintained.

Our common stock only began trading on the Nasdaq Global Select Market, or Nasdaq, in February 2019, and we can provide no assurance that we will be able to maintain an active trading market for our common stock. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price has been and is likely to be volatile. Since the shares were sold in our initial public offering, or IPO, in February 2019 at a price of $16.00 per share, the price per share of our common stock has ranged as low as $0.45 and as high as $27.15 through March 6, 2025. The stock market in general and the market for stock of biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- our ability to enroll subjects in our ongoing and planned clinical trials;
- results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- regulatory approval of seralutinib, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process;
- regulatory developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems, especially in light of current reforms to the U.S. healthcare system;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- innovations or new products developed by us or our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- manufacturing, supply or distribution delays or shortages;
- any changes to our relationship with Chiesi or any manufacturers, suppliers, licensors, future collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;

- an inability to obtain additional funding;
- sales of our stock by insiders and stockholders;
- general economic, industry and market conditions other events or factors, many of which are beyond our control, such as health pandemics, the military conflict between Russia and Ukraine and Israel and Hamas, inflation and interest changes and financial institution instability;
- additions or departures of key personnel; and
- intellectual property, product liability or other litigation against us.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical 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.

Our failure to meet the continued listing requirements of the Nasdaq could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of the Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to control or significantly influence all matters submitted to stockholders for approval. Furthermore, many of our current directors were appointed by our principal stockholders.

Our executive officers, directors and greater than 5% stockholders, in the aggregate, own approximately 20.0% of our outstanding common stock as of March 6, 2025. As a result, such persons or their appointees to our board of directors, acting together, have the ability to control or significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation, if any, in the price of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes

in our management without the consent of our board of directors. The provisions in our charter documents include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, and our amended and restated bylaws provide that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated bylaws also provide that unless we consent in writing to the selection of an

alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions 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, which may discourage such lawsuits against us and our directors, officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Our ability to use net operating loss carryforwards and other tax attributes may be limited.

We have incurred substantial losses during our history, do not expect to become profitable in the near future, and may never achieve profitability. To the extent that we continue to generate losses for tax purposes, such losses will carry forward to offset future taxable income, if any, until such losses are used to offset taxable income (if ever) or expire (if at all). As of December 31, 2024, we had federal and state net operating loss carryforwards, or NOLs, of approximately $398.1 million and $3.3 million, respectively. Our state NOLs that are subject to expiration will begin to expire in 2036, unless previously utilized. Our federal NOLs are not subject to expiration but may only be used to offset 80% of our taxable income. As of December 31, 2024, the Company has foreign NOLs of approximately $113.0 million. The foreign NOLs can be carried forward indefinitely. As of December 31, 2024, we also had orphan drug credit and federal research tax credit carryforwards of approximately $48.2 million and California research tax credits of $13.2 million. The federal research tax credit carryforwards begin to expire in 2038. The California research tax credit carryforward does not expire and can be carried forward indefinitely until utilized.

Our NOLs and credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, our federal NOLs and credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders (or groups of stockholders) in excess of 50 percentage points over a rolling three-year period. Similar rules may apply under state and foreign tax laws. In connection with our IPO in February 2019, we experienced an ownership change for purposes of Section 382 and 383 of the Code. We also experienced an ownership change in July 2023. Consequently, our federal NOLs and tax credits generated through July 2023 will be subject to annual limitations. Our NOLs are not expected to expire unused as a result of such annual limitations, assuming we otherwise have taxable income or income tax liabilities in future periods; however, we expect that some or all of the federal credits generated through July 2023 will expire prior to utilization. If additional ownership changes occur in the future as a result of changes in our stock ownership, many of which are outside our control, the NOL and credit carryforwards could be subject to further annual limitations. If we earn taxable income, such annual limitations could result in increased future tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

We have been involved in securities class action litigation and could be subject in the future to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us, because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. On April 3, 2020, we, certain of our executive officers and directors, and the underwriters of our IPO were named as defendants in a purported securities class action lawsuit. The complaint, as amended, was filed on behalf of all investors who purchased our securities pursuant to or traceable to our February 8, 2019 IPO, and alleged that we, and such executive officers and directors and the underwriters of our IPO, made false and/or misleading statements and failed to disclose material adverse facts about our business, operations and prospects. On September 30, 2022, the court entered a judgment approving the class action settlement in which we agreed to pay approximately $2.4 million, in exchange for customary releases and settlement terms. This lawsuit and any future lawsuits to which we may become a party are subject to inherent uncertainties and may be expensive and time-consuming to investigate, defend and resolve, and may divert our management's attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of future litigation, and we may not prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal, or in payments of substantial monetary damages or fines, or we may decide to settle this or other lawsuits on similarly unfavorable terms, which could adversely affect our business, financial condition, results of operations or stock price.

We are a smaller reporting company within the meaning of the Securities Act, and if we decide to take advantage of certain exemptions from various reporting requirements applicable to smaller reporting companies, our common stock could be less attractive to investors.

We are a smaller reporting company. For so long as we qualify as a smaller reporting company, we will have the option to take advantage of certain exemptions from various reporting and other requirements that are applicable to other public companies that are not smaller reporting companies, including, but not limited to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, for as long as we are deemed neither a large accelerated filer nor accelerated filer, we may continue to use the exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act.

We will remain a smaller reporting company and non-accelerated filer until we have a public float of $700 million or more as of the last business day of our most recently completed second fiscal quarter and annual revenues of less than $100 million, or a public float of $250 million or more as of the last business day of our most recently completed second fiscal quarter and annual revenues of $100 million or more. We will need to reassess, as of June 30, 2025, whether we will continue to qualify as a smaller reporting company and a non-accelerated filer for filings beyond the fiscal year ending December 31, 2025. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

General Risk Factors

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We and any of our third-party manufacturers or suppliers will use biological materials, potent chemical agents and may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, we cannot eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

Although we maintain workers' compensation insurance for certain costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Our information technology, or IT, systems, or those of any of our CROs, manufacturers, other contractors or consultants or Chiesi or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our seralutinib development program, which could materially affect our results.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on IT systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information, clinical trial data, and personal information, or collectively, Confidential Information, of customers and our employees and contractors. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information.

There can be no assurance that our cybersecurity program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and Confidential Information. Despite the implementation of security measures as part of our cybersecurity program, our IT systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to attack and damage from computer viruses and malware (e.g., ransomware), misconfigurations, "bugs" or other vulnerabilities, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon IT systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the continued hybrid working environment, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

We, Chiesi and certain of our service providers are from time to time subject to cyberattacks and security incidents, including but not limited to persistent brute force attempts and password spraying, targeted spearphishing and smishing (text message phishing), email phishing including malware attempts, and third-party vendor cybersecurity incidents and related data breaches. . While we do not believe that we have experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access Confidential Information, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. The loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We could also incur liability and the further development and commercialization of seralutinib could be delayed. In addition, we also rely on third parties to manufacture seralutinib, so similar events relating to their computer systems could also have a material adverse effect on our business. Some of the federal, state and foreign government requirements under data privacy and security laws include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our service providers or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. Further, our insurance coverage may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems. To the extent that any disruption or security breach were to result in violations of privacy and security laws, we could also be subject to significant fines, penalties or liabilities, which could adversely affect our business, financial condition, results of operations and prospects.

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

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce seralutinib. Our ability to obtain clinical supplies of seralutinib could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. In addition, our corporate headquarters is located in San Diego, California near major earthquake faults and fire zones, and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Unfavorable global economic conditions and adverse developments with respect to financial institutions and associated liquidity risk could adversely affect our business, financial condition and stock price.

The global credit and financial markets are currently, and have from time to time experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine and Israel and Hamas, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Additionally, any adverse developments with

respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. For example, in 2023 the closures of Silicon Valley Bank, or SVB, and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation, or FDIC created bank-specific and broader financial institution liquidity risk and concerns. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, clinical research organizations, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell seralutinib abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, clinical research organizations, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed as a result of military conflicts in other countries may impact our ability to continue activities at clinical trial sites within regions covered by such sanctions. For example, as a result of the military conflict between Russia and Ukraine, the United States and its European allies have recently announced the imposition of sanctions on certain industry sectors and parties in Russia and the regions of Donetsk and Luhansk in Ukraine, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls, as well as any economic countermeasures by the governments of Russia or other jurisdictions, could adversely impact our ability to continue activities at clinical trial sites within regions covered by such sanctions or directly or indirectly disrupt our supply chain. 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.

We incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that

apply to us. Stockholder activism, the current 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 we cannot currently anticipate.

The rules and regulations applicable to public companies have increased and may continue to increase our legal and financial compliance costs and to make some activities more time consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations make it more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If these analysts cease coverage of our company, the trading price for our stock would be negatively impacted. If one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to annually report upon the effectiveness of our internal control over financial reporting. However, as a smaller reporting company and a non-accelerated filer and in accordance with new SEC rules effective in 2020, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 for as long as we are not deemed an “accelerated filer” or “large accelerated filer. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Although we have determined that our internal control over financial reporting was effective as of December 31, 2024, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. 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 once that firm begin its Section 404 reviews, 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.

Changes in tax laws may materially adversely affect our financial condition, results of operations and cash flows.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances, including in the United States or Ireland, could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. We are currently unable to predict whether such changes will occur and, if such changes do occur, the ultimate impact on our business. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may materially and adversely impact our business, financial condition, results of operations and cash flows.

Item 1B. Unresolved Staff Comments.

Not Applicable.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity governance program intended to protect the confidentiality, integrity, and availability of our critical systems and information.

We design and assess our program based on the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF). This does not imply we meet any particular technical standards, specifications, or requirements, only that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Our cybersecurity governance program includes reporting channels to the executive management team and an internal Cybersecurity Oversight Committee, as well as governance processes which communicate cybersecurity risks to departments across the organization, including legal, strategic, operational, and financial areas. This encourages consideration of cybersecurity oversight, accountability and diligence across the organization.

Key elements of our cybersecurity governance program includes but are not limited to the following:

- Processes to assess cybersecurity risk, designed to help identify material risks from cybersecurity threats to critical systems and information;
- a security team principally responsible for coordinating and managing (1) cybersecurity risk evaluation processes, (2) implementation of cybersecurity controls, and (3) response to cybersecurity incidents;
- the use of external service providers, where appropriate, to assess, test or otherwise assist with aspects of the organization's cybersecurity processes;
- cybersecurity awareness training of employees, including incident response personnel including third party providers, and senior management;
- a cybersecurity incident response plan which includes procedures for responding to cybersecurity incidents; and
- a third-party risk management process for key service providers based on our assessment of their criticality to our operations and respective risk profile.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents, which have materially affected us, including our operations, business strategy, results of operations, or financial condition. We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect the organization, including operations, business strategy, results of operations, or financial condition. See "Risk Factors - *Our information technology systems, or those of any of our CROs, manufacturers, other contractors or consultants or Chiesi or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our seralutinib development program, which could materially affect our results."*

Cybersecurity Governance

Our Board considers cybersecurity risk as part of its risk oversight function and has delegated oversight of cybersecurity risks, including oversight of management's implementation of the cybersecurity governance program.

The Audit Committee receives formal annual reports from IT management regarding cybersecurity risks. In addition, management would update the Audit Committee and Board, where it deems appropriate, regarding cybersecurity incidents it considers to be significant or potentially significant. The Audit Committee reports to the full Board regarding its activities, including those related to cybersecurity.

Assessment and management of material risks from cybersecurity threats are performed by the Executive Director, Information Security, Risk & Compliance and the Vice President, IT and Facilities, reporting to the Executive Vice President, Technical Operations and Administration. Our Executive Vice President, Technical Operations and Administration reports to the President and Chief Executive Officer. This group holds primary responsibility for our overall cybersecurity governance program, along with our internal Cybersecurity Oversight Committee, which includes senior personnel from key departments in the organization. The collective experience of the individuals listed above, along with the Cybersecurity Oversight Committee, includes decades of experience working in and overseeing IT and cybersecurity functions and enterprise, IT and cybersecurity risk management functions, in addition to holding active technical cybersecurity certifications and maintaining active membership in cybersecurity professional organizations, as well as local groups, to support knowledge share and ongoing cybersecurity professional development.

Our management team takes steps to stay informed about and monitor efforts to prevent, detect, mitigate, and remediate cybersecurity risks and incidents through various means, which may include briefings from internal security personnel; threat intelligence and other information obtained from governmental, public or private sources, including external consultants engaged by us and alerts and reports produced by security tools deployed in our IT environment.

Item 2. Properties.

Our corporate headquarters are located in San Diego, California, where we currently lease approximately 18,421 square feet of office space. We use our corporate headquarters primarily for corporate, research, development, clinical, regulatory, manufacturing and quality functions. Our lease for this facility expires in October 2029. We believe that our facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms, if required.

Item 3. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may be involved in legal proceedings or subject to claims incident to the ordinary course of business. Regardless of the outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources 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

Our common stock is listed on the Nasdaq Global Select Market under the symbol "GOSS."

Holders of Common Stock

As of March 6, 2025, there were 227,221,261 shares of our common stock outstanding held by approximately 34 holders of record of our common stock. This number was derived from our shareholder records and does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

Dividend Policy

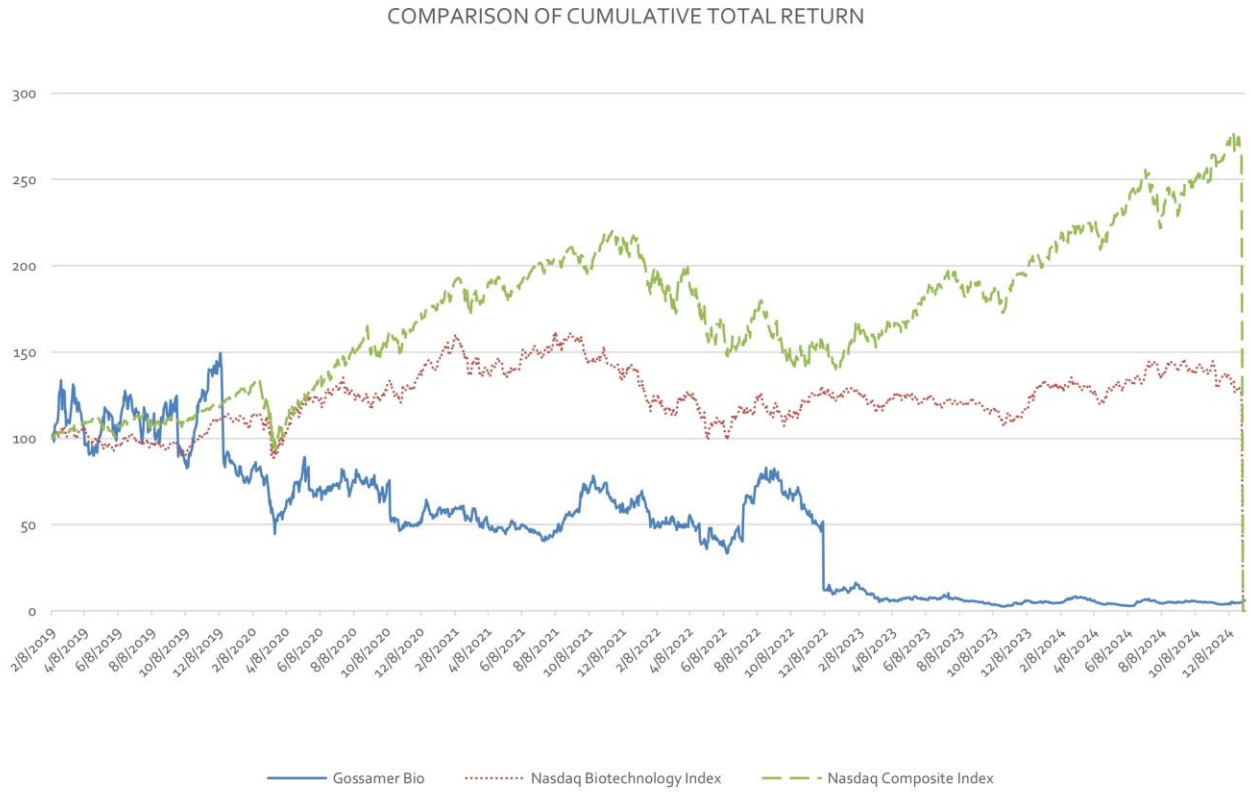
We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Securities Authorized for Issuance Under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K for information about our equity compensation plans which is incorporated by reference herein.

Stock Performance Graph

The following stock performance graph compares our total stock return with the total return for (i) the Nasdaq Composite Index and the (ii) the Nasdaq Biotechnology Index for the period from February 8, 2019 (the date our common stock commenced trading on the Nasdaq Global Select Market) through December 31, 2024. The figures represented below assume an investment of $100 in our common stock at the closing price of $17.94 on February 8, 2019 and in the Nasdaq Composite Index and the Nasdaq Biotechnology Index on February 8, 2019 and the reinvestment of dividends into shares of common stock. The comparisons in the graph are not intended to forecast or be indicative of possible future performance of our common stock.



Unregistered Sales of Equity Securities

None.

Issuer Repurchases of Equity Securities

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 consolidated financial statements and related notes included elsewhere in this annual report. This discussion and analysis contains forward-looking statements based upon our current beliefs, plans and expectations that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" or in other parts of this annual report.

Overview

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of PH, including PAH and PH-ILD. Our goal is to be an industry leader in, and to enhance the lives of patients living with PH. In May 2024, we entered into the collaboration agreement for seralutinib with Chiesi. In December 2022, we announced positive topline results from the Phase 2 TORREY Study in PAH patients. In the fourth quarter of 2023, we initiated the registrational Phase 3 PROSERA Study in PAH. We expect to report topline data from the PROSERA study in the fourth quarter of 2025. In addition to PAH, we believe that seralutinib holds potential as a therapeutic for the treatment of PH-ILD. We expect to activate clinical sites for a global registrational Phase 3 for the treatment of PH-ILD in the second half of 2025. We have assembled a deeply experienced and highly skilled group of industry veterans, scientists, clinicians and key opinion leaders from leading biotechnology and pharmaceutical companies, as well as leading academic centers from around the world. Our employees are a team of highly dedicated, passionate individuals who pride themselves on a culture of respect, humility, transparency, inclusion, dedication, collaboration and fun. Our ultimate goal is to enhance and extend the lives of patients.

We were incorporated in October 2015 and commenced operations in 2017. To date, we have focused primarily on organizing and staffing our company, business planning, raising capital, identifying, acquiring and in-licensing our product candidates and conducting preclinical studies and clinical trials. We have funded our operations primarily through equity financings and the collaboration agreement. We raised $1,401.1 million from October 2017 through December 31, 2024 through the sale of Series A and Series B convertible preferred stock, issuance of convertible notes, proceeds from our IPO, completed in February 2019, proceeds from 2027 Notes (as defined below), issuance of common stock in May 2020 and July 2022, issuance of common stock and accompanying warrants in July 2023 and entry into the collaboration agreement in May 2024. As of December 31, 2024, we had $294.5 million in cash, cash equivalents and marketable securities.

We have incurred significant operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future. For the years ended December 31, 2024 and 2023, our net loss was $56.5 million and $179.8 million, respectively. As of December 31, 2024, we had an accumulated deficit of $1,268.6 million. We expect to incur expenses and operating losses for the foreseeable future as we continue our development of and seek regulatory approvals for seralutinib, including the conduct of ongoing and planned clinical trials and other research and development activities; and as we hire additional personnel, protect our intellectual property and incur additional costs associated with being a public company. In addition, as seralutinib progresses through development and toward commercialization, we will need to make milestone payments to Pulmokine from whom we have in-licensed seralutinib. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending in particular on the timing of our clinical trials and preclinical studies and our expenditures on other research and development activities.

On May 3, 2024, we announced a strategic global partnership with Chiesi. Under the terms of the collaboration agreement, we granted Chiesi exclusive licenses for the worldwide development, manufacture and commercialization of seralutinib and licensed products and an Equity Option to purchase our common stock. The total potential transaction value includes the one-time $160.0 million development cost reimbursement payment for licenses, research and development funding, and certain regulatory and commercial milestones. We and Chiesi share equally in the costs of ongoing global seralutinib clinical development and the costs of commercialization in the United States, with the exception of the PROSERA Phase 3 study, for which we bear all costs. We are also eligible for double-digit royalties in the mid-to-high teens percentage on tiers of annual net sales outside of the U.S. and to an equal share of profits and losses from the commercialization of seralutinib and licensed products in the U.S. . For additional information regarding the collaboration agreement, as well as our license agreement with Pulmokine, see the section titled “Business—License and Collaboration Agreements” in this annual report.

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for seralutinib, which we expect will take a number of years. If we obtain regulatory approval for seralutinib, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, until such time as we can generate substantial product revenues to support our cost structure, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional capital when needed, we could be forced to delay, limit, reduce or terminate seralutinib development or future commercialization efforts or grant additional rights to develop and market seralutinib even if we would otherwise prefer to retain such right.

Components of Results of Operations

Revenue

To date, we have generated all of our revenue from our collaboration agreement with Chiesi. Our revenue consists of a one-time development cost reimbursement payment for licenses and ongoing cost-sharing payments for performance of research and development services classified as revenue from contracts with collaborators.

In the future, we may generate revenue from a combination of license fees and other upfront payments, other funded research and development agreements, milestone payments, product sales, other third-party funding, US profit/loss share and royalties in connection with strategic alliances. We expect that any revenue we generate will fluctuate from quarter-to-quarter as a result of the timing of performance of research and development services, the timing of our achievement of regulatory and commercialization milestones, the timing and amount of payments relating to such milestones and the extent to which any of our products are approved and successfully commercialized. If we are unable to fund our development costs or we are unable to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues and our results of operations and financial position would be adversely affected.

Operating expenses

Research and development

Research and development expenses relate primarily to preclinical and clinical development of seralutinib, as well as our discontinued clinical product candidates. Research and development expenses are recognized as incurred and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include or could include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations, or CROs, investigative sites and consultants to conduct our clinical trials and preclinical and non-clinical studies;
- laboratory supplies;
- costs related to manufacturing our product candidates for clinical trials and preclinical studies, including fees paid to third-party manufacturers;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance, equipment and other supplies.

Our direct research and development expenses consist principally of external costs, such as fees paid to CROs, investigative sites and consultants in connection with our clinical trials, preclinical and non-clinical studies, and costs related to manufacturing clinical trial materials. We deploy our personnel and facility related resources across all of our research and development activities. We track external costs and personnel expense on a program-by-program basis and allocate common expenses, such as facility related resources, to each program based on the personnel resources allocated to such program. Stock-based compensation and personnel and common expenses not attributable to a specific program are considered unallocated research and development expenses. We categorize Terminated Programs as any research and development expenses attributable to our clinical stage product candidates that were terminated prior to December 31, 2023.

We expect to incur research and development expenses for the foreseeable future as we continue the development of seralutinib. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future preclinical studies and clinical trials of seralutinib due to the inherently unpredictable nature of preclinical and clinical development. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to how much funding to direct to seralutinib on an ongoing basis in response to the results of ongoing and future preclinical studies and clinical trials, regulatory

developments and our ongoing assessments as to seralutinib's commercial potential. We will need to raise substantial additional capital in the future.

Our clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing seralutinib;
- the costs incurred as a result of health epidemics and pandemics, including the COVID-19 pandemic, and clinical site staff shortages, including clinical trial delays;
- the phase 3 stage of development for seralutinib; and
- the efficacy and safety profile of seralutinib.

In process research and development

In process research and development, or IPR&D, expenses include IPR&D acquired as part of an asset acquisition or in-license for which there is no alternative future use, are expensed as incurred.

General and administrative

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation, for personnel in executive, finance and other administrative functions. Other significant costs include facility-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and insurance costs.

We expect to incur general and administrative expenses for the foreseeable future to support our current infrastructure and continued costs of operating as a public company. These expenses will likely include audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations costs associated with operating as a public company.

Other income (expense), net

Other income (expense), net consists of (1) interest income on our cash, cash equivalents and marketable securities, (2) investment accretion, (3) interest expense related to our Credit Facility, prior to its termination and the 2027 Notes, (4) research and development tax credit and (5) other miscellaneous income (expense).

Provision for income taxes

Our tax provision from income taxes is determined using an estimate of our annual effective tax rate, adjusted for discrete items, if any, that are taken into account in the relevant period.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenue, expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions (See Note 2 to our consolidated financial statements).

Accrued expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Collaborative Arrangements

We assess whether our licensing and other agreements are collaborative arrangements based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. For arrangements that we determine are collaborations, we identify each unit of account, and then determine whether a customer relationship exists for that unit of account. If we determine a performance obligation within the collaborative arrangement to be with a customer, we apply our revenue recognition accounting policy. If a portion of a distinct bundle of goods or services within the collaborative arrangement is not with a customer, we apply recognition and measurement based on an analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational and consistently applied accounting policy election. To the extent the arrangement is within the scope of Accounting Standards Codification, or ASC, Topic 808, we assess whether aspects of the arrangement between us and the collaboration partner are within the scope of other accounting literature. If we conclude that some or all aspects of the arrangement represent a transaction with a customer, we account for those aspects of the arrangement within the scope of ASC Topic 606, Revenue from Contracts with Customers (ASC 606).

Revenue Recognition

We recognize revenue in accordance with ASC 606, Revenue from Contracts with Customers, or Topic 606, which applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for contracts with customers, we perform the following

five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only 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. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price, reduced by a consideration payable to a customer, that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. We utilize key assumptions to determine a stand-alone selling price for performance obligations, which may include forecasted revenues or costs, expected development timelines, discount rates and probabilities of technical and regulatory success.

Results of Operations for the Years Ended December 31, 2024 and 2023

The following table sets forth our selected statements of operations data for the years ended December 31, 2024 and 2023:

	Years Ended December 31,		2024 vs 2023 Change
	2024	2023	
	(in thousands)		
Revenue:			
Revenue from sale of licenses	$ 90,682	$ —	$ 90,682
Revenue from contracts with collaborators	24,019	—	24,019
Total revenue	114,701	—	114,701
Operating expenses:			
Research and development	138,487	135,304	3,183
In process research and development	—	10,000	(10,000)
General and administrative	36,133	38,455	(2,322)
Total operating expenses	174,620	183,759	(9,139)
Loss from operations	(59,919)	(183,759)	123,840
Other income (expense)			
Interest income	1,779	1,997	(218)
Interest expense	(11,517)	(13,511)	1,994
Other income, net	14,022	15,456	(1,434)
Total other income (expense), net	4,284	3,942	342
Loss before provision for income taxes	(55,635)	(179,817)	124,182
Provision for income taxes	893	—	893
Net loss	$ (56,528)	$ (179,817)	$ 123,289

Operating Expenses

Revenue

For the year ended December 31, 2024, our revenue was $114.7 million. Our revenue is generated from our ongoing collaboration with Chiesi and consists of a one-time development cost reimbursement payment for the licenses and ongoing cost-sharing payments for performance of research and development and pre-commercial services.

Research and development expenses

Research and development expenses were $138.5 million for the year ended December 31, 2024, compared to $135.3 million for the year ended December 31, 2023, for an increase of $3.2 million, which was primarily attributable to an increase of $36.1 million of costs associated with clinical trials for seralutinib, offset by a decrease of $32.9 million of costs associated with preclinical studies and clinical trials for terminated programs.

The following table shows our research and development expenses by program for the years ended December 31, 2024 and 2023:

	Years Ended December 31,	
	2024	2023
	(in thousands)	
Seralutinib	$ 129,247	$ 93,158
Terminated programs	9,240	42,146
Total research and development	$ 138,487	$ 135,304

In process research and development expenses

There were no IPR&D expenses for the year ended December 31, 2024. IPR&D expenses for the year ended December 31, 2023 were $10.0 million, which was attributable to a milestone obligation incurred upon the initiation of the Phase 3 clinical trial of seralutinib in the fourth quarter of 2023 and paid to Pulmokine in 2024.

General and administrative expenses

General and administrative expenses were $36.1 million for the year ended December 31, 2024, compared to $38.5 million for the year ended December 31, 2023, for a decrease of $2.3 million, which was primarily attributable to a $2.2 million decrease in stock-based compensation expense, a decrease of $0.8 million in legal expense, a decrease of $0.6 million in insurance costs, offset by an increase of $0.6 million in professional services expense and an increase of $0.4 million in travel costs.

Other income (expense), net

Other income, net was $4.3 million for the year ended December 31, 2024, compared to other income, net of $3.9 million for the year ended December 31, 2023, for an increase of $0.3 million, which was primarily attributable to a $3.2 million increase in investment accretion and a $2.0 million decrease in interest expense, offset by a $3.6 million decrease in other income primarily related to $2.8 million of employee retention credit under the CARES Act and $1.0 million of Ireland Corporate R&D tax credit.

Provision for income taxes

For the year ended December 31, 2024, the tax expense was $0.9 million, which was primarily attributable to the treatment of the Chiesi income and a partial release of the valuation allowance. There was no provision for income taxes for the year ended December 31, 2023.

Results of Operations for the Years Ended December 31, 2023 and 2022

The discussion of our financial condition and results of operations for the year ended December 31, 2023 and the comparison of 2023 and 2022 results included in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2023 is incorporated by reference into this MD&A.

Liquidity and Capital Resources

We have incurred substantial operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2024 and 2023, we had an accumulated deficit of $1,268.6 million and $1,212.0 million, respectively.

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We may also use cash on hand to repurchase 2027 Notes through open-market transactions, including through a Rule 10b5-1 trading plan to facilitate open-market repurchases, or otherwise, from time to time.

Under our license agreement with Pulmokine, we have payment obligations that are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and are required to make royalty payments in connection with the sale of products developed under the agreement. As of December 31, 2024, we were

unable to estimate the timing or likelihood of achieving the milestones or making future product sales. Other contractual obligations include future payments under the 2027 Notes and existing operating leases.

From our inception through the year ended December 31, 2024, our operations have been financed primarily by proceeds of $1,401.1 million from the sale of Series A and Series B convertible preferred stock, proceeds from our IPO, proceeds from the 2027 Notes, proceeds from issuance of common stock in May 2020 and July 2022, proceeds from issuance of common stock and accompanying warrants in July 2023 and the collaboration agreement with Chiesi. As of December 31, 2024, we had cash, cash equivalents and marketable securities of $294.5 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation and liquidity.

On April 10, 2020, we filed a registration statement on Form S-3, or the 2020 Shelf Registration Statement, covering the offering from time to time of common stock, preferred stock, debt securities, warrants and units, which registration statement became automatically effective on April 10, 2020.

On May 21, 2020, we issued $200.0 million aggregate principal amount 5.00% convertible senior notes due 2027 in a registered public offering, or the 2027 Notes. The interest rate on the 2027 Notes is fixed at 5.00% per annum. Interest is payable semi-annually in arrears on June 1 and December 1 of each year commencing on December 1, 2020. The total net proceeds from the 2027 Notes, after deducting the underwriting discounts and commissions and other offering costs, were approximately $193.6 million. Concurrent with the registered underwritten public offering of the 2027 Notes, we completed an underwritten public offering of 9,433,963 shares of our common stock. We received net proceeds of $117.1 million, after deducting underwriting discounts and commissions and other offering costs. Our concurrent offerings of 2027 Notes and common stock were registered pursuant to the 2020 Shelf Registration Statement.

On July 15, 2022, we completed a private placement of 16,649,365 shares of our common stock. The aggregate gross proceeds for the private placement were approximately $120.1 million, before deducting offering expenses. On August 9, 2022, we filed a registration statement on Form S-3 registering the resale of the shares of common stock issued in the private placement, which became automatically effective on August 9, 2022.

On July 24, 2023, we completed a private placement of 129,869,440 shares of our common stock and 32,467,360 accompanying warrants. The aggregate gross proceeds for the private placement were $212.1 million, before deducting offering expenses. On August 18, 2023, we filed a registration statement on Form S-3 registering the resale of the shares of common stock and shares of common stock issuable upon the exercise of warrants issued in the private placement, which was declared effective on August 28, 2023.

On May 3, 2024, we entered into the collaboration agreement with Chiesi. In consideration and as reimbursement for our development costs, Chiesi paid us an up-front, nonrefundable payment of $160.0 million. In addition, we and Chiesi share equally in the costs of ongoing global seralutinib clinical development, with the exception of the PROSERA Phase 3 study, and the costs of commercialization in the United States. For the year ended on December 31, 2024, we received cost-sharing payments from Chiesi in the amount of $7.8 million.

Additional information about our long-term borrowings is presented in Note 5 “Indebtedness” and operating leases is presented in Note 11 "Commitments and Contingencies" to the Notes to Consolidated Financial Statements included in Part II, Item 8, of this Form 10-K, herein by this reference.

The following table shows a summary of our cash flows for each of the years shown below:

	Years Ended December 31,		
	2024	2023	2022
	(in thousands)		
Net cash used in operating activities	$ (3,468)	$ (159,158)	$ (187,032)
Net cash provided by (used in) investing activities	29,023	(110,970)	(1,035)
Net cash provided by (used in) financing activities	(11,488)	190,154	117,090
Effect of exchange rate changes on cash and cash equivalents	(102)	110	(517)
Net increase (decrease) in cash and cash equivalents	$ 13,965	$ (79,864)	$ (71,494)

Operating activities

During the year ended December 31, 2024, operating activities used approximately $3.5 million of cash, primarily resulting from a net loss of $56.5 million and changes in amortization of premium on investments, net of accretion of

discount, of $13.1 million, reduced by stock-based compensation expense of $20.6 million and changes in contract liabilities of $55.9 million.

During the year ended December 31, 2023, operating activities used approximately $159.2 million of cash, primarily resulting from a net loss of $179.8 million and changes in accrued research and development expenses of $7.8 million, changes in amortization of premium on investments of $9.5 million, reduced by stock-based compensation expense of $28.5 million and in process research and development expense of $10.0 million.

During the year ended December 31, 2022, operating activities used approximately $187.0 million of cash, primarily resulting from a net loss of $229.4 million and payments against operating lease liabilities of $2.7 million, partially reduced by stock-based compensation expense of $42.6 million and amortization of operating lease right-of-use assets of $2.6 million.

Investing activities

During the year ended December 31, 2024, investing activities provided approximately $29.0 million of cash, primarily resulting from the maturities of marketable securities of $523.8 million, offset by purchases of marketable securities of $494.8 million.

During the year ended December 31, 2023, investing activities used approximately $111.0 million of cash, primarily resulting from the purchases of marketable securities of $441.7 million, offset by the maturities of marketable securities of $330.7 million.

During the year ended December 31, 2022, investing activities used approximately $1.0 million of cash, primarily resulting from the purchase of marketable securities of $238.0 million and the purchase of property and equipment of $0.4 million, partially offset by maturities of marketable securities of $237.5 million.

Financing activities

During the year ended December 31, 2024, financing activities used $11.5 million of cash, resulting from the principal repayment of long-term debt of $12.6 million, reduced by the proceeds from the issuance of equity option pursuant to stock purchase agreement with Chiesi of $0.5 million and the proceeds from issuance of common stock pursuant to the ESPP of $0.6 million.

During the year ended December 31, 2023, financing activities provided $190.2 million of cash, primarily resulting from proceeds from the issuance of common stock and warrants in a private offering of $201.3 million, reduced by the principal repayments of long-term debt of $11.6 million.

During the year ended December 31, 2022, financing activities provided $117.1 million of cash, primarily resulting from proceeds from the purchase of shares pursuant to our 2019 Employee Stock Purchase Plan, or ESPP, of $1.2 million, proceeds from the private offering of $119.9 million, and proceeds from the exercise of stock options of $1.7 million, partially offset by the principal repayments of long-term debt of $5.8 million.

Funding requirements

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations through at least the next 12 months from the date these consolidated financial statements were available to be issued. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Additionally, the process of testing seralutinib in clinical trials is costly, and the timing of progress and expenses in these trials is uncertain.

Our future capital requirements will depend on many factors, including:

- the type, number, scope, progress, enrollment pace, expansions, results, costs and timing of, our preclinical studies and clinical trials of seralutinib which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing for seralutinib;

- the costs, timing and outcome of regulatory review of seralutinib;
- the costs of obtaining, maintaining and enforcing our patents and other intellectual property rights;
- our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company, including enhanced internal controls over financial reporting;
- the costs associated with hiring additional personnel and consultants to continue the development and potential commercialization of seralutinib;
- the timing and amount of the milestone or other payments we must make to Pulmokine from whom we have in-licensed seralutinib;
- the costs and timing of establishing or securing sales and marketing capabilities if seralutinib is approved;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- costs associated with any products or technologies that we may in-license or acquire; and
- any delays and cost increases that result from epidemic diseases.

Until such time as we can generate substantial product revenues to support our cost structure, if ever, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements.

However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. Our failure to raise capital or enter into such other arrangements when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. If we are unable to raise additional capital when needed, we could be forced to delay, limit, reduce or terminate seralutinib development or future commercialization efforts or grant rights to develop and market seralutinib even if we would otherwise prefer to develop and market seralutinib ourselves.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included elsewhere in this annual report.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. As of December 31, 2024 our cash and cash equivalents consisted of cash, money market funds and commercial paper, and our marketable securities consisted of commercial paper, corporate debt securities and U.S. Treasury and agency securities. We do not believe that we have a material exposure to interest rate risk. A 100 basis points change in interest rates would not have a significant impact on the total value of our portfolio.

We are exposed to market risk related to changes in foreign currency exchange rates associated with our foreign operations where we conduct business in local currencies. We also contract with vendors that are located outside of the United States and certain invoices are denominated in foreign currencies. We are subject to fluctuations in foreign currency rates in connection with these arrangements. We do not currently hedge our foreign currency exchange rate risk. As of December 31, 2024 and 2023, we had minimal assets and liabilities denominated in foreign currencies and an immediate

change of 10% in the exchange rate of the foreign currencies would result in a net impact of approximately $0.1 million in our consolidated balance sheets and consolidated statement of operations and comprehensive loss.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. Inflationary factors, such as increases in the cost of our materials, supplies, and overhead costs may adversely affect our operating results. Although we do not believe that inflation had a material effect on our business, financial condition or results of operations during the periods presented, we may experience adverse effects if inflation rates increase. Significant adverse changes in inflation and prices in the future could result in material losses.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements required pursuant to this item are incorporated by reference herein from the applicable information included in Item 15 of this annual report and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this annual report. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2024 that have materially affected, or are 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) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission

in its 2013 Internal Control — Integrated Framework. Based on this assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2024.

Item 9B. Other Information.

During the three months ended December 31, 2024, none of our officers or directors adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any “non Rule 10b5-1 trading arrangement."

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our definitive proxy statement to be filed with the Securities and Exchange Commission in connection with our 2025 Annual Meeting of Stockholders, or the Definitive Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2024, under the headings “Election of Directors,” “Corporate Governance,” “Our Executive Officers,” and, if applicable, “Delinquent Section 16(a) Reports,” and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees, which is available on our website at www.gossamerbio.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics and is intended to qualify as a “code of ethics” within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future. Information contained in our website does not constitute a part of this report or our other filings with the SEC.

We have adopted a policy on insider trading and procedures that govern the purchase, sale, and/or other dispositions of our securities by our directors, officers, employees and other covered persons that are designed to promote compliance with insider trading laws, rules and regulations, and the NASDAQ listing rules, as applicable. A copy of our policy on insider trading is filed as Exhibit 19.1 to this annual report on Form 10-K. It is our policy to comply with U.S. insider trading laws and regulations, including with respect to transactions in our own securities.

Item 11. Executive Compensation.

The information required by this item will be set forth in the section headed “Executive Compensation and Other Information” in our Definitive Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in the section headed “Security Ownership of Certain Beneficial Owners and Management” in our Definitive Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed "Executive Compensation and Other Information" in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in the section headed “Certain Relationships and Related Person Transactions,” “Board Independence” and “Board Committees and Independence” in our Definitive Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the section headed “Independent Registered Public Accounting Firm's Fees” in our Definitive Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) All Financial statements

The consolidated financial statements of Gossamer Bio, Inc., together with the report thereon of Ernst & Young LLP, an independent registered public accounting firm, are included in this annual report on Form 10-K beginning on page F-1.

(2) Financial statement schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

(3) Exhibits

A list of exhibits is set form on the Exhibit Index immediately preceding the signature page of this annual report on Form 10-K and is incorporated herein by reference.

Item 16. Form 10–K Summary.

None.

Gossamer Bio, Inc.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Gossamer Bio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Gossamer Bio, Inc. (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

Critical Audit Matters

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

Accrued Research and Development Expenses

Description of the Matter

As of December 31, 2024, the Company accrued $10.4 million for research and development expenses. As described in Note 2 of the consolidated financial statements, the Company records accruals for estimated research and development costs, comprising payments due for work performed by third party contractors, laboratories, participating clinical trial sites, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered. Clinical trial site costs are accrued as patients enter and progress through the trial.

Auditing management's accounting for accrued research and development expenses is especially challenging as evaluating the progress or stage of completion of the activities under the Company's research and development agreements is dependent upon a high volume of data from third-party service providers and internal clinical personnel, which is tracked in spreadsheets and other end user computing programs.

How We Addressed the Matter in Our Audit

To test the completeness of the Company's accrued research and development expenses, among other procedures, we obtained supporting evidence of the research and development activities performed for significant clinical trials. We corroborated the status of significant research and development activities through meetings with accounting and clinical project managers. To verify the appropriate measurement of accrued research and development costs, we compared the costs for a sample of transactions against the related invoices and contracts, and confirmed amounts incurred to-date with third-party service providers. We also examined a sample of subsequent payments to evaluate the completeness of the accrued research and development expenses.

Initial accounting for the Chiesi Collaboration Agreement

Description of the Matter

As more fully described in Note 12 to the consolidated financial statements, the Company entered into a global collaboration agreement with Chiesi Farmaceutici S.P.A and Chiesi USA, Inc. (collectively, "Chiesi"), which granted exclusive licenses to develop and commercialize products that contain or incorporate seralutinib for the treatment of pulmonary hypertension. The Company determined the transaction price was equal to the up-front fee reduced by the fair value of the Equity Option and the transaction price was allocated to the performance obligations based on the relative stand-alone selling price estimated for each performance obligation.

Auditing the Company's initial accounting for the Chiesi collaboration agreement was complex and required the Company to apply significant judgement related to the estimation of the standalone selling price of each identified performance obligation. The estimates of the standalone selling price for the performance obligations relating to the licenses reflect management's assumptions, which included forecasted revenues, expected development timelines, discount rates and probabilities of technical and regulatory success.

How We Addressed the Matter in Our Audit

To test the standalone selling price of each identified performance obligation, our audit procedures included, among others, evaluating the projected discounted cash flow assumptions used by the Company in developing the estimates of standalone selling price of the licenses by comparing the significant assumptions described above to current industry trends using available information from other similar companies within the same industry and other relevant factors. We involved our valuation professionals to assist in the assessment of the estimation methodology and the significant assumptions used in determining the estimated standalone selling price of these performance obligations. We also performed a sensitivity analysis of the significant assumptions to evaluate the change in the estimated standalone selling price of these performance obligations resulting from the changes in the assumptions. Further, we assessed the resulting impact from the sensitivity analysis on the allocation of transaction price to each performance obligation as well as revenue recognized during the period.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

San Diego, California
March 13, 2025

GOSSAMER BIO, INC.
Consolidated Balance Sheets
(in thousands, except share and par value amounts)

	December 31,	
	2024	**2023**
ASSETS		
Current assets		
Cash and cash equivalents	$ 46,074	$ 32,109
Marketable securities	248,444	264,316
Receivable from contracts with collaborators	5,338	—
Prepaid expenses and other current assets	10,032	10,094
Total current assets	309,888	306,519
Property and equipment, net	10	1,648
Operating lease right-of-use assets	5,111	3,131
Other assets	283	618
Total assets	**$ 315,292**	**$ 311,916**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,319	$ 5,526
Accrued research and development expenses	10,455	7,779
Current portion of long-term debt	—	11,613
Current contract liabilities	17,050	—
Accrued expenses and other current liabilities	15,186	26,680
Total current liabilities	45,010	51,598
Long-term convertible senior notes	197,523	196,591
Long-term debt	—	814
Operating lease liabilities - long-term	4,398	144
Long-term contract liabilities	38,869	—
Total liabilities	**285,800**	**249,147**
Commitments and contingencies (Note 11)		
Stockholders' equity		
Common stock, $0.0001 par value; 700,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 226,604,138 shares issued and outstanding as of December 31, 2024, and 225,409,315 shares issued and outstanding as of December 31, 2023	23	23
Additional paid-in capital	1,296,848	1,275,136
Accumulated deficit	(1,268,568)	(1,212,040)
Accumulated other comprehensive income (loss)	1,189	(350)
Total stockholders' equity	29,492	62,769
Total liabilities and stockholders' equity	**$ 315,292**	**$ 311,916**

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

GOSSAMER BIO, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2024	**2023**	**2022**
Revenue:			
Revenue from sale of licenses	$ 90,682	$ —	$ —
Revenue from contracts with collaborators	24,019	—	—
Total revenue	114,701	—	—
Operating expenses:			
Research and development	138,487	135,304	170,919
In process research and development	—	10,000	65
General and administrative	36,133	38,455	47,609
Total operating expenses	174,620	183,759	218,593
Loss from operations	**(59,919)**	**(183,759)**	**(218,593)**
Other income (expense)			
Interest income	1,779	1,997	1,583
Interest expense	(11,517)	(13,511)	(13,880)
Other income, net	14,022	15,456	1,512
Total other income (expense), net	4,284	3,942	(10,785)
Loss before provision for income taxes	**(55,635)**	**(179,817)**	**(229,378)**
Provision for income taxes	893	—	—
Net loss	**$ (56,528)**	**$ (179,817)**	**$ (229,378)**
Other comprehensive income (loss):			
Foreign currency translation	1,450	33	(544)
Unrealized income (loss) on marketable securities	89	191	(75)
Other comprehensive income (loss)	1,539	224	(619)
Comprehensive loss	**$ (54,989)**	**$ (179,593)**	**$ (229,997)**
Net loss per share, basic and diluted	$ (0.25)	$ (1.18)	$ (2.71)
Weighted average common shares outstanding, basic and diluted	226,228,016	152,621,669	84,574,869

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

GOSSAMER BIO, INC.
Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)

	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total stockholders equity
	Shares	Amount				
Balance as of December 31, 2021	75,752,664	$ 8	$ 932,944	$ (811,534)	$ 45	$ 121,463
Cumulative-effect adjustment from change in accounting principle (See Note 2)	—	—	(53,527)	8,689	—	(44,838)
Issuance of common stock in connection with a private offering, net of offering costs of $184	16,649,365	2	119,944	—	—	119,946
Vesting of restricted stock	662,700	—	—	—	—	—
Exercise of stock options	270,707	—	1,736	—	—	1,736
Stock-based compensation	—	—	42,553	—	—	42,553
Issuance of common stock pursuant to Employee Stock Purchase Plan	157,858	—	1,214	—	—	1,214
Issuance of common stock for restricted stock units vested	929,887	—	—	—	—	—
Net loss	—	—	—	(229,378)	—	(229,378)
Other comprehensive loss	—	—	—	—	(619)	(619)
Balance as of December 31, 2022	94,423,181	$ 10	$ 1,044,864	$	$ (574)	$ 12,077
Issuance of common stock and warrants in connection with a private offering, net of offering costs of $10,779	129,869,440	13	201,310	—	—	201,323
Vesting of restricted stock	55,225	—	—	—	—	—
Stock-based compensation	—	—	28,518	—	—	28,518
Issuance of common stock pursuant to Employee Stock Purchase Plan	336,795	—	444	—	—	444
Issuance of common stock for restricted stock units vested	724,674	—	—	—	—	—
Net loss	—	—	—	(179,817)	—	(179,817)
Other comprehensive income	—	—	—	—	224	224
Balance as of December 31, 2023	225,409,315	$ 23	$ 1,275,136	$	$ (350)	$ 62,769
Stock-based compensation	—	—	20,619	—	—	20,619
Issuance of common stock pursuant to Employee Stock Purchase Plan	767,125	—	629	—	—	629
Issuance of common stock for restricted stock units vested	427,698	—	—	—	—	—
Grant of equity option pursuant to Chiesi Collaboration Agreement	—	—	464	—	—	464
Net loss	—	—	—	(56,528)	—	(56,528)
Other comprehensive income	—	—	—	—	1,539	1,539
Balance as of December 31, 2024	226,604,138	$ 23	$ 1,296,848	$	$ 1,189	$ 29,492

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

GOSSAMER BIO, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2024	**2023**	**2022**
Cash flows from operating activities			
Net loss	$ (56,528)	$ (179,817)	$ (229,378)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	833	1,607	1,832
Stock-based compensation expense	20,619	28,518	42,553
In process research and development expenses	—	10,000	65
Amortization of operating lease right-of-use assets	3,318	2,778	2,597
Amortization of long-term debt discount and issuance costs	1,086	1,321	1,163
Amortization of premium on investments, net of accretion of discounts	(13,062)	(9,450)	(1,405)
Loss on disposal of property and equipment	806	726	—
Changes in operating assets and liabilities:			
Receivable from contracts with collaborators	(5,338)	—	—
Prepaid expenses and other current assets	62	(3,892)	296
Other assets	335	62	400
Operating lease liabilities	(3,386)	(2,982)	(2,721)
Accounts payable	(1,656)	3,990	(1,813)
Accrued expenses	(10,718)	(835)	(1,659)
Accrued research and development expenses	2,676	(7,847)	(579)
Accrued compensation and benefits	1,701	(3,240)	1,618
Contract liabilities	55,919	—	—
Accrued interest expense	(135)	(97)	(1)
Net cash used in operating activities	(3,468)	(159,158)	(187,032)
Cash flows from investing activities			
Research and development asset acquisitions, net of cash acquired	—	—	(65)
Purchase of marketable securities	(494,777)	(441,670)	(238,060)
Maturities of marketable securities	523,800	330,700	237,500
Purchase of property and equipment	—	—	(410)
Net cash provided by (used in) investing activities	29,023	(110,970)	(1,035)
Cash flows from financing activities			
Proceeds from issuance of common stock and warrants in a private offering, net of offering costs	—	201,323	119,946
Proceeds from issuance of common stock under Employee Stock Purchase Plan	629	444	1,214
Proceeds from the exercise of stock options	—	—	1,736
Proceeds from issuance of equity option pursuant to stock purchase agreement	464	—	—
Principal repayments of long-term debt	(12,581)	(11,613)	(5,806)
Net cash provided by (used in) financing activities	(11,488)	190,154	117,090
Effect of exchange rate changes on cash and cash equivalents	(102)	110	(517)
Net increase (decrease) in cash and cash equivalents	13,965	(79,864)	(71,494)
Cash and cash equivalents, at the beginning of the period	32,109	111,973	183,467
Cash and cash equivalents, at the end of the period	**$ 46,074**	**$ 32,109**	**$ 111,973**
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 10,561	$ 12,288	$ 12,712
Supplemental disclosure of noncash investing and financing activities:			
Right-of-use assets obtained in exchange for lease liabilities	$ 5,298	$ —	$ 3,029
Change in unrealized gain (loss) on marketable securities, net	$ 89	$ 191	$ (75)
Purchases of property and equipment included in accounts payable and accrued expenses and other current liabilities	$ —	$ —	$ 83

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

Gossamer Bio, Inc. Notes to Consolidated Financial Statements

Note 1—Description of Business

Gossamer Bio, Inc. (including its subsidiaries, referred to as "we," "us," "our,", or the “Company”) is a clinical-stage biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary hypertension ("PH') including pulmonary arterial hypertension ("PAH") and PH associated with interstitial lung disease ("PH-ILD"). The Company was incorporated in the state of Delaware on October 25, 2015 (originally as FSG Bio, Inc.) and is based in San Diego, California.

The consolidated financial statements include the accounts of Gossamer Bio, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions among the consolidated entity have been eliminated in consolidation.

Liquidity and Capital Resources

The Company has incurred significant operating losses since its inception. As of December 31, 2024, the Company had an accumulated deficit of $1,268.6 million. From the Company’s inception through the year ended December 31, 2024, the Company has funded its operations primarily through equity financings, convertible senior notes and the Chiesi Collaboration Agreement (as defined in Note 12 below).

The Company expects to continue to incur significant operating losses for the foreseeable future and may never become profitable. As a result, the Company will need to raise additional capital through equity offerings, debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. Management believes that it has sufficient working capital on hand to fund operations through at least the next 12 months from the date these consolidated financial statements were available to be issued. There can be no assurance that the Company will be successful in acquiring additional funding, that the Company’s projections of its future working capital needs will prove accurate, or that any additional funding would be sufficient to continue operations in future years.

Note 2—Summary of Significant Accounting Policies

Basis of Presentation

The Company’s consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“GAAP”).

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The most significant estimates in the Company’s consolidated financial statements relate to accrued research and development expenses, stand-alone selling price of performance obligations and estimated collaboration expenses associated with the Company’s collaboration and license agreement. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. Actual results could differ from those estimates.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents. The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents are valued at cost, which approximate their fair value.

Marketable Securities

The Company considers securities with original maturities of greater than 90 days to be marketable securities. The Company has the ability, if necessary, to liquidate any of its marketable securities to meet its liquidity needs in the next 12 months. Accordingly, those investments with contractual maturities greater than one year from the date of purchase are classified as current assets on the accompanying consolidated balance sheets which reflects management's intention to use the proceeds from sales of these securities to fund our operations, as necessary. The Company's marketable securities consist of U.S. Treasury and agency securities, commercial paper and corporate debt securities. Marketable securities are recorded at fair value and unrealized gains and losses are recorded within accumulated other comprehensive loss. The estimated fair value of the marketable securities is determined based on quoted market prices or rates for similar instruments. The Company evaluates securities with unrealized losses to determine whether such losses, if any, are due to credit-related factors. The Company records an allowance for credit losses when unrealized losses are due to credit-related factors. Realized gains and losses are calculated using the specific identification method and recorded in other income, net in the Company's consolidated statements of operation and comprehensive loss. The Company does not generally intend to sell the investments and it is not more likely than not that it will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity. The Company has determined that there were no material declines in fair values of its investments due to credit-related factors as of December 31, 2024.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash, cash equivalents and marketable securities are financial instruments that are potentially subject to concentrations of credit risk. The Company's cash and cash equivalents are deposited in accounts at large financial institutions, and amounts may exceed federally insured limits. The Company believes it is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash and cash equivalents are held. The Company maintains its cash equivalents in U.S. Treasury and agency securities and commercial paper with maturities less than three months and in money market funds that invest in U.S. Treasury and agency securities.

The Company's available for sale securities are also invested in U.S. Treasury and agency securities. The Company has not recognized any losses from credit risks on such accounts during any of the periods presented. The Company believes it is not exposed to significant credit risk on its cash, cash equivalents and available for sale securities.

Property and Equipment, Net

Property and equipment, net, which consists mainly of lab equipment and leasehold improvements, are carried at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the respective assets, generally two to seven years, using the straight-line method.

Convertible Senior Notes

Prior to the adoption of ASU 2020-06, the Company accounted for the 2027 Notes as a liability and equity component. The carrying amount of the liability component was calculated by measuring the fair value of similar debt instruments that do not have associated convertible features. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the 2027 Notes. The equity component was not re-measured as long as it continued to meet the condition for equity classification. The excess of the principal amount of the liability component over its carrying amount ("debt discount") was amortized to interest expense over the term of the 2027 Notes.

The Company allocated the issuance costs incurred to the liability and equity components of the 2027 Notes based on their relative fair values. Issuance costs attributable to the liability component were recorded as a reduction to the liability portion of the 2027 Notes and were amortized to interest expense over the term of the 2027 Notes. Issuance costs attributable to the equity component, representing the conversion option, were netted with the equity component in stockholders' equity.

Effective January 1, 2022 the Company adopted ASU 2020-06. After adoption, the Company now accounts for the 2027 Notes as a single liability measured at amortized cost. The impact upon adoption on the Consolidated Balance Sheets was an increase of approximately $44.8 million in convertible senior notes, net, a write-off of $9.4 million in deferred income tax liabilities and a decrease of $53.5 million in additional paid-in capital. In addition, upon adoption, there was an adjustment of $8.7 million to increase the beginning balance of accumulated deficit on the Consolidated Balance Sheets for previously recognized interest expense related to amortization of debt discount related to the carrying value of the embedded conversion feature upon issuance.

Leases

In accordance with Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), the Company determines if an arrangement is a lease at inception. Operating leases are included in the balance sheet as right-of-use assets and operating lease liabilities at the present value of the lease payments calculated using the Company's incremental borrowing rate, unless the implicit rate is readily available. The Company applied the short-term lease recognition exemption for leases with terms at inception not greater than 12 months and elected to not separate lease and non-lease components for its long-term leases. The Company records rent expense on a straight-line basis over the term of the lease.

Research and Development

All research and development costs are expensed as incurred. Research and development costs consist primarily of salaries, employee benefits, costs associated with preclinical studies and clinical trials (including amounts paid to clinical research organizations and other professional services). Payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

The Company records accruals for estimated research and development costs, comprising payments for work performed by third party contractors, laboratories, participating clinical trial sites, and others. Some of these contractors bill monthly based on actual services performed, while others bill periodically based upon achieving certain contractual milestones. For the latter, the Company accrues the expenses as goods or services are used or rendered. Clinical trial site costs related to patient enrollment are accrued as patients enter and progress through the trial. Upfront costs, such as costs associated with setting up clinical trial sites for participation in the trials, are expensed immediately once incurred as research and development expenses.

In process research and development

In process research and development costs relate to a milestone payment to Pulmokine for the initiation of the Phase 3 clinical trial for seralutinib.

Patent Costs

Costs related to filing and pursuing patent applications are expensed as incurred, as recoverability of such expenditures is uncertain. These costs are included in general and administrative expenses.

Income Taxes

Income taxes are recorded in accordance with Financial Accounting Standards Board ("FASB") ASC 740, *Income Taxes*, which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. 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. The Company's policy is to include interest and penalties related to income taxes within its provision (benefit) for income taxes.

The Company is subject to taxation in the United States, California, Florida, Ireland and Luxembourg. As of December 31, 2024, the Company's tax years since inception are subject to examination by taxing authorities due to the Company's unutilized net operating losses ("NOLs") and tax credits.

Collaborative Arrangements

The Company assesses whether its licensing and other agreements are collaborative arrangements based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. For arrangements that the Company determines are collaborations, it identifies each unit of account, and then determines whether a customer relationship exists for that unit of account. If the Company determines

a performance obligation within the collaborative arrangement to be with a customer, it applies its revenue recognition accounting policy. If a portion of a distinct bundle of goods or services within the collaborative arrangement is not with a customer, the Company applies recognition and measurement based on an analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational and consistently applied accounting policy election. To the extent the arrangement is within the scope of ASC 808, the Company assesses whether aspects of the arrangement between the Company and the collaboration partner are within the scope of other accounting literature. If the Company concludes that some or all aspects of the arrangement represent a transaction with a customer, the Company accounts for those aspects of the arrangement within the scope of ASC Topic 606, Revenue from Contracts with Customers (ASC 606). See Note 12, "Significant Agreements and Contracts," for more information.

Revenue Recognition

The Company recognizes revenue when a customer obtains control of promised goods or services in a contract for an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. For contracts with customers, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. As part of the accounting for contracts with customers, the Company develops assumptions that require judgment to determine the standalone selling price of each distinct performance obligation identified in the contract. In addition, variable consideration such as milestone payments are evaluated to determine if they are constrained and, therefore, excluded from the transaction price. The Company then allocates the total transaction price proportionally to each distinct performance obligation based on their estimated standalone selling prices, unless an allocation exception applies. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective distinct performance obligation when (or as) the performance obligation is satisfied.

In a contract with multiple performance obligations, the Company must develop estimates and assumptions that require judgment to determine the underlying standalone selling price for each distinct performance obligation, which determines how the transaction price is allocated among the distinct performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each distinct performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a distinct performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

If a license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from the allocated transaction price. The Company evaluates the measure of progress at each reporting period and, if necessary, adjusts the measure of performance and related revenue or expense recognition as a change in estimate.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company’s or a collaboration partner’s control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within its or a collaboration partner’s control, such as operational developmental milestones and any related constraint, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which will affect revenue from sale of licenses and revenue from contracts with collaborators in the period of adjustment. Revisions to the Company’s estimate of the transaction price may also result in negative revenue from sale of licenses and revenue from contracts with collaborators in the period of adjustment.

For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and a license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied, or partially satisfied. To date, the Company has not recognized any royalty revenue from collaborative arrangements.

For arrangements that include cost-share reimbursements, we will recognize such payments when control of the related goods or services are transferred to the customer. Cost-sharing reimbursements are presented as revenue from contracts with collaborators.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and non-employees over the requisite service period based on the estimated grant-date fair value of the awards. The Company records the expense for stock-based compensation awards subject to performance-based milestone vesting over the requisite service period when management determines that achievement of the milestone is probable. Management evaluates when the achievement of a performance-based milestone is probable based on the expected satisfaction of the performance conditions at each reporting date. The Company estimates the fair value of stock option grants and shares purchasable under the Company's 2019 Employee Stock Purchase Plan ("ESPP") using the Black-Scholes option pricing model, and the assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. The Company estimates the fair value of restricted stock units based on the closing price of the Company's common stock on the date of grant. The Company accounts for forfeitures as they occur. All share-based compensation costs are recorded in the statements of operations based upon the underlying employees or non-employee's roles within the Company.

Foreign Currency

Assets and liabilities of non-U.S. subsidiaries that operate in a local currency environment, where that local currency is the functional currency, are translated to U.S. dollars at exchange rates in effect at the balance sheet date. Income and expense accounts are translated at average exchange rates during the year which approximate the rates in effect at the transaction dates. The resulting translation adjustments are recorded in accumulated other comprehensive income (loss) in the Company's consolidated balance sheets. Foreign exchange transaction gains and losses are included in other income, net in the Company's consolidated statement of operations and comprehensive loss.

Recent Accounting Pronouncements - Adopted

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280) Improvements to Reportable Segment Disclosures ("Topic 280"), which modifies the disclosure and presentation requirements of reportable segments. The amendments in the update require the disclosure of significant segment expenses that are regularly provided to the Chief Operating Decision Maker ("CODM") and included within each reported measure of segment profit and loss. The amendments also require disclosure of all other segment items by reportable segment and a description of its composition. Additionally, the amendments require disclosure of the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss in assessing segment performance and deciding how to allocate resources. Lastly, the amendment requires that a public entity that has a single reportable segment provide all the disclosures required by ASU 2023-07 and all existing segment disclosures in Topic 280. This update is effective for annual periods beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. We have adopted this standard for our fiscal year ended December 31, 2024. We have applied this standard retrospectively for all prior periods presented in the financial statements. There was no impact on our reportable segments identified and additional required disclosures have been included in Note 13, Segment Reporting.

Recent Accounting Pronouncements - Not Yet Adopted

In December 2023, the FASB issued ASU 2023-09 "Income Taxes (Topics 740): Improvements to Income Tax Disclosures" to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. ASU 2023-09 is effective for our annual periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the potential effect that the updated standard will have on our consolidated financial statement disclosures.

Net Loss Per Share

Basic net loss per share of common stock is computed by dividing net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. The Company uses the if-converted method for assumed conversion of the 2027 Notes to compute the weighted average shares of common stock outstanding for diluted net loss per share. Diluted net loss per share excludes the potential impact of the Company's common stock options, warrants for the purchase of common stock, unvested shares of restricted stock and the potential shares issuable upon conversion of the 2027 Notes because their effect would be anti-dilutive due to the Company's net loss. Since the

Company had a net loss in each of the periods presented, basic and diluted net loss per common share are the same because the otherwise dilutive potential common shares become anti-dilutive and are therefore excluded.

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per share because to do so would be anti-dilutive (in common stock equivalent shares):

	December 31,		
	2024	2023	2022
2027 Notes	12,321,900	12,321,900	12,321,900
Shares issuable upon exercise of stock options	34,416,337	23,626,115	17,487,165
Shares issuable upon exercise of Chiesi Equity Option	22,433,809	—	—
Shares issuable upon exercise of warrants	32,467,360	32,467,360	—
Non-vested shares under restricted stock grants	—	427,698	1,350,035
Total potentially dilutive securities	101,639,406	68,843,073	31,159,100

Note 3—Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2024	2023
Accrued compensation and benefits	$ 11,995	$ 10,294
Operating lease liabilities	961	3,302
Accrued consulting fees	841	643
Accrued interest	833	968
Accrued legal fees	65	385
Accrued in process research and development	—	10,000
Accrued accounting fees	180	234
Accrued other	311	854
Total accrued expenses and other current liabilities	$ 15,186	$ 26,680

Note 4—Fair Value Measurements and Available for Sale Investments

Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;
Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company classifies its cash equivalents and available-for-sale investments within Level 1 or Level 2. The fair value of the Company's investment grade corporate debt securities and commercial paper classified as Level 2 is determined using proprietary valuation models and analytical tools, which utilize market pricing or prices for similar instruments that are both objective and publicly available, such as matrix pricing or reported trades, benchmark yields, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, and offers.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table presents the hierarchy for assets measured at fair value on a recurring basis as of December 31, 2024 and 2023 (in thousands):

	Fair Value Measurements at End of Period Using:			
	Total Fair Value	Quoted Market Prices for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
As of December 31, 2024				
Money market funds	$ 25,264	$ 25,264	$ —	$ —
U.S. Treasury and agency securities	56,900	56,900	—	—
Commercial paper	188,653	—	188,653	—
Corporate debt securities	19,963	—	19,963	—
As of December 31, 2023				
Money market funds	$ 25,222	$ 25,222	$ —	$ —
U.S. Treasury and agency securities	92,309	92,309	—	—
Commercial paper	168,534	—	168,534	—
Corporate debt securities	3,473	—	3,473	—

The Company did not reclassify any investments between levels in the fair value hierarchy during the periods presented.

Fair Value of Other Financial Instruments

As of December 31, 2024 and 2023, the carrying amounts of the Company’s financial instruments, which include cash, prepaid and other current assets, interest receivable, accrued research and development expenses, accounts payable and accrued expenses and other current liabilities, approximate fair values because of their short-term maturities.

There was $0.2 million interest receivable as of December 31, 2024. There was no significant interest receivable as of December 31, 2023. Interest receivable is recorded as a component of prepaid expenses and other current assets on the consolidated balance sheets.

As of December 31, 2024 and 2023 the fair value of the Company's 2027 Notes was $110.0 million and $74.9 million, respectively. The fair value was determined on the basis of market prices observable for similar instruments and is considered Level 2 in the fair value hierarchy (see Note 5).

Available for Sale Investments

The Company invests its excess cash in U.S. Treasury and agency securities, corporate debt securities, and commercial paper, which are classified as available-for-sale investments. These investments are carried at fair value and are included in the tables below. The Company evaluates securities with unrealized losses to determine whether such losses, if any, are due to credit-related factors. Realized gains and losses are calculated using the specific identification method and recorded in other income, net in the Company's consolidated statements of operations and comprehensive loss. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recover of their amortized cost basis.

The aggregate market value, cost basis, and gross unrealized gains and losses of available-for-sale investments by security type, classified in marketable securities as of December 31, 2024 and 2023 are as follows (in thousands except securities amounts):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
As of December 31, 2024				
U.S Treasury and agency securities	$ 56,875	$ 25	$ —	$ 56,900
Corporate debt securities	19,950	13	—	19,963
Commercial paper	188,537	142	(26)	188,653
Total marketable securities	$ 265,362	$ 180	$ (26)	$ 265,516
Number of securities with unrealized losses			5	
As of December 31, 2023				
U.S. Treasury and agency securities	$ 92,294	$ 20	$ (5)	$ 92,309
Corporate debt securities	3,467	$ 6	—	3,473
Commercial paper	168,488	76	(30)	168,534
Total marketable securities	$ 264,249	$ 102	$ (35)	$ 264,316
Number of securities with unrealized losses			12	

As of December 31, 2024 and December 31, 2023, the Company classified $25.3 million and $25.2 million, respectively, of assets with original maturities of 90 days or less as cash and cash equivalents.

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are due to credit-related factors. The Company records an allowance for credit losses when unrealized losses are due to credit-related factors. Factors considered when evaluating available-for-sale investments for impairment include the severity of the impairment, changes in underlying credit ratings, the financial condition of the issuer, the probability that the scheduled cash payments will continue to be made and the Company's intent and ability to hold the investment until recovery of the amortized cost basis. The Company intends and has the ability to hold its investments in unrealized loss positions until their amortized cost basis has been recovered. As of December 31, 2024 and 2023, there were no material declines in the market value of the Company's available-for-sale investments due to credit-related factors.

Contractual maturities of available-for-sale debt securities, as of December 31, 2024, were as follows (in thousands):

	Estimated Fair Value
Less than one year	$ 265,516
Greater than one year	—
Total	$ 265,516

The Company has the ability, if necessary, to liquidate any of its cash equivalents and marketable securities to meet its liquidity needs in the next 12 months.

Note 5—Indebtedness

Credit Facility

On May 2, 2019, the Company entered into a credit, guaranty and security agreement, as amended on September 18, 2019, July 2, 2020, December 7, 2022 and February 14, 2023 (the "Credit Facility"), with MidCap Financial Trust ("MidCap"), as agent and lender, and the additional lenders party thereto from time to time (together with MidCap, the "Lenders"), pursuant to which the Lenders, agreed to make term loans available to the Company for working capital and general business purposes, in a principal amount of up to $150.0 million in term loan commitments, including a $30.0 million term loan that was funded at the closing date, with the ability to access the remaining $120.0 million in two additional tranches (each $60.0 million), subject to specified availability periods, the achievement of certain clinical development milestones, minimum cash requirements and other customary conditions. On May 3, 2024, the Credit Facility was terminated and the Company recorded a $7.7 million payment of the outstanding debt balance in full and discharged, which released the Company from the obligations under the Credit Facility, and Lenders' security interests in the Company's assets and property were

released. Unamortized debt discount and issuance costs were written off and recorded in interest expense on the consolidated statements of operations and comprehensive loss. Since the Credit Facility was terminated, there was no debt outstanding as of December 31, 2024.

5.00% Convertible Senior Notes due 2027

On May 21, 2020, the Company issued $200.0 million aggregate principal amount of 5.00% convertible senior notes due 2027 in a public offering (the "2027 Notes"). The 2027 Notes were registered pursuant to the Company's shelf registration statement on Form S-3 filed with the SEC on April 10, 2020. The interest rate on the 2027 Notes is fixed at 5.00% per annum. Interest is payable semi-annually in arrears on June 1 and December 1 of each year, commencing on December 1, 2020. The 2027 Notes will mature on June 1, 2027. The net proceeds from the offering, after deducting the underwriting discounts and commissions and other offering costs, were approximately $193.6 million. The 2027 Notes may be settled in cash, shares of the Company's common stock, or a combination thereof, solely at the Company's election. The initial conversion rate of the 2027 Notes is 61.6095 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $16.23 per share, subject to adjustments. In addition, following certain corporate events that occur prior to the maturity date or if the Company issues a notice of redemption, the Company will increase the conversion rate for a holder who elects to convert its 2027 Notes in connection with such a corporate event during the related redemption period in certain circumstances.

The 2027 Notes are senior unsecured obligations of the Company, ranking senior in right of payment to any of the Company's indebtedness that is expressly subordinated in right of payment to the 2027 Notes, and are effectively subordinated to the Company's existing and future secured indebtedness, to the extent of the value of the collateral securing that indebtedness.

Holders may convert their notes at their option only in the following circumstances: (1) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on September 30, 2020, if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price for each of at least 20 trading days (whether or not consecutive) during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter; (2) during the five consecutive business days immediately after any 10 consecutive trading day period (such 10 consecutive trading day period, the "measurement period") in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate on such trading day; (3) upon the occurrence of certain corporate events or distributions on the Company's common stock; (4) if the Company calls such notes for redemption; and (5) at any time from, and including, March 1, 2027 until the close of business on the scheduled trading day immediately before the maturity date.

The Company did not have the right to redeem the 2027 Notes prior to June 6, 2024. As of December 31, 2024, the Company has not redeemed the 2027 Notes. On or after June 6, 2024 and on or before the 50th scheduled trading day immediately before the maturity date, the Company may redeem the 2027 Notes, in whole or in part, if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect on (1) each of at least 20 trading days (whether or not consecutive) during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends the related redemption notice; and (2) the trading day immediately before the date the Company sends such notice. In the case of any optional redemption, the Company will redeem the 2027 Notes at a redemption price equal to 100% of the principal amount of such Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

If the Company undergoes a fundamental change prior to the maturity date of the 2027 Notes, holders of the 2027 Notes may require the Company to repurchase for cash all or part of their 2027 Notes at a repurchase price equal to 100% of the principal amount of the 2027 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The indenture governing the 2027 Notes provides for customary terms and covenants, including that upon certain events of default, either the trustee or the holders of not less than 25% in aggregate principal amount of the 2027 Notes then outstanding may declare the unpaid principal amount of the 2027 Notes and accrued and unpaid interest, if any, thereon immediately due and payable. As of December 31, 2024, the Company was in compliance with these covenants. In the case of certain events of bankruptcy, insolvency or reorganization, the principal amount of the 2027 Notes together with accrued and unpaid interest, if any, thereon will automatically become and be immediately due and payable.

As of December 31, 2024 and 2023, there were no events or market conditions that would allow holders to convert the 2027 Notes. When the 2027 Notes become convertible within 12 months of the balance sheet date, the carrying value of the 2027 Notes will be reclassified to short-term.

The Company accounts for the 2027 Notes as a single liability measured at amortized cost. As the equity component is no longer required to be split into a separate component, the Company recorded an adjustment to reflect this update.

The Company recorded $0.4 million of the debt issuance costs related to the 2027 Notes as a reduction to the liability and amortizes these costs to interest expense over the term of the 2027 Notes.

The net carrying amount of the 2027 Notes was as follows (in thousands):

	December 31,	
	2024	2023
Principal amount	$ 200,000	$ 200,000
Unamortized debt discount	(2,321)	(3,194)
Unamortized debt issuance cost	(156)	(215)
Net carrying amount	$ 197,523	$ 196,591

The following table sets forth the interest expense recognized related to the 2027 Notes (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Contractual interest expense	$ 10,000	$ 10,000	$ 10,000
Amortization of debt discount	873	826	782
Amortization of debt issuance cost	59	56	53
Total interest expense related to the 2027 Notes	$ 10,932	$ 10,882	$ 10,835

Note 6—Licenses, Asset Acquisitions and Contingent Consideration

The following purchased assets were accounted for as asset acquisitions as substantially all of the fair value of the assets acquired were concentrated in a group of similar assets and/or the acquired assets were not capable of producing outputs due to the lack of employees and early stage of development. Because the assets had not yet received regulatory approval, the fair value attributable to these assets was recorded as in process research and development ("IPR&D") expenses in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2024, 2023, and 2022.

The Company accounts for contingent consideration payable upon achievement of certain regulatory, development or sales milestones in such asset acquisitions when the underlying contingency is met.

License from Pulmokine, Inc. (Seralutinib)

On October 2, 2017, the Company entered into a license agreement with Pulmokine, Inc. under which it was granted an exclusive worldwide license and sublicense to certain intellectual property rights owned or controlled by Pulmokine to develop and commercialize seralutinib and certain backup compounds for the treatment, prevention and diagnosis of any and all disease or conditions. On November 26, 2024, Pulmokine became a wholly-owned subsidiary of XOMA Royalty Corporation. The Company also has the right to sublicense its rights under the license agreement, subject to certain conditions. The assets acquired are in the early stages of the FDA approval process, and the Company intends to further develop the assets acquired through potential FDA approval as evidenced by the milestone arrangement in the contract. The development activities cannot be performed without significant cost and effort by the Company. The agreement will remain in effect from the effective date, unless terminated earlier, until, on a licensed product-by-licensed product and country-by-country basis, the later of ten years from the date of first commercial sale or when there is no longer a valid patent claim covering such licensed product or specified regulatory exclusivity for the licensed product in such country. The Company is obligated to make future development and regulatory milestone payments of up to $48.0 million, which includes a payment of $5.0 million due upon initiation of a Phase 3 clinical trial in a second indication, commercial milestone payments of up to $45.0 million, and sales milestone

payments of up to $190.0 million. The Company is also obligated to pay tiered royalties on sales for each licensed product, at percentages ranging from the mid-single digits to the high single-digits. In addition, if the Company chooses to sublicense or assign to any third parties its rights under the agreement with respect to a licensed product, or the Company's seralutinib operating subsidiary undergoes a change of control, the Company must pay to Pulmokine a specified percentage of all revenue to be received in connection with such transaction. The Company made an upfront payment of $5.5 million in October 2017. The Company made a milestone payment of $5.0 million in connection with the initiation of the first Phase 2 clinical trial of seralutinib in January 2021 and made a milestone payment of $10.0 million, which was accrued in 2023, in connection with the initiation of the Phase 3 clinical trial of seralutinib in January 2024. The Company recognized these milestone payments as research and development expense on its consolidated statements of operations and comprehensive loss. As of December 31, 2024, no other milestones had been accrued as the underlying contingencies had not yet been met.

The Company recorded the following IPR&D expense on the consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Seralutinib	$ —	$ 10,000	$ —
Terminated programs	—	—	65
Total in process research and development	$ —	$ 10,000	$ 65

Note 7—Income Taxes

The amount of net loss before taxes for the years ended December 31, 2024, 2023, and 2022 is as follows:

	December 31,		
	2024	2023	2022
	(in thousands)		
U.S. loss before taxes	$ 32,178	$ 134,073	$ 175,777
Foreign loss before taxes	23,457	45,736	53,593
Pre-tax Loss	$ 55,635	$ 179,809	$ 229,370

A reconciliation of income tax expense for the years ended December 31, 2024, 2023 and 2022 is as follows:

	December 31,		
	2024	2023	2022
	(in thousands)		
Current:			
Federal	$ 886	$ —	$ —
State	7	8	8
Total income tax expense	$ 893	$ 8	$ 8

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities at December 31, 2024, 2023 and 2022 are shown below. The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of the deferred assets. At such time as it is determined that it is more likely than not that the deferred tax asset will be realized, the valuation allowance will be reduced. The change in the valuation allowance for the year ended December 31, 2024 was an increase of $7.4 million.

	December 31,		
	2024	2023	2022
	(in thousands)		
Deferred tax assets:			
Net operating losses	$ 97,940	$ 122,987	$ 128,989
Deferred loss	10,575	—	—
Capital loss	20,348	—	—
Tax credits	44,803	45,445	34,193
Amortization	2,646	6,919	8,487
Stock-based compensation	10,984	9,886	8,445
Lease liability	1,135	726	1,354
Accrued compensation	547	1,887	2,514
Section 174 capitalization	35,715	34,268	21,840
Other	5,076	43	37
Total gross deferred tax assets	229,769	222,161	205,859
Deferred tax liabilities:			
Other	(3)	—	—
Right of use asset	(1,083)	(660)	(1,244)
Property, plant and equipment	—	(108)	(565)
Total gross deferred tax liabilities	(1,086)	(768)	(1,809)
Valuation allowance	(228,683)	(221,393)	(204,050)
Net deferred tax asset	$ —	$ —	$ —

As of December 31, 2024, the Company had federal and state NOL carryforwards of approximately $398.1 million and $3.3 million, respectively. The federal NOL carryforwards can be carried forward indefinitely and be available to offset up to 80% of future taxable income each year. The California NOL carryforwards begin to expire in 2036. As of December 31, 2024, the Company also has Irish NOL carryforwards of approximately $113.0 million, which can be carried forward indefinitely. In the current year, the Company removed federal and foreign NOL carryforwards of $141.0 million and $0.4 million, respectively, as a result of mergers and liquidations.

As of December 31, 2024, the Company also had orphan drug credit and federal research tax credit carryforwards of approximately $48.2 million and California research tax credits of $13.2 million. The federal research tax credit carryforwards begin to expire in 2038, and the California research tax credit carryforward does not expire and can be carried forward indefinitely until utilized. In the current year, the Company removed federal and California credit carryforwards of $9.7 million and $0.4 million, respectively, as a result of mergers.

A reconciliation of the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	December 31,		
	2024	2023	2022
Federal statutory income tax rate	21.00%	21.00%	21.00%
Change in valuation allowance	(12.38%)	(8.73%)	(20.25%)
Research and experimentation credits	3.03%	5.69%	3.39%
Foreign rate differential	(3.75%)	(2.13%)	(1.88%)
GILTI	(4.72%)	—%	—%
Stock-based compensation	(4.61%)	(1.44%)	(0.90%)
Nondeductible interest	(4.13%)	(1.27%)	(0.99%)
Domestic/Foreign Restructuring Impact	2.52%	(12.49%)	—%
Other	1.44%	(0.62%)	(0.37%)
Provision for income taxes	(1.60%)	—%	—%

The NOL carryforward may be subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state provisions if the Company experienced one or more ownership changes which would limit the amount of NOL and tax credit carryforwards that can be utilized to offset future taxable income and tax respectively. In general, an ownership change as defined by Sections 382 and 383, results from the transactions increasing ownership of certain stockholders or public groups in the stock of the corporation of more than 50 percentage points over a three-year period. The Company had an ownership change with the IPO in February of 2019 which resulted in no forfeiture of NOLs or credits. The Company had an additional ownership change in July of 2023, which resulted in a significant limitation on the Company's utilization of its NOLs and is expected to result in forfeiture of some or all of the federal credits. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

The Company files income tax returns in the United States, California, Florida, Ireland, and Luxembourg. Due to the Company's losses incurred, the Company is subject to the income tax examination by authorities since inception. The Company's policy is to recognize interest expense and penalties related to income tax matters as tax expense. For the years ended December 31, 2024, 2023 and 2022 and as of December 31, 2024 and 2023, there were no accruals for interest related to unrecognized tax benefits or tax penalties.

A reconciliation of the beginning and ending amount of unrecognized tax benefits for 2024, 2023, and 2022, excluding interest and penalties, is as follows:

	December 31,		
	2024	2023	2022
	(in thousands)		
Balance at beginning of the year	$ 13,654	$ 10,572	$ 7,551
Decrease related to prior year positions	(2,028)	—	—
Increase related to current year positions	2,293	3,082	3,021
Balance at the end of the year	$ 13,919	$ 13,654	$ 10,572

Included in the balance of unrecognized tax benefits at December 31, 2024 is $13.9 million that, if recognized, would not impact the Company's income tax benefit or effective tax rate as long as the Company's deferred tax asset remains subject to a full valuation allowance. The Company does not expect any significant increases or decreases to the Company's unrecognized tax benefits within the next 12 months.

Note 8—Stockholders' Equity

Common Stock

Each share of common stock is entitled to one vote. Common stock owners are entitled to dividends when funds are legally available and declared by the Company's board of directors.

Shelf Registration Statement and Stock Offering

On April 10, 2020, the Company filed a universal shelf registration statement on Form S-3, covering the offering from time to time of common stock, preferred stock, debt securities, warrants and units, which registration statement became automatically effective on April 10, 2020 (the "Shelf Registration Statement").

On May 21, 2020, the Company completed a public offering of 9,433,963 shares of its common stock at a public offering price of $13.25 per share. The net proceeds from the offering, after deducting underwriting discounts and commissions and other offering costs, were approximately $117.1 million. The shares sold in the offering were registered pursuant to the Company's Shelf Registration Statement.

Private Placement Financing

On July 15, 2022, the Company completed a private placement of 16,649,365 shares of the Company's common stock at purchase price of $7.21 per share. The gross proceeds for the private placement were $120.1 million, before deducting offering expenses, which equaled $0.2 million. On August 9, 2022, the Company filed a registration statement on Form S-3 registering the shares of common stock issued in the private placement, which registration statement became automatically effective on August 9, 2022.

On July 24, 2023, the Company completed a private placement of 129,869,440 shares of the Company's common stock and accompanying warrants to purchase up to 32,467,360 shares of the Company's common stock at a combined

purchase price of $1.63125 per share and accompanying warrant, or with respect to any purchaser that was an officer, director, employee or consultant of the Company $1.85125, per share and accompanying warrant. Each warrant has an exercise price per share of $2.04, was immediately exercisable on the date of issuance and will expire five years from the closing of the private placement. The aggregate gross proceeds for the private placement were $212.1 million, before deducting offering expenses, which equaled $10.8 million. On August 18, 2023, the Company filed a registration statement on Form S-3 registering the shares of common stock and shares of common stock issuable upon the exercise of warrants issued in the private placement, which registration statement was declared effective on August 28, 2023.

Shares of Common Stock Subject to Repurchase

On December 3, 2015, the Company issued 9,160,888 shares of common stock as founder shares for services rendered to the Company, valued at $0.0001 par value per share, for a total of approximately $4,100 (the “founder shares”). On January 4, 2018, incremental vesting conditions were placed on the previously issued founder shares. Fifty percent of the previously issued founder shares vested on January 4, 2018, and the remaining founder shares are subject to vesting restrictions over a period of five years. These shares are subject to repurchase by the Company upon a founder's termination of employment or service to the Company.

Pursuant to the employment agreements with the Company’s founders executed January 4, 2018, the Company provided for certain potential additional issuances of common stock (the “anti-dilution shares”) to each of the founders to ensure the total number of shares of common stock held by them and their affiliates (inclusive of any shares subject to equity awards granted by the Company) would represent 15% of the Company’s fully-diluted capitalization until such time as the Company raised $300.0 million in equity capital, including the capital raised in the Series A financing.

In furtherance of this obligation, on May 21, 2018, the Company issued 251,547 shares of common stock to the founders for services rendered to the Company, valued at $2.61 per share with an additional 251,547 shares of restricted stock subject to the same vesting restrictions and vesting period as the founder shares. In addition, on September 6, 2018, the Company issued 1,795,023 shares of common stock to the founders for services rendered to the Company, valued at $9.63 per share, with an additional 1,795,023 shares of restricted stock subject to the same vesting restrictions and vesting period as the founder shares.

Any shares subject to repurchase by the Company are not deemed, for accounting purposes, to be outstanding until those shares vest. As such, the Company recognizes the measurement date fair value of the restricted stock over the vesting period as compensation expense. As of December 31, 2024, there were no shares of common stock subject to repurchase by the Company. The unvested stock liability related to these awards is immaterial to all periods presented.

Chiesi Equity Option

On May 3, 2024, pursuant to the Chiesi Collaboration Agreement (as defined in Note 12 below) the Company granted to Chiesi (as defined in Note 12 below) an option to purchase directly from the Company, on one or more occasions, up to an aggregate number of shares of the Company’s common stock (the "Equity Option") such that immediately following such issuance, Chiesi’s beneficial ownership of the Company’s common stock shall not exceed 9.9% of the total number of issued and outstanding shares of the Company’s common stock. The Equity Option shall be exercisable by Chiesi, in whole or in part, at any time prior to the earliest to occur of the date on which (a) the last patient is last dosed in either (i) the PROSERA Phase 3 study for PAH or (ii) a Phase 3 clinical trial for the PH-ILD Indication, (b) any third party commences a tender offer or exchange offer for more than 50% of the outstanding shares of the Company’s common stock, and (c) the Company publicly announces its intent to consummate a GB002, Inc. change of control. The purchase price of each share the Company’s common stock subject to the Equity Option shall be equal to 107.5% of the daily volume-weighted average per share price of the Company’s common stock on The Nasdaq Stock Market over the 30-trading day period ending on and including the last trading day prior to the date on which Chiesi delivers an exercise notice to the Company; provided that such purchase price shall be no less than $1.63 per share. The shares of the Company’s common stock to be issued will be issued in a private placement in reliance on Section 4(a)(2) of the Securities Act of 1933, as amended, for transactions by an issuer not involving any public offering, pursuant to the terms of a stock issuance agreement to be entered into between the Company and Chiesi in connection with each such exercise of the Equity Option. The Company evaluated the Equity Option granted to Chiesi as consideration payable to a customer and determined it qualified under ASC 718. Due to the market condition included in the Equity Option, the Company used the Geometric Brownian Motion/Monte Carlo model to determine fair market value. The value of the Equity Option is $0.5 million, which is included in additional paid-in capital on the Company's consolidated balance sheets.

Note 9—Equity Incentive Plans

2023 Equity Inducement Incentive Plan

In November 2023, the Company approved the 2023 Employment Inducement Incentive Plan (the "2023 Inducement Plan"). The terms of the 2023 Inducement Plan are substantially similar to the terms of the Company's 2019 Incentive Award Plan (as described below) with the exception that incentive stock options may not be issued under the 2023 Inducement Plan and awards under the 2023 Inducement Plan may only be issued to eligible recipients under the applicable Nasdaq rules. The 2023 Inducement Plan was adopted without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, awards under the 2023 Inducement Plan may only be made to an employee who has not previously been an employee or member of the board of directors of the Company or any parent or subsidiary, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. The Company has initially reserved 6,762,279 shares of the Company's common stock for issuance pursuant to awards granted under the 2023 Inducement Plan. As of December 31, 2024, an aggregate of 4,152,779 shares of common stock were available for issuance under the 2023 Inducement Plan, and 2,609,500 shares of common stock were subject to outstanding awards under the 2023 Inducement Plan.

2019 Equity Incentive Plan

In January 2019, the Company's board of directors and stockholders approved and adopted the 2019 Incentive Award Plan (the "2019 Plan"). The 2019 Plan became effective on February 6, 2019, the day prior to the effectiveness of the registration statement filed in connection with the IPO. Under the 2019 Plan, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock or cash-based awards to individuals who are then employees, officers, directors or consultants of the Company, and employees and consultants of the Company's subsidiaries. A total of 5,750,000 shares of common stock were approved to be initially reserved for issuance under the 2019 Plan. The number of shares that remained available for issuance under the 2017 Plan (as defined below) as of the effective date of the 2019 Plan were, and shares subject to outstanding awards under the 2017 Plan as of the effective date of the 2019 Plan that are subsequently canceled, forfeited or repurchased by the Company will be added to the shares reserved under the 2019 Plan. In addition, the number of shares of common stock available for issuance under the 2019 Plan will be automatically increased on the first day of each calendar year during the ten-year term of the 2019 Plan, beginning with January 1, 2020 and ending with January 1, 2029, by an amount equal to 5% of the outstanding number of shares of the Company's common stock on December 31 of the preceding calendar year or such lesser amount as determined by the Company's board of directors. As of December 31, 2024, an aggregate of 2,308,197 shares of common stock were available for issuance under the 2019 Plan and 29,747,623 shares of common stock were subject to outstanding awards under the 2019 Plan.

2019 Employee Stock Purchase Plan

In January 2019, the Company's board of directors and stockholders approved and adopted the 2019 Employee Stock Purchase Plan (the "ESPP"). The ESPP became effective as of February 6, 2019, the day prior to the effectiveness of the registration statement filed in connection with the IPO. The ESPP permits participants to purchase common stock through payroll deductions of up to 20% of their eligible compensation. A total of 700,000 shares of common stock were approved to be initially reserved for issuance under the ESPP. In addition, the number of shares of common stock available for issuance under the ESPP will be automatically increased on the first day of each calendar year during the first ten-years of the term of the ESPP, beginning with January 1, 2020 and ending with January 1, 2029, by an amount equal to 1% of the outstanding number of shares of the Company's common stock on December 31 of the preceding calendar year or such lesser amount as determined by the Company's board of directors. During the years ended December 31, 2024 and 2023, 767,125 shares and 336,795 shares were issued pursuant to the ESPP, respectively. As of December 31, 2024, an aggregate of 4,545,812 shares of common stock were available for issuance under the ESPP.

2017 Equity Incentive Plan

The Company's 2017 Equity Incentive Plan (the "2017 Plan") permitted the granting of incentive stock options, non-statutory stock options, restricted stock, restricted stock units and other stock-based awards. Subsequent to the adoption of the 2019 Plan, no additional equity awards can be made under the 2017 Plan. As of December 31, 2024, 2,059,214 shares of common stock were subject to outstanding options under the 2017 Plan, and no shares of restricted stock awards granted under the 2017 Plan were unvested.

Stock Options

The fair value of each employee and non-employee time-vested stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company uses its own volatility to the extent it has sufficient trading history, and for awards in which sufficient trading history is not available, a peer group is used to calculate the expected volatility. Due to the lack of historical exercise history, the expected term of the Company's stock options for employees has been determined utilizing the "simplified" method for awards. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

On May 5, 2023, the Company granted to its Chairman and Chief Executive Officer 750,000 options with an exercise price of $1.36 per share. This grant contains both service and market based vesting conditions. The awards vest on the later of the date of achievement and the one-year anniversary of the grant date. The market condition becomes satisfied in 50%, 25% and 25% tranches upon achieving the average per-share closing price of the Company's common stock over any 30 consecutive calendar days following the grant date equal to or exceeding $5.00, $7.50 and $10.00, respectively. In the event a stock price tranche has not vested prior to the fourth anniversary of the grant date, any portion of the option attributable to such tranche will be forfeited. Due to the market condition included in this grant, the Company used the Geometric Brownian Motion/Monte Carlo model to value this award. The total stock-based compensation expense related to this award is $0.4 million, which is included in general and administrative expense on the consolidated statements of operations and comprehensive loss. The Company expects to recognize this expense over a weighted average period of approximately 2.2 years.

Effective May 5, 2023, and in accordance with the terms of the 2019 Plan, the Company's board of directors approved a stock option repricing (the "Option Repricing") whereby the exercise price of each Eligible Option (as defined below) was immediately reduced to $1.36 per share, the closing stock price on May 5, 2023. For purposes of the Option Repricing, "Eligible Options" are 6,817,057 outstanding stock options as of May 5, 2023 (vested or unvested) granted under the 2019 Plan prior to November 30, 2022 and held by those eligible employees of the Company identified by the Company's board of directors, including the Company's executive officers, except for the Company's Chairman and Chief Executive Officer.

The participation of the executive officers of the Company in the Option Repricing was subject to their agreement to cancel a portion of their Eligible Options effective immediately (the "Cancelled Options"). Each executive was required to agree to cancel one-third of his or her Eligible Options, on a grant-by-grant basis. The Cancelled Options were deducted proportionately from the vested and unvested portions of each Repriced Option grant.

To the extent an Eligible Option is exercised prior to the Premium End Date (as defined below), or the eligible employee's employment terminates prior to the Premium End Date, the eligible employee will be required to pay the original exercise price per share of the Eligible Options in connection with any exercise of the Eligible Option. The "Premium End Date" means the earliest of (i) May 5, 2024, (ii) the date of a change in control, (iii) the eligible employee's death or disability, or (iv) if an eligible employee is an executive subject to the cancellation of a portion of Eligible Options and is terminated under circumstances giving rise to severance under his or her employment agreement, the date of such termination. Except for the reduction in the exercise prices of the Eligible Options as described above, the Eligible Options will retain their existing terms and conditions as set forth in the 2019 Plan and the applicable award agreements.

The repricing resulted in $3.4 million of incremental cost, which was calculated using the Black-Scholes option-pricing model, of which $2.0 million of the incremental cost was recognized immediately, and $1.4 million of the incremental cost will be recognized on the straight-line basis over the remaining vesting period of the repriced options. The incremental cost is included in general and administrative expense and research and development expense on the consolidated statements of operations and comprehensive loss.

The following assumptions were used to estimate the fair value of stock option awards granted to employees under the Company's equity incentive plans and the shares purchasable under the ESPP during the periods presented:

	Year Ended December 31,		
	2024	2023	2022
Employee Stock Options			
Expected term (in years)	4.6 - 6.1	1.0 - 7.0	4.4 - 6.1
Risk-free interest rate	3.59% - 4.50%	3.36% - 4.73%	1.31% - 4.35%
Volatility	100.72% - 104.51%	70.01% - 170.69%	71.10% - 89.87%
Dividend yield	—	—	—
Employee Stock Purchase Plan			
Expected term (in years)	0.5 - 2.0	0.5 - 2.0	0.5 - 2.0
Risk-free interest rate	3.88% -5.27%	4.87% - 5.47%	0.60% - 3.51%
Volatility	83.96% - 151.54%	115.19% - 216.45%	64.98% - 121.43%
Dividend yield	—	—	—

The following table summarizes stock option activity for the years ended December 31, 2024, 2023 and 2022:

	Shares Subject to Options Outstanding		Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
	Shares	Weighted-Average Exercise Price		(in thousands)
Outstanding as of December 31, 2021	9,434,660	$ 12.24	7.4	$ 15,822
Options granted	9,271,272	$ 6.75		
Options exercised	(270,707)	$ 6.41		
Options forfeited/cancelled	(948,060)	$ 15.69		
Outstanding as of December 31, 2022	17,487,165	$ 9.24	8.1	$ 47
Options granted	17,159,617	$ 1.16		
Options exercised	—	$ —		
Options forfeited/cancelled	(11,020,667)	$ 11.07		
Outstanding as of December 31, 2023	23,626,115	$ 2.52	7.9	$ 369
Options granted	13,006,228	$ 0.96		
Options exercised	—	$ —		
Options forfeited/cancelled	(2,216,006)	$ 2.25		
Outstanding as of December 31, 2024	34,416,337	$ 1.95	7.5	$ 598
Options vested and expected to vest as of December 31, 2024	34,416,337	$ 1.95	7.5	$ 598
Options exercisable as of December 31, 2024	14,126,062	$ 3.20	6.1	$ 100

The weighted-average grant date fair value per share for the stock options granted during the year ended December 31, 2024, 2023 and 2022 was $0.78, $3.88 and $4.77, respectively.

The aggregate fair value of stock options that vested during the years ended December 31, 2024, 2023 and 2022 was $15.7 million, $22.7 million and $20.7 million, respectively.

The aggregate intrinsic value in the above table is calculated as the difference between fair value of the Company's common stock price and the exercise price of the stock options. There were no options exercised during the years ended December 31, 2024 and 2023. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2022 was $1.5 million.

Warrants

On July 24, 2023, the Company completed a private placement of 129,869,440 shares of the Company's common stock and accompanying warrants to purchase up to 32,467,360 shares of the Company's common stock at a combined purchase price of $1.63125 per share and accompanying warrant, or with respect to any purchaser that was an officer, director, employee or consultant of the Company, $1.85125 per share and accompanying warrant. Each warrant has an exercise price per share of $2.04, was immediately exercisable on the date of issuance and will expire five years from the closing of the private placement. Given that the warrants are indexed to the Company's shares of common stock (and otherwise meet the requirements to be classified in equity), the Company recorded the consideration received from the issuance of the warrants as additional paid-in capital on the Company's consolidated balance sheets. As of December 31, 2024, there were 32,467,360 warrants outstanding.

Restricted Stock

The summary of the Company's restricted stock activity during the years ended December 31, 2024, 2023 and 2022 is as follows:

	Number of Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2021	2,561,219	$ 8.67
Granted	572,901	11.94
Vested	(1,592,588)	7.78
Forfeited / cancelled	(191,497)	10.68
Nonvested at December 31, 2022	1,350,035	$ 10.83
Granted	—	—
Vested	(779,900)	10.67
Forfeited / cancelled	(142,437)	11.39
Nonvested at December 31, 2023	427,698	$ 10.92
Granted	—	—
Vested	(427,698)	10.92
Forfeited / cancelled	—	—
Nonvested at December 31, 2024	—	$ —

As of December 31, 2024, there was no unrecognized stock-based compensation expense related to the unvested restricted stock awards.

Stock-Based Compensation Expense

Stock-based compensation expense has been reported in the Company's consolidated statements of operations and comprehensive loss as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Research and development	$ 10,172	$ 15,871	$ 24,415
General and administrative	10,447	12,647	18,138
Total stock-based compensation expense	$ 20,619	$ 28,518	$ 42,553

At December 31, 2024, the total unrecognized compensation related to unvested stock option awards granted was $14.0 million, which the Company expects to recognize over a weighted-average period of approximately 2.6 years.

As of December 31, 2024, total unrecognized compensation expense related to the ESPP was $0.8 million, which the Company expects to recognize over a weighted-average period of approximately 0.8 years.

Note 10—Property and Equipment, Net

The Company's property and equipment, net consisted of the following (in thousands):

	Estimated Useful Life (in years)	December 31, 2024	December 31, 2023
Office equipment	3-7	$ —	$ 1,097
Computer equipment	5	—	123
Software	3	—	52
Lab equipment	2-5	193	3,246
Leasehold improvements	6-7	—	2,562
Total property and equipment		193	7,080
Less: accumulated depreciation		(183)	(5,432)
Property and equipment, net		$ 10	$ 1,648

Depreciation expense for the years ended December 31, 2024, 2023 and 2022 was approximately $0.8 million, $1.6 million and $1.8 million, respectively, and was recorded in general and administrative expense and research and development expense, respectively, on the consolidated statements of operations and comprehensive loss.

Note 11—Commitments and Contingencies

Leases

The Company previously leased certain office and laboratory space under a non-cancelable operating lease which expired in January 2025.

On July 9, 2024, the Company entered into a lease agreement for office space located at 3115 Merryfield Row, Suite 120, San Diego, CA 92121, consisting of approximately 18,421 square feet. The term of the lease is 63 months commencing on August 1, 2024. The base rent is $109,605 per month effective October 1, 2024, and it is subject to a 3% annual increase every October. The lease expires on October 31, 2029 with an option for a one-year extension and an option to terminate on December 1, 2027 with the payment of a termination fee equal to four months of the then-current base rent upon the termination date. As of December 31, 2024, the Company was not reasonably certain that it would exercise the extension options, and therefore did not include these options in the determination of the total operating lease term for accounting purposes.

Monthly rent expense is recognized on a straight-line basis over the term of the leases. The operating leases are included in the consolidated balance sheets at the present value of the lease payments at an incremental borrowing rate of 7% for each of the initial leased space and expansion space expiring in January 2025 and 12.4% for the office lease commenced on August 1, 2024 using the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment as the leases do not provide an implicit rate. As of December 31, 2024, the weighted average remaining lease term was 4.7 years, and weighted-average discount rate was 12.4%.

Lease costs were comprised of the following (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Operating lease cost	$ 3,706	$ 3,114	$ 3,097
Short-term lease cost	48	52	45
Total lease cost	$ 3,754	$ 3,166	$ 3,142

Cash paid for amounts included in the measurement of operating lease liabilities as of December 31, 2024 and 2023 was $3.8 million and $3.3 million, respectively.

Gross future minimum annual rental commitments as of December 31, 2024, were as follows (in thousands):

	Undiscounted Rent Payments
Year ending December 31,	
2025	$ 1,550
2026	1,417
2027	1,406
2028	1,448
2029	1,237
Total undiscounted rent payments	$ 7,058
Present value discount	(1,699)
Present value of lease payments	$ 5,359
Current portion of operating lease liabilities (included as a component of accrued expenses and other current liabilities)	961
Operating lease liabilities - long-term	4,398
Total operating lease liability	$ 5,359

Note 12 - Significant Agreements and Contracts

On May 3, 2024, the Company, GB002, Inc., a Delaware corporation and wholly-owned subsidiary of the Company and Gossamer Bio 002 Ltd., a corporation organized and existing under the laws of Ireland and indirect wholly-owned subsidiary of the Company, entered into a global collaboration and license agreement (the "Chiesi Collaboration Agreement") with Chiesi Farmaceutici S.p.A and Chiesi USA, Inc. (collectively, "Chiesi"). The Company concluded that there were four distinct performance obligations under the Chiesi Collaboration Agreement: the U.S. Territory license (as defined below), the ROW Territory license (as defined below), and the research and development services of both PAH and PH-ILD clinical development. Revenue associated with the licenses was recognized upon delivery in May 2024. In addition, the Company granted to Chiesi an option to purchase the Equity Option, as described in Note 8, "Stockholders Equity."

The collaboration is focused on the development and commercialization of seralutinib and licensed products including seralutinib and related licensed compounds ("Licensed Products") in the U.S. ("U.S. Territory") and the rest of the world ("ROW Territory"), for therapeutic, prophylactic and diagnostic uses in humans and animals, for the treatment of PAH and PH-ILD and other indications, as may be permitted under the Chiesi Collaboration Agreement.

Pursuant to the Chiesi Collaboration Agreement, the Company granted two exclusive, sublicensable (with the Company's consent required in the U.S. Territory for third party sublicenses) licenses to Chiesi under intellectual property rights controlled by the Company relating to seralutinib and Licensed Products, for the worldwide development, manufacture and commercialization of seralutinib and Licensed Products. The licenses granted to Chiesi are subject to retained rights of the Company for the worldwide development and manufacture of seralutinib and Licensed Products, commercialization of Licensed Products in the U.S. Territory, and performance of its obligations and exercise of its rights that may be set forth in the global development plan and US commercialization plan, in each case in accordance with the Chiesi Collaboration Agreement.

The parties agreed to use commercially reasonable efforts to conduct development and commercialization activities in relation to seralutinib and Licensed Products, under the global development plan and US commercialization plan in accordance with the timelines therein. The Company will continue to lead global development of seralutinib in PAH and PH-ILD, and the parties will equally share the costs for the activities included in the global development plan for all Licensed Products, with the exception of the PROSERA Phase 3 study, which the Company will be solely responsible for conducting at the Company's own cost and expense. With respect to each country in the ROW Territory, such obligation to equally share such development costs shall end when regulatory approval is received for a Licensed Product in such country. With respect to U.S. Territory, the development costs incurred following regulatory approval shall continue to be shared equally. The Company will lead potential commercialization for PAH and PH-ILD in the US, with both parties contributing 50 percent of commercial efforts, including performing 50 percent of the commercialization activities. Chiesi will lead potential commercialization in the US Territory in any additional indications, and Chiesi will have the exclusive right to commercialize Licensed Products in the ROW Territory. Chiesi further agreed to use commercially reasonable efforts to commercialize Licensed Products in certain specified countries in the ROW Territory following receipt of regulatory approvals. Generally, the Company will have the right to lead in manufacturing commercial supply of seralutinib and Licensed Products for the U.S. Territory for PAH and PH-ILD,

and, subject to any existing obligations of the Company to third party manufacturers, Chiesi will have the right to lead in manufacturing commercial supply of seralutinib and Licensed Products in the ROW Territory, in each case in accordance with the Chiesi Collaboration Agreement.

Pursuant to the Chiesi Collaboration Agreement, neither party nor its affiliates is permitted to develop or commercialize any compound or product throughout the term whose primary mechanism of action is inhibition of a tyrosine kinase for the treatment of PAH or PH-ILD in the U.S. Territory or ROW Territory, subject to certain restrictions for the EU and UK.

In consideration and as reimbursement for the Company's development costs, Chiesi agreed to pay the Company an up-front, nonrefundable payment of $160 million. Additionally, the Company will be eligible to receive up to $146 million in regulatory milestones and $180 million in sales milestones. In the U.S. Territory, the parties agreed to share commercial profits and losses equally. In the ROW Territory, Chiesi will pay the Company an escalating mid-to-high teens percentage royalty on net sales of Licensed Product for PAH and additional indications on a Licensed Product-by-Licensed Product and country-by-country basis with such payment obligations beginning on the first commercial sale of Licensed Product in such country and expiring on a country-by-country basis on the latest of (a) the expiration of a valid claim to a the Company patent right in such country, (b) the expiration of regulatory exclusivity, and (c) the date that is 10 years after the first commercial sale of such Licensed Product in such country.

Potential future payments for variable consideration, such as regulatory and commercial milestones, development costs, and profit sharing U.S. Territory will be recognized when it is probable that, if recorded, a significant reversal will not take place. Potential future royalty payments will be recorded as revenue when the associated sales occur.

Unless earlier terminated, the Chiesi Collaboration Agreement will remain in force until no Licensed Products are being developed or commercialized in the US Territory and in the ROW Territory, on a country-by-country basis, until no royalty terms are in effect for all countries. Either party may terminate the Chiesi Collaboration Agreement for the other party's material breach, subject to a specified notice and cure periods, or due to an insolvency event of the other party. In lieu of termination upon a party's material breach due to non-payment of development costs within a specified time the non-breaching party may elect an alternative remedy which may involve modifications to their performance and payment obligations. The Company has the right to terminate by providing written notice in the event Chiesi or its affiliates or sublicensee brings a patent challenge and Chiesi does not take certain steps to withdraw from or cease supporting such challenge. Chiesi may terminate the Chiesi Collaboration Agreement without cause upon prior written notice to the Company, subject to a notice period in which all rights to Licensed Products and Licensed Compounds will revert back to the Company.

The Company concluded that progress towards completion of the research and development services performance obligation related to the Chiesi Collaboration Agreement is best measured in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses. The Company periodically reviews and updates the estimated collaboration expenses, when appropriate, which may adjust revenue recognized for the period. While such changes to the Company's estimates have no impact on the Company's reported cash flows, the amount of revenue recorded in the period could be materially impacted. The transaction price to be recognized as revenue from sale of licenses and revenue from contracts with collaborators under the Chiesi Collaboration Agreement consists of the one-time non-refundable and non-creditable development cost reimbursement payment and research and development costs. The transaction price was reduced by the fair value of the Equity Option.

Revenue Recognition

The Company determined the transaction price pursuant to the Chiesi Collaboration Agreement is equal to the one-time development cost reimbursement payment of $160.0 million less the fair market value of the Equity Option of $0.5 million. The price allocated for the Equity Option was determined to be at fair market value utilizing the Geometric Brownian Motion/Monte Carlo model and was considered a reduction in the transaction price. The transaction price was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each distinct performance obligation. In estimating the stand-alone selling price for each distinct performance obligation, the Company developed assumptions that require judgment and included forecasted revenues or costs, expected development timelines, discount rates and probabilities of technical and regulatory success. A description of the distinct performance obligations identified under the Chiesi Collaboration Agreement, as well as the amount of revenue allocated to each distinct significant performance obligation, is as follows:

Licenses of Intellectual Property. The licenses to the Company's intellectual properties, bundled with the associated know-how, represents two distinct performance obligations. The licenses and associated know-how were transferred to Chiesi in June 2024, therefore the Company recognized the full revenue related to these distinct performance obligations in the amount of $90.7 million during the year ended December 31, 2024 as revenue from sale of licenses on its consolidated statements of operations and comprehensive loss.

Research and Development Services. The progress towards completion of the two distinct performance obligations related to PAH and PH-ILD research and development services for the Licensed Products is measured in an amount proportional to the research and development expenses incurred and the total estimated PAH and PH-ILD research and development expenses. In addition, the Company and Chiesi share equally in the costs of ongoing global seralutinib clinical development, with the exception of the PROSERA Phase 3 study, and the costs of commercialization in the US. The Company records the revenue from performing research and development services and the cost-sharing payments due from Chiesi as revenue from contracts with collaborators on its consolidated statements of operations and comprehensive loss. For the year ended December 31, 2024, the Company recognized $24.1 million for the PAH and PH-ILD research and development performance obligations and commercialization activities.

Milestone Payments. The Company determined that as of December 31, 2024, it is not probable that a significant revenue reversal will not occur related to the potential milestone payments as their achievement is highly dependent on factors outside the Company's control or are otherwise constrained under the sales and usage based royalty exception. Therefore, these payments have been fully constrained and are therefore not included in the transaction price. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint. No milestone payments were recognized during the year ended December 31, 2024.

Royalties. As the licenses are deemed to be the predominant item to which sales-based royalties relate, the Company will recognize revenue when the related sales occur. No royalty revenue was recognized during the year ended December 31, 2024.

The following table presents a summary of the activity in the Company's contract liabilities related to the Chiesi Collaboration Agreement (recorded as contract liabilities on the balance sheet) during the year ended December 31, 2024 (in thousands):

Balance, December 31, 2023	$ —
Payments received in advance	159,536
Revenue from sale of US license	(78,947)
Revenue from sale of ROW license	(11,721)
Revenue from PAH research and development service performance obligations satisfied during reporting period	(9,555)
Revenue from PH-ILD research and development service performance obligations satisfied during reporting period	(1,291)
Effect of exchange rate changes on contract liabilities	(2,103)
Balance, December 31, 2024	$ 55,919

As of December 31, 2024, the contract liability amount of $55.9 million represents the aggregate transaction price allocated to performance obligations that are unsatisfied under the Chiesi Collaboration Agreement. This amount is expected to be recognized over 4.0 years, which represents the remaining research period under the Chiesi Collaboration Agreement. As of December 31, 2024, the current contract liability balance of $17.1 million is classified as a current liability since the rights to the research and development service are expected to be satisfied within one year, and the remaining contract liability balance of $38.9 million is classified as a long-term liability.

As of December 31, 2024, the Company recorded $5.3 million in accounts receivable associated with the Chiesi Collaboration Agreement. The payments are typically due 30 days after quarterly invoices are issued.

The following table presents our contract revenues from Chiesi Collaboration Agreement disaggregated by timing of revenue recognition and excluding royalty revenue (in thousands):

	Year Ended December 31, 2024
Revenue from Chiesi Collaboration Agreement:	
Point in Time:	
US License	$ 78,947
ROW License	11,721
Over Time:	
Revenue from PAH research and development service performance obligation satisfied during reporting period	9,555
Revenue from PH-ILD research and development service performance obligation satisfied during reporting period	1,291
Revenue from PAH research and development costs subject to reimbursement	10,246
Revenue from PH-ILD research and development costs subject to reimbursement	2,380
Revenue from PAH commercial costs subject to reimbursement	538
Revenue from PH-ILD commercial costs subject to reimbursement	116
Effect of exchange rate changes on revenue	(93)
Total revenue from Chiesi Collaboration Agreement	$ 114,701

Note 13 - Segment Information

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the CODM in making decisions regarding the allocation of resources and assessing performance. The Company's CODM is its chief executive officer. The Company views its operations and manages its business as one operating segment. The Company's operating segment derives its revenues from its collaboration agreement with Chiesi and is wholly attributable to the United States. The CODM assesses performance for the Company's single operating segment and decides how to allocate resources based on research and development expenses incurred, which is a component of the Company's consolidated net loss as reported on the consolidated statement of operations and comprehensive loss. The measure of segment assets is reported on the balance sheet as total consolidated assets. Further, segment depreciation expense and segment asset additions are consistent with consolidated amounts reported within the consolidated statement of cash flows given the Company's operations are aggregated within a single reportable segment. The CODM uses research and development expenses and results of clinical trial activities completed to date to evaluate how to allocate the Company's resources to advance seralutinib.

Significant segment expenses which are regularly reported to the CODM for purposes of making decisions regarding the allocation of resources are included within the table below and are reconciled to consolidated net loss:

	Years Ended December 31,		
	2024	2023	2022
	(in thousands)		
Total revenue	$ 114,701	$ —	$ —
Less:			
Seralutinib	129,247	103,158	63,048
Other segment items [1]	45,373	80,601	155,545
Interest income	(1,779)	(1,997)	(1,583)
Interest expense	11,517	13,511	13,880
Other income, net	(14,022)	(15,456)	(1,512)
Income tax expense	893	—	—
Segment net loss	$ (56,528)	$ (179,817)	$ (229,378)

[1] Other segment items include R&D expenses for other terminated programs. These costs include employee expenses, as well as allocations of consolidated overhead and stock compensation. Further, general and administrative expenses are also provided to the CODM regularly, but are included within other segment items as they are not utilized as part of the decision making process as it relates to the allocation of resources.

Subsequent events

The Company has evaluated all subsequent events and transactions through the filing date. There were no material events that impacted the audited consolidated financial statements or disclosures.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	10-Q	8/8/2023	3.1	
3.2	Amended and Restated Bylaws.	8-K	11/27/2023	3.1	
4.1	Form of Common Stock Certificate.	S-1/A	1/23/2019	4.1	
4.2	Description of Securities Registered under Section 12 of the Exchange Act.	10-K	2/26/2021	4.3	
4.3	Indenture, dated as of May 21, 2020, by and between the Registrant and Wilmington Trust, National Association.	8-K	5/21/2020	4.1	
4.4	First Supplemental Indenture, dated May 21, 2020, by and between the Registrant and Wilmington Trust, National Association.	8-K	5/21/2020	4.2	
4.5	Form of Global Note representing 5.00% Convertible Senior Notes due 2027 (included as part of Exhibit 4.5).	8-K	5/21/2020	4.3	
4.6	Form of Warrant.	8-K	7/20/2023	4.1	
10.1#	Gossamer Bio, Inc. 2017 Equity Incentive Plan, as amended.	S-1	12/21/2018	10.1	
10.2#	Form of stock option grant notice and stock option agreement under Gossamer Bio, Inc. 2017 Equity Incentive Plan, as amended.	S-1	12/21/2018	10.2	
10.3#	Form of restricted stock grant notice and restricted stock agreement under Gossamer Bio, Inc. 2017 Equity Incentive Plan, as amended.	S-1	12/21/2018	10.3	
10.4#	Form of Founder restricted stock grant notice and restricted stock agreement.	S-1	12/21/2018	10.4	
10.5#	Gossamer Bio, Inc. 2019 Incentive Award Plan and form of stock option grant notice and stock option agreement thereunder.	S-1/A	1/23/2019	10.5	
10.6#	Gossamer Bio, Inc. 2019 Employee Stock Purchase Plan.	S-1/A	1/23/2019	10.6	
10.7#	Gossamer Bio, Inc. Non-Employee Director Compensation Program.				X
10.8#	Gossamer Bio, Inc. Restricted Stock Unit Agreement under the 2019 Equity Incentive Plan.	10-Q	5/12/2020	10.1	
10.9#	Gossamer Bio, Inc. 2023 Employment Inducement Incentive Award Plan and Form of Stock Option Agreement thereunder.	8-K	11/27/2023	10.1	
10.10#	Letter Agreement, dated November 16, 2020, by and between Faheem Hasnain and the Registrant.	10-K	2/26/2021	10.11	
10.11#	Employment Letter, dated December 4, 2018, by and between Bryan Giraudo and the Registrant.	S-1	12/21/2018	10.10	
10.12#	Employment Letter, dated December 4, 2018, by and between Christian Waage and the Registrant.	S-1	12/21/2018	10.11	
10.13#	Employment Letter, dated April 16, 2021, by and between Caryn Peterson and the Registrant.	10-Q	8/9/2021	10.1	
10.14#	Employment Letter, dated June 21, 2021, by and between Richard Aranda and the Registrant.	10-Q	8/9/2021	10.3	
10.15#	Employment Letter, dated November 25, 2023, by and between Robert Smith and the Registrant.	10/K	3/5/2024	10.15	
10.16#	Form of Indemnification Agreement.	S-1	12/21/2018	10.14	
10.17†	Exclusive License Agreement, dated October 2, 2017, by and between GB002, Inc., the Registrant and Pulmokine, Inc.	S-1	12/21/2018	10.17	
10.18	Stock Purchase Agreement, dated July 12, 2022, by and among the Registrant and the Purchasers named therein.	8-K	7/13/2022	10.1	
10.19	Securities Purchase Agreement, dated July 19, 2023, by and among the Registrant and the Purchasers named therein.	8-K	7/20/2023	10.1	
10.20#	Form of Option Repricing and Cancellation Agreement.	10-Q	8/8/2023	10.1	
10.21†	Collaboration and License Agreement dated May 3, 2024 by and among GB002, Inc., Gossamer Bio 002 Ltd. and Gossamer Bio, Inc. on the one hand and CHIESI Farmaceutici S.p.A and CHIESI USA, Inc. on the other hand.	10-Q	8/12/2024	10.1	
19.1	Gossamer Bio, Inc. Insider Trading Compliance Policy and Procedures				X
21.1	List of Subsidiaries of the Registrant.				X
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.				X

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
31.1	Certification of Chief Executive Officer of Gossamer Bio, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X
31.2	Certification of Chief Financial Officer of Gossamer Bio, Inc., as required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.				X
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97	Policy for Recovery of Erroneously Awarded Compensation.	10-K	3/5/2024	97	
101.INS	XBRL Report Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document				X
101.CAL	XBRL Taxonomy Calculation Linkbase Document				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	XBRL Taxonomy Label Linkbase Document				X
101.PRE	XBRL Presentation Linkbase Document				X

# Indicates management contract or compensatory plan.

† Portions of this exhibit (indicated by asterisks) have been omitted for confidentiality purposes pursuant to Item 601(b)(10)(iv) of Regulation S-K.

* These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

GOSSAMER BIO, INC.

By: /s/ Faheem Hasnain
Faheem Hasnain
President and Chief Executive Officer

Date March 13, 2025

SIGNATURES AND POWER OF ATTORNEY

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/ Faheem Hasnain Faheem Hasnain	President, Chief Executive Officer and Chairman of the Board of Directors (principal executive officer)	March 13, 2025
/s/ Bryan Giraudo Bryan Giraudo	Chief Operating Officer and Chief Financial Officer (principal financial and accounting officer)	March 13, 2025
/s/ Russell Cox Russell Cox	Director	March 13, 2025
/s/ Thomas Daniel, M.D. Thomas Daniel, M.D.	Director	March 13, 2025
/s/ Sky Drynan Sky Drynan	Director	March 13, 2025
/s/ Sandra Milligan, M.D., J.D. Sandra Milligan, M.D., J.D.	Director	March 13, 2025
/s/ Steven Nathan, M.D. Steven Nathan, M.D.	Director	March 13, 2025
/s/ John Quisel, J.D., Ph.D. John Quisel, J.D., Ph.D.	Director	March 13, 2025