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, 2020

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.)**
3013 Science Park Road 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. ☒

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 30, 2020 (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 $774.8 million, based on the closing price of the registrant's common stock on the Nasdaq Global Select Market of $13.00 per share.

As of February 19, 2021, the registrant had 75,527,707 shares of common stock ($0.0001 par value) outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement for the 2021 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.

TABLE OF CONTENTS

PART I

FORWARD-LOOKING STATEMENTS

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. 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 strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, 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.

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.

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.

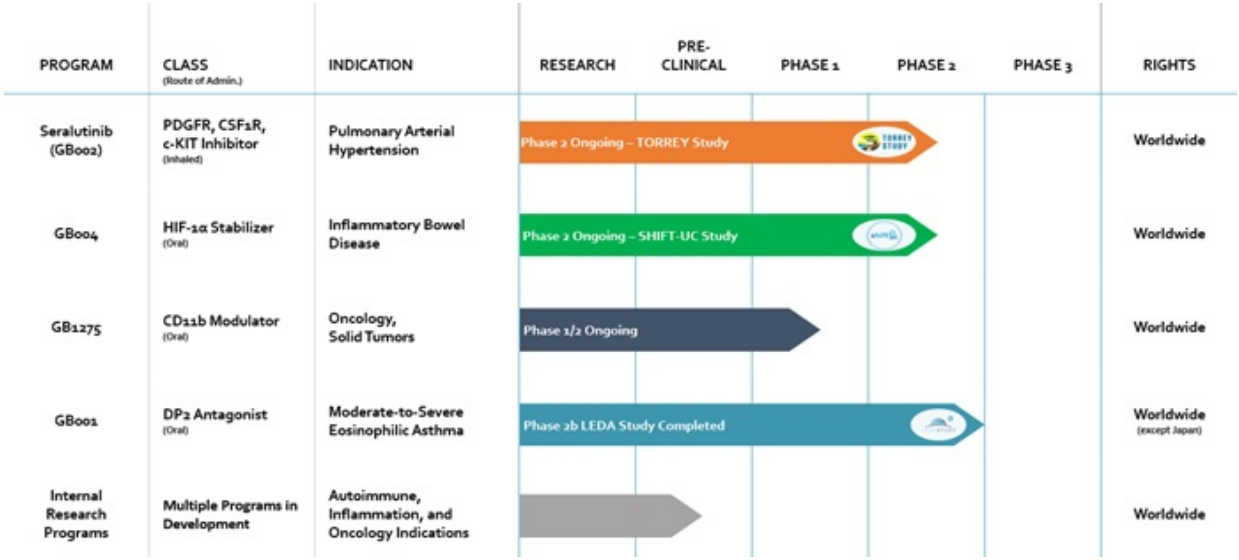
Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology. Our goal is to be an industry leader in each of these therapeutic areas and to enhance and extend the lives of patients suffering from such diseases. 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. Our collective immunology and translational discovery and development expertise serves as the foundation of our company. We intend to maintain a scientifically rigorous and inclusive corporate culture where employees strive to bring improved therapeutic options to patients.

We are pursuing product candidates with strong scientific rationale to address indications where there is both a high unmet need and an opportunity to develop best-in-class or first-in-class therapeutics. We currently have four clinical-stage product candidates, in addition to six preclinical programs.

The following table summarizes our current programs:



Seralutinib (GB002: PDGFR, CSF1R and c-KIT Inhibitor)

Seralutinib, also known as GB002, is an inhaled, small molecule, platelet-derived growth factor receptor, or PDGFR, colony-stimulating factor 1 receptor, or CSF1R, and c-KIT inhibitor in development for the treatment of pulmonary arterial hypertension, or PAH. Seralutinib has been generally well tolerated in completed clinical trials. In contrast to the three classes of marketed vasodilatory therapies for PAH, we believe that seralutinib has the potential to be disease-modifying by addressing the cellular overgrowth, fibrosis and vascular remodeling which 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 2013, results from a Phase 3 clinical trial in PAH of imatinib (Gleevec), an oral tyrosine kinase inhibitor with known activity against PDGF and c-KIT, marketed for oncology indications, showed statistically significant improvement in its primary efficacy endpoint, however systemic toxicities were also observed. To date, these toxicities have not been observed with seralutinib in our completed Phase 1 single-ascending dose / multiple ascending dose, or SAD / MAD, studies in healthy volunteers or in our Phase 1b study in PAH patients. In the two-week Phase 1b clinical trial in PAH patients, seralutinib demonstrated rapid systemic clearance, target engagement via whole blood CSF1R stabilization assay and was generally well tolerated. We commenced the Phase 2 TORREY trial in PAH patients in December 2020. Topline results from this trial are expected in the first half of 2022, subject to developments in the ongoing COVID-19 pandemic. We in-licensed seralutinib from Pulmokine, Inc. in 2017 and retain worldwide rights. The United States Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, have granted seralutinib orphan drug designation for the treatment of patients with PAH.

GB004 (HIF-1α Stabilizer)

GB004 is a novel, gut-targeted, oral small molecule being developed for the treatment of inflammatory bowel disease, or IBD, including ulcerative colitis, or UC, and Crohn's disease, or CD. GB004 stabilizes hypoxia-inducible factor 1α, or HIF-1α, through the inhibition of prolyl hydroxylase domains, or PHDs, key enzymes involved in HIF degradation. Preclinical data from animal models of IBD demonstrated that HIF-1α stabilization restores intestinal epithelial barrier integrity and function and results in immunomodulatory effects that we believe are important in reducing inflammation and enhancing mucosal healing in IBD patients. We have completed Phase 1 SAD and MAD studies in healthy volunteers and a Phase 1b study in patients with active UC, and GB004 has been generally well tolerated. In a 28-day Phase 1b clinical trial in patients with active UC, GB004 was well-tolerated, demonstrated a gut-targeted PK profile, showed evidence of target engagement, and initial signs of potential clinical efficacy were observed. We commenced the Phase 2 SHIFT-UC trial in patients with active mild-to-moderate UC in October 2020. Topline results from this trial are expected in the first half of 2022, subject to developments in the ongoing COVID-19 pandemic. We in-licensed GB004 from Aerpio Pharmaceuticals, Inc., or Aerpio, in June 2018 and retain worldwide rights.

GB1275 (CD11b Modulator)

GB1275 is an oral, small molecule, CD11b modulator in clinical development for the treatment of oncology indications. CD11b and CD18 are members of the integrin family of cell adhesion receptors that combine to form the functional adhesion receptor CD11b / CD18, also known as Mac-1, CR3 or alpha-M beta-2, on cell surfaces. CD11b is highly expressed on myeloid cells of the immune system, including tumor-associated macrophages, or TAMs, and myeloid derived suppressor cells, or MDSCs, which play a significant role in promoting tumor growth, immune evasion and metastasis. Increased presence of CD11b positive MDSCs in tumors is observed across multiple tumor types and is associated with poor prognosis in multiple cancers. GB1275 is currently being tested in an ongoing Phase 1/2 clinical trial (KEYNOTE-A36) for the treatment of selected solid tumor types. In the fourth quarter of 2019, we announced a clinical trial and supply agreement with Merck & Co., Inc., or Merck, to evaluate the combination of GB1275 and pembrolizumab (Keytruda) in advanced solid tumors, as part of the ongoing Phase 1/2 clinical trial. In this ongoing Phase 1/2 clinical trial, oral GB1275 alone and in combination with pembrolizumab, up to 1,200 mg twice daily, or BID, has been generally well tolerated. To date, one partial response, or PR, has been observed in a patient with microsatellite stable colorectal cancer, or MSS CRC, and biomarker data suggest that GB1275, alone or in combination with pembrolizumab, may modulate myeloid cell biology in the tumor microenvironment, or TME, inducing a more inflamed tumor phenotype. We expect to report further data from this trial in 2021. The FDA and the EMA have granted GB1275 orphan drug designation for the treatment of patients with pancreatic cancer. We retain worldwide rights to GB1275.

GB001 (DP2 Antagonist)

GB001 is an oral prostaglandin D2 receptor 2, or DP2, antagonist in development for the treatment of moderate-to-severe eosinophilic asthma. GB001 has been studied in over 800 subjects who have received at least 1 dose in completed clinical trials to date and has been generally well tolerated up to a dose of 40 mg. In the global Phase 2b LEDA study, GB001 showed a consistent numerical reduction of 32-35% across all three dose groups in proportion of patients with asthma worsening by week 24, as compared to placebo, which was the primary endpoint of the clinical trial, but these results were not statistically significant for any of three dose groups. Additionally, in the same clinical trial, GB001 showed a nominally statistically significant reduction in time-to-first asthma worsening for the 20 mg and the 60 mg dose groups of GB001, as compared to placebo, which was the key secondary endpoint. The 40 mg dose of GB001 also demonstrated a numeric improvement, as compared to placebo, but this result was not statistically significant. One adverse event of interest was a serious adverse event, or SAE, of liver chemistry elevations meeting Hy's Law criteria in the GB001 60 mg group. The patient was asymptomatic during the event, which was reversible and resolved without sequelae. In a Phase 2 clinical trial conducted in Japan, GB001 showed a statistically significant improvement in time-to-first asthma worsening compared to placebo. A single SAE, intrahepatic cholestasis, a liver disorder, deemed by the investigator likely to be related to study drug was observed in a Japanese patient who had received a 160 mg dose of GB001 in a Phase 1 clinical trial conducted by Teijin Pharma Limited, or Teijin. The patient had GB001 exposure levels approximately three to five times higher than the other patients receiving the 160 mg dose. We engaged with the FDA and the EMA about the clinical development path in asthma, and based off those interactions, we believe that there is a viable clinical development path for GB001, or its backup molecule, in asthma. We do not currently plan to move forward with GB001, or its backup molecule, in further clinical trials without a partner. As previously announced, we do not plan to continue further development of GB001 in chronic rhinosinusitis, or CRS. We retain worldwide rights to GB001, excluding Japan.

Our Research Capabilities and Preclinical Programs

We currently have multiple programs in preclinical development. We are continuing to build our research capabilities, specifically focusing on our areas of expertise within immunology, inflammation and oncology, in order to advance new programs into the clinic, as well as to optimize our existing programs. We have six programs in preclinical development, and we expect at least one additional product candidate to enter clinical trials within the next 12 months.

Our Team

Our founders and management team have held senior positions at leading biopharmaceutical companies, including Receptos, Inc., Bristol-Myers Squibb Company, and Celgene Corporation, among others, and possess substantial experience and expertise across the spectrum of drug discovery, 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.

Luisa Salter-Cid, Ph.D., our Chief Scientific Officer, was previously the Head of Immunology Discovery at Bristol-Myers Squibb, having overseen immunology and immuno-oncology discovery efforts since 2005. Bryan Giraudo, our Chief Financial Officer, has extensive biotechnology and medical technology investment banking experience, having previously served as Senior Managing Director at Leerink Partners (now known as SVB Leerink) and Managing Director at Merrill Lynch, Pierce, Fenner & Smith Incorporated. Christian Waage, our Executive Vice President and General Counsel, has extensive biotechnology experience, having previously held various positions at Receptos, most recently as Managing Director after its acquisition by Celgene, and served at Ardea Biosciences, Inc. as Vice President, General Counsel.

Our Strategy

We are a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology. Our goal is to be an industry leader in each of these therapeutic areas and to enhance and extend the lives of patients suffering from such diseases. Critical components of our business strategy include:

- **Create deep therapeutic centers of excellence by leveraging our immunology and translational discovery and development expertise.** We currently have four clinical-stage product candidates and six preclinical-stage programs across the areas of immunology, inflammation and oncology. We will continue to build out our portfolio, focusing on these therapeutic areas, through both internal discovery and strategic transactions to create a diversified portfolio of early and late-stage product candidates.

- **Maximize the impact of our product candidates by expanding development across multiple indications.** We aim to focus our development efforts on product candidates that have the potential to treat multiple diseases and plan to develop them in additional indications where warranted. For example, we plan to develop GB004 in both UC and CD, and we are evaluating GB1275 for the treatment of multiple solid tumor types.

- **Expeditiously generate proof-of-concept data from our preclinical programs to facilitate value creation and efficient capital deployment.** We view our preclinical programs as important drivers of the long-term sustainability of our company. We plan to advance our preclinical programs to generate meaningful data to determine quickly whether each warrants clinical development.

- **Leverage the drug discovery, development and commercialization expertise of our world-class team.** Our executive management team and key scientific leaders have successfully discovered, developed and commercialized small molecule and biologic agents at both large and small biopharmaceutical companies. We plan to utilize this deep, broad set of expertise and experiences as we execute on our in-house discovery and development strategies and evaluate new external acquisition opportunities.

Our Product Candidates

Seralutinib (GB002: PDGFR, CSF1R and c-KIT Inhibitor)

Seralutinib, also known as GB002, is an inhaled, small molecule, PDGFR, CSF1R and c-KIT inhibitor in development for the treatment of PAH. As of December 31, 2020, seralutinib has been generally well tolerated in completed clinical trials. In contrast to the three classes of marketed vasodilatory therapies for PAH, we believe that seralutinib has the potential to be disease-modifying by addressing the cellular overgrowth, fibrosis and vascular remodeling which underlie PAH. Inhaled seralutinib, which is designed to act on both isoforms of the PDGF receptor, α and β, as well as the CSF1R and c-KIT pathways, inhibited and reversed cellular overgrowth in lung blood vessels in animal PAH models. In 2013, results from a Phase 3 clinical trial in PAH of imatinib (Gleevec), an oral tyrosine kinase inhibitor with known activity against PDGF and c-KIT, marketed for oncology indications, showed statistically significant improvement in its primary efficacy endpoint, however systemic toxicities were also observed. To date, these toxicities have not been observed with seralutinib in our completed Phase 1 SAD / MAD studies in healthy volunteers or in our Phase 1b study in PAH patients. In the two-week Phase 1b clinical trial in PAH patients, seralutinib rapid systemic clearance, target engagement via whole blood CSF1R stabilization assay and was generally well tolerated. We commenced the Phase 2 TORREY trial in PAH patients in December 2020. Topline results from this trial are expected in the first half of 2022, subject to developments in the ongoing COVID-19 pandemic. We in-licensed

seralutinib from Pulmokine, Inc. in 2017 and retain worldwide rights. The FDA and the EMA have granted seralutinib orphan drug designation for the treatment of patients with PAH.

Mechanism of Action

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, c-KIT and CSF1R.

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 PDGF 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 PDGF 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 studies 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 has 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. 202 patients were enrolled in the IMPRES trial, of which 41% were being treated with prostanoids, oral phosphodiesterase type 5, or PDE5, inhibitors and oral endothelin receptor agonists, or

ERAs. The study met its primary endpoint, improvement in six-minute walk distance, or 6MWD, versus placebo at week 24 from baseline, with statistical significance (p = 0.002). 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. The FDA's evidentiary standard of efficacy generally relies on a p-value of less than or equal to 0.05.

Patients on imatinib also demonstrated statistically significant improvements in measures of hemodynamics, including pulmonary vascular resistance, or PVR, a standard measurement in the evaluation of patients with PAH. 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 study. 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 Pulmonary Arterial Hypertension

PAH 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 symptom severity. Worsening symptoms, and thus higher numbered functional classes, are associated with higher mortality. The four functional classes established by the World Health Organization 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, NT-proBNP, which is a biomarker for heart failure and measures of right heart function.

Despite the introduction of many new therapies over the last several years, PAH continues to have a high morbidity and mortality. Based on 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

Diagnosed PAH prevalence in the United States is approximately 53,000 patients, as of 2018, and prevalence is highest among women between the ages of 30-60. 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. Total PAH drug sales worldwide in 2019 exceeded $5 billion.

Treatment Paradigm in PAH

Currently approved PAH therapies consist of three classes of vasodilators: PDE5 inhibitors (and guanylate cyclase stimulators), ERAs, and prostanoids. 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. While existing treatments have led to significant improvements in time to clinical worsening and other composite endpoints in PAH patients, none directly alter the underlying disease process. The effect of vasodilation, while improving blood flow through the lungs, may eventually be overtaken by the worsening cellular proliferation and arterial remodeling underlying the condition. We believe an agent with disease-modifying characteristics that safely addresses the underlying cellular overgrowth could provide utility across functional classes and risk categories.

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 more potent against CSF1R, as compared to imatinib. We believe seralutinib has the potential to be a differentiated and disease-modifying PAH therapeutic that may provide:

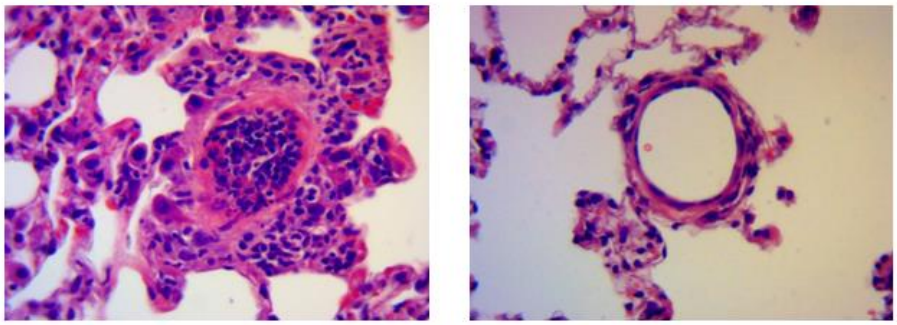
- an improved response to PDGF-driven abnormal cell proliferation in pulmonary arteries by addressing the underlying mechanism that leads to arterial wall thickening;
- a more tolerable safety profile than systemic imatinib; and
- a convenient, simple and portable inhalation methodology and delivery system.

Clinical Development History of Seralutinib

Summary of Preclinical Program

Seralutinib inhibits both PGDFR α and β, and it inhibited and reversed cell overgrowth in lung blood vessels in a rat model of PAH, as shown below in Figure 1. This rat model 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.

Figure 1. Reversed Vascular Remodeling by Seralutinib Through Inhibition of PDGFR



In a separate rat model of PAH, the SU5416 hypoxia model, seralutinib demonstrated a statistically significant reduction in circulating plasma NT-proBNP 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.

Summary of Completed Phase 1a Study

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 SAEs were reported, and no reported 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 initial 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. At the time of announcement, eight patients had completed the two-week blinded portion of the study. Enrollment for this study was temporarily paused due to the ongoing 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 trials 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 2-week Phase 1b study, patients were given the option of entering into an open-label extension phase.

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

In December 2020, we commenced the Phase 2 TORREY trial, a randomized, double-blind, placebo-controlled, multi-center clinical trial in PAH patients. We are enrolling approximately 80 functional class II and III PAH patients who are on background therapy, including patients on triple therapy. Patients will be randomized in a 1:1 fashion to seralutinib and placebo. Patients will remain on their background PAH therapies throughout the trial. The primary endpoint of the TORREY trial is change from baseline in pulmonary vascular resistance at week 24, with a key secondary endpoint of change from baseline to week 24 in 6MWD, although the trial is not powered for statistical significance in 6MWD. We are also assessing relevant safety endpoints and exploratory endpoints, including changes in echocardiogram readings, functional class, and biomarkers, such as NT-proBNP. We have implemented COVID-19 mitigation plans related to this trial, including opening more sites, spread regionally across the globe, and incorporating countries less impacted by the pandemic. Upon completion of the 24-week TORREY trial, patients will have the option of entering a stand-alone open-label extension study. Topline results from the TORREY trial are expected in the first half of 2022, subject to developments in the ongoing COVID-19 pandemic.

GB004 (HIF-1α Stabilizer)

GB004 is a novel, gut-targeted, oral small molecule being developed for the treatment of IBD including UC and CD. GB004 stabilizes HIF-1α through the inhibition of PHDs, key enzymes involved in HIF degradation. Preclinical data from animal models of IBD demonstrated that HIF-1α stabilization restores intestinal epithelial barrier integrity and function and results in immunomodulatory effects that we believe are important in reducing inflammation and enhancing mucosal healing in IBD patients. We have completed Phase 1 SAD and MAD studies in healthy volunteers and a Phase 1b study in patients with active UC, and GB004 was generally well tolerated. In a 28-day Phase 1b clinical trial in patients with active UC, GB004 was well-tolerated, demonstrated a gut-targeted PK profile, showed evidence of target engagement, and initial signs of potential clinical efficacy were observed. We commenced the Phase 2 SHIFT-UC trial in patients with active mild-to-moderate UC in October 2020. Topline results from this trial are expected in the first half of 2022, subject to developments in the ongoing COVID-19 pandemic. We in-licensed GB004 from Aerpio in June 2018 and retain worldwide rights.

Mechanism of Action

Stable expression of HIF-1α results in translocation to the nucleus and induces expression of genes known to promote epithelial integrity and mucosal barrier function. When oxygen levels within the cell and tissue are normal, HIFs are rapidly degraded by PHD enzymes. However, when oxygen levels are low, as in hypoxia in inflamed intestinal epithelium, HIF-1α accumulates in the cytoplasm and translocates to the nucleus. HIF-1α binds to constitutively expressed HIF-1β in the nucleus and drives the expression of hypoxia-induced genes, which improve oxygen delivery, regulate the glycolytic pathway, reduce cellular apoptosis, and upregulate epithelial barrier integrity. The state of chronic tissue injury in patients with IBD leads to dysregulation of HIF stability, which can lead to epithelial apoptosis, disruption of the intestinal wall barrier and inflammation.

Through inhibition of PHDs, GB004 stabilizes HIF-1α in preclinical models and in studies of healthy volunteers and patients with active UC. This stabilization results in an increase in the activation of HIF-1α mediated protective pathways. In preclinical rodent models of colitis, GB004 demonstrated statistically significant restitution of the epithelial barrier and mucosal healing as compared to placebo, with similar improvements to dexamethasone, a corticosteroid used for the treatment of moderate-to-severe IBD. Gut biopsies from patients with active UC in our Phase 1b trial showed increased expression of genes associated with HIF-1α stabilization and enhanced epithelial barrier function, such as tight junction protein 1, or TJP1, and Claudin 1, or CLDN1, and evidence of reduced gut epithelial neutrophil activity in the GB004 group compared to placebo.

Modulation of HIF stability is being evaluated in other diseases contexts, including in the treatment of anemia due to chronic kidney disease. The systemic PHD inhibitors being developed in this setting have on-target effects of increased erythropoietin, or EPO, and vascular endothelial growth factor, or VEGF. As this would be an undesirable effect in patients with IBD, we have designed GB004 to be gut-targeted, with multi-fold higher concentrations in the gut than in the periphery. In our Phase 1 healthy volunteer trials and in our Phase 1b trial in patients with active UC, no differences in plasma EPO or VEGF levels were observed for GB004 relative to placebo or with respect to GB004 dose.

In addition to promoting the expression of protective pathways, HIF-1α is also an important modulator of the innate and adaptive immune response. Stabilized HIF-1α increases antimicrobial peptides, factors that protect the host from infection. HIF-1α may also be critical for directly regulating immune cell function in the local inflammatory response, which may lead to the reduction of inflammation in IBD.

Overview of IBD

IBD refers to two conditions, UC and CD, which are characterized by chronic inflammation of the gastrointestinal, or GI, tract. Global epidemiology of IBD varies greatly from region to region. Although the incidence of IBD has remained stable or fallen in western countries over the last 2 decades, it is currently on a sharp rise in developing, newly industrialized areas. Due to the chronic nature of IBD, prevalence rates continue to grow slowly across Europe and North America, and IBD is estimated to affect up to 0.5% of the population in many countries.

Ulcerative Colitis

UC is characterized by chronic mucosal inflammation and loss of epithelial barrier function, and both contribute to disruption of local immune homeostasis in the colon. UC follows a relapsing / remitting disease course. The primary cause of UC is not precisely known but may include environmental, dietary and genetic factors, or it may be related to the gut microbiome.

Typically presenting as abdominal pain, bloody diarrhea and fecal urgency / incontinence, UC is associated with a notable psychosocial burden; the symptoms of UC negatively impact patients' physical and mental well-being and their ability to work, socialize, and maintain relationships. This impact tends to increase with disease severity, with up to 20% of patients experiencing acute, severe UC requiring hospitalization. Notably, due to chronic inflammation associated with UC, the risk of colorectal cancer is 2.4 times higher in patients with UC as compared with the general population.

Crohn's Disease

CD is a chronic, inflammatory condition that involves the full thickness of the wall of the GI tract and is characterized by erosions, strictures and perforations of the intestine. Symptoms include diarrhea, abdominal pain, blood in the stool, and weight loss. Maintaining symptomatic control and obtaining remission are critical to minimizing short-term and long-term complications and to improving the outcomes and quality of life for patients with CD. The natural course of CD is a progression from inflammation of the mucosa to stricture formation of the intestine and of mucosal penetration or fistula formation, with the risk of stricture and fistula increasing with the duration of CD.

Overview of the IBD Market

Approximately three million Americans report being diagnosed with either UC or CD. The current biologic market is dominated by the anti-TNF antibodies Humira, marketed by AbbVie Inc., and Remicade, marketed by Janssen Pharmaceuticals, Inc., or Janssen, and the growing share of the anti-integrin antibody Entyvio, marketed by Takeda Pharmaceuticals America, Inc.

Treatment Paradigm in IBD

Treatment of IBD consists mainly of immunosuppressive therapies. Treatment choices depend on the patient's disease severity and responsiveness to therapy. Medications that treat mild-to-moderate IBD are generally well tolerated. However, as the severity of IBD increases, the potential toxicities of the medications required to manage the disease also increase. For example, treatment of mild-to-moderate patients typically starts with topical agents, such as 5-aminosalicylic acid, or 5-ASA. For those IBD patients who do not respond to 5-ASAs, or those with more severe disease, corticosteroids are generally used to induce clinical remission. However, longer-term treatment with corticosteroids is associated with multiple adverse effects.

Patients with moderately to severely active IBD, who become nonresponsive or intolerant to corticosteroids, are treated with immunomodulators, biologics or a Janus kinase, or JAK, inhibitor. Immunomodulators show a delay in onset of action of one to three months and can result in neutropenia, pancreatitis, nephrotoxicity and hepatotoxicity. Therefore, the treatment of IBD patients with moderate-to-severe active disease is dominated by anti-TNF biologics. This paradigm is shifting because of the approval of agents in other classes, such as an anti-integrin, an anti-IL-12 / IL-23 and a JAK inhibitor. There is potential that the approval of biosimilar anti-TNF biologics moves the class further up in the treatment paradigm. Additional immune suppressive therapies for the treatment of IBD are expected in the coming years with the anticipated introduction of oral S1P1 inhibitors and additional oral JAK inhibitors.

GB004 Product Differentiation

GB004 is designed to be gut-targeted with higher intestinal exposure than systemic exposure. In IBD animal models, GB004 has demonstrated greater accumulation of HIF-1α than HIF-2α which may lead to restoration of epithelial barrier function and resolution of inflammation, while avoiding the potential adverse effects of increased EPO. In the Phase 1b study in patients with active UC, GB004 showed rapid clearance from systemic circulation, suggesting gut-targeted PK, and multi-fold higher concentrations of drug in the gut as compared to the plasma after eight hours of dosing. Additionally, in this study, GB004 continued to demonstrate no effects on systemic EPO or VEGF.

GB004 is distinct, and may have a differentiated profile, from the immunomodulatory or immunosuppressive mechanisms of approved IBD medicines and those in late-stage development. By reducing local inflammation and potentially restoring intestinal epithelial barrier function and restitution through GB004's gut-targeted nature and preferential stabilization of HIF-1α, we believe GB004 could improve outcomes for IBD patients. We believe this mechanism has potential as a standalone therapeutic as well as a combination therapy with other therapeutic mechanisms in IBD.

Clinical Development History of GB004

Summary of Completed Phase 1 Clinical Studies in Healthy Volunteers

GB004 was evaluated by Aerpio in a first-in-human Phase 1 SAD study in healthy male volunteers. The primary objective of the study was to evaluate the safety and tolerability of ascending dose levels of GB004 after single oral administrations. The secondary objective was to characterize PK. A total of 40 subjects were randomized into five cohorts with 8 subjects each. All subjects completed the study. The five dose levels evaluated in this study were 20 mg, 60 mg, 120 mg, and 240 mg in 50 ml of solution and 240 mg in 100 ml of solution. GB004 was generally well tolerated. No SAEs occurred. There were no differences in systemic levels of VEGF and EPO between GB004 and placebo.

GB004 was also evaluated in a randomized, double-blind, placebo-controlled, MAD study to assess the safety, tolerability, PK and pharmacodynamic, or PD, effects in healthy male and female volunteers. A total of 42 subjects were randomized to GB004 or placebo. Evaluated dose levels of GB004 solution were 60 mg, 120 mg and 240 mg per day. All GB004 doses evaluated in this study were well tolerated. No SAEs occurred. The PK profile for GB004 was consistent with its intended preferential exposure in the gut. There were no differences in systemic levels of VEGF and EPO between GB004 and placebo. GB004 engaged the target and stabilized HIF-1α, as demonstrated by upregulated gene expression in the gut.

GB004 was also evaluated in a randomized, double-blind, placebo-controlled Phase 1a study to assess the safety, tolerability, PK and PD, effects of various doses and formulations in healthy male and female volunteers. Volunteers received daily doses of 120 mg solution or placebo, or up to 240 mg tablet, or up to 240 mg delayed-release tablet, or placebo for 7 days. All formulations of GB004 were generally well tolerated, and in this study, the tolerability of 240 mg tablet was comparable to the 120 mg solution dose. No SAEs occurred. There were no differences in systemic levels of VEGF and EPO between GB004 and placebo. In the Phase 2 SHIFT-UC trial, Gossamer will be utilizing a tablet formulation of GB004.

Summary of Completed Phase 1b Clinical Trial in UC

The Phase 1b study was designed to evaluate the safety, tolerability and PK of a 120 mg once-daily dose of GB004 in a solution formulation over a 28-day treatment period in UC patients with active disease despite treatment with 5-ASA therapy. In addition, PD and clinical activity were studied as exploratory measures. 34 patients were randomized 2:1 to receive either GB004 (n=23) or placebo (n=11). GB004 was generally well tolerated during the study with no effects on systemic EPO or VEGF observed, relative to placebo. The most frequent AEs experienced by patients on the GB004 group were nausea and dysgeusia, all of which were mild in severity, aside from one case of moderate nausea. All patients completed the study, except for a single patient in the GB004 group who experienced an SAE of worsening UC, which was deemed by the investigator to be unrelated to study drug.

GB004 demonstrated a gut-targeted PK profile with rapid clearance from systemic circulation and multi-fold higher concentrations of drug in the gut, as compared to the plasma after eight hours of dosing. Data from gut biopsies showed increased expression of genes associated with HIF-1α stabilization and enhanced epithelial barrier function, such as TJP1 and CLDN1, and evidence of reduced gut epithelial neutrophil activity in the GB004 group compared to placebo. While this four-week study was not powered to show differences in clinical outcomes, several encouraging trends related to treatment with GB004 were observed at day 28. Mucosal healing, defined as the achievement of both histologic remission and endoscopic improvement in the sigmoid or rectum, was observed in four of 23 patients (17.4%) in the GB004 group compared to zero of 11 patients in the placebo group. Ten of 23 patients (43.5%) in the GB004 group achieved histologic remission in either the sigmoid or rectum compared to two of 11 patients (18.2%) in the placebo group. Favorable trends were also observed in clinical response (6/20 [30.0%] vs. 2/11 [18.2%]) and improvement in the rectal bleeding sub-score (13/21 [61.9%] vs. 5/11 [45.5%]). Rectal bleeding resolution was seen in 12 of 21 (57.1%) patients receiving GB004 vs. four of 11 placebo patients (36.4%). One patient in the GB004 group achieved clinical remission; no patients in the placebo group achieved clinical remission.

Summary of Ongoing Phase 2 Clinical Trial in UC (SHIFT-UC Study)

In October 2020, we commenced the Phase 2 SHIFT-UC trial, a randomized, double-blind, placebo-controlled, multi-center clinical trial in UC patients with active mild-to-moderate UC. We are enrolling approximately 195 patients with active mild-to-moderate UC disease despite treatment with 5-ASA therapy. Patients will be randomized in a 1:1:1 ratio to one of two doses of GB004 in tablet form and placebo. Patients are required to remain on stable background 5-ASA therapy throughout the study. The primary endpoint of the SHIFT-UC study is clinical remission at week 12, with secondary endpoints including clinical response, histological remission, endoscopic improvement and mucosal healing. The study will also evaluate these endpoints at week 36. We are also assessing relevant safety endpoints and exploratory endpoints. Patients may also enter an open-label extension upon completion of the placebo-controlled period or by meeting disease activity criteria during the placebo-controlled period at or after week 12. Topline 12-week results from the SHIFT-UC trial are expected in the first half of 2022, subject to developments in the ongoing COVID-19 pandemic.

GB1275 (CD11b Modulator)

GB1275 is an oral, small molecule, CD11b modulator in clinical development for the treatment of oncology indications. CD11b and CD18 are members of the integrin family of cell adhesion receptors that combine to form the functional adhesion receptor CD11b / CD18, also known as Mac-1, CR3 or alpha-M beta-2, on cell surfaces. CD11b is highly expressed on myeloid cells of the immune system, including TAMs and MDSCs, which play a significant role in promoting tumor growth, immune evasion and metastasis. Increased presence of CD11b positive MDSCs in tumors is observed across multiple tumor types and is associated with poor prognosis in multiple cancers. GB1275 is currently being tested in an ongoing Phase 1/2 clinical trial (KEYNOTE-A36) for the treatment of selected solid tumor types. In the fourth quarter of 2019, we announced a clinical trial and supply agreement with Merck to evaluate the combination of GB1275 and pembrolizumab (Keytruda) in advanced solid tumors, as part of the ongoing Phase 1/2 clinical trial. In this ongoing Phase 1/2 clinical trial, oral GB1275 alone and in combination with pembrolizumab, up to 1,200mg BID, has been generally well tolerated. To date, one PR has been observed in a patient with MSS CRC, and biomarker data suggest that GB1275, alone or in combination with pembrolizumab, may modulate myeloid cell biology in the TME, inducing a more inflamed tumor phenotype. We expect to report further data from this trial in 2021. The FDA and the EMA have granted GB1275 orphan drug designation for the treatment of patients with pancreatic cancer. We retain worldwide rights to GB1275.

Mechanism of Action

The introduction of immune checkpoint therapies has revolutionized the treatment of many cancers in recent years. Despite this, the effectiveness of approved immunotherapies has been limited to a minority of patients in only a small number of approved indications, and many cancers show little to no response to checkpoint therapy. In many cancers, innate immune cells, such as TAMs and MDSCs, are recruited into the TME, where they induce a suppressive state which down-

regulates the activation and infiltration of cytotoxic T lymphocyte, or CD8+ T cells. The result is an immunologically ‘cold’ tumor state, which allows for tumor growth and metastasis, ultimately resulting in reduced survival.

GB1275 is being developed to address the immunological state leading to cold tumors, which state down-regulates the activation and infiltration of tumor-killing cytotoxic CD8+ T cells in the TME. GB1275 binds to CD11b on TAMs and MDSCs, and preclinical data showed that GB1275 reduced tumor influx of CD11b-positive MDSCs and re-polarized immuno-suppressive (M2) TAMs towards the pro-immune M1 phenotype. These pharmacodynamic effects have the potential to convert the TME from an immunosuppressive / cold state to an immunologically hot, or active state, which would ultimately allow the influx of activated, tumoricidal CD8+ T cells.

Preclinical studies of GB1275 have demonstrated reduced tumor burden and improved survival as a single agent and in combination with chemotherapy and immuno-oncology therapies across multiple tumor mouse models, including pancreatic, breast and colon cancer. Preclinical studies and profile characterization of GB1275 support daily oral dosing with no significant preclinical toxicology findings.

Clinical Development Plan in Selected Solid Tumors

Summary of Ongoing Phase 1/2 Clinical Trial (KEYNOTE-A36 Study)

We commenced a Phase 1/2 open-label, multi-center trial (KEYNOTE-A36 Study) with GB1275 in the third quarter of 2019. The Phase 1 portion of the trial is studying patients with selected tumor types, including pancreatic adenocarcinoma, esophageal adenocarcinoma, esophageal squamous cell carcinoma, gastric adenocarcinoma, gastroesophageal junction adenocarcinoma, triple negative breast cancer, castration-resistant prostate cancer and MSS CRC. The Phase 1 portion of the trial consists of dose escalation of GB1275 monotherapy, dose escalation in combination with pembrolizumab (Keytruda), and in patients with pancreatic adenocarcinoma, dose escalation in combination with standard-of-care chemotherapy. The dose escalation portion of the Phase 1 has been completed, and the study will enroll up to 40 patients in a Phase 1 expansion cohort, studying the recommended Phase 2 dose, in patients with gastric or esophageal cancer that have progressed after initial response to anti-PD-1 therapy and patients with advanced MSS CRC. Subject to the results of the Phase 1 expansion cohort, the Phase 1 portion of the trial will be followed by a Phase 2 basket expansion phase in patients with specified metastatic solid tumors. The primary endpoints of the Phase 1 portion of the trial are safety, tolerability and PK. The primary endpoint of the Phase 2 portion of the trial is objective response rate.

Clinical safety data to date from the Phase 1 portion of the ongoing Phase 1/2 clinical trial suggest that GB1275 alone and combined with pembrolizumab, up to 1,200 mg BID, has been generally well tolerated in these clinical trials. The maximum tolerated dose of GB1275 has not been reached, and no significant overlapping toxicities between GB1275 and pembrolizumab were observed, suggesting that GB1275 can be safely combined with pembrolizumab. Encouraging anti-tumor activity has been observed, particularly at GB1275 doses greater than or equal to 800 mg BID in tumor types that are known to be less responsive to checkpoint inhibitors, including triple negative breast cancer, castration-resistant prostate cancer, MSS CRC or gastric cancer. As of October 14, 2020, seven cases of prolonged stable disease (greater than 84 days) have been observed, among which one MSS CRC patient subsequently had a PR. Five of these seven cases have occurred at doses 800mg BID or greater. Biological activity, including the down-regulation of peripheral MDSCs, the increase in tumor-infiltrating lymphocytes, and CD8+ T cell changes in tumor tissue, was observed with GB1275 alone and in combination with pembrolizumab, supporting the mechanism of action of GB1275 in modulating myeloid cell biology in the TME, potentially to enhance anti-tumor response when it is combined with a checkpoint inhibitor. We expect to release additional data from this trial in 2021. Further clinical development of GB1275 in cancer indications will be informed by the results of the ongoing Phase 1/2 study.

GB001 (DP2 Antagonist)

GB001 is an oral DP2 antagonist in development for the treatment of moderate-to-severe eosinophilic asthma. GB001 has been studied in over 800 subjects who have received at least one dose in completed clinical trials to date and has been generally well tolerated up to a dose of 40 mg. In the global Phase 2b LEDA study, GB001 showed a consistent numeric reduction in odds of 32-35% across all three dose groups in proportion of patients with asthma worsening by week 24, as compared to placebo, which was the primary endpoint of the clinical trial, but these results were not statistically significant for any of three dose groups. Additionally, in the same clinical trial, GB001 showed a nominally statistically significant reduction in time-to-first asthma worsening for the 20 mg and the 60 mg dose groups of GB001, as compared to placebo, which was the key secondary endpoint. The 40 mg dose of GB001 also demonstrated a numeric improvement, as compared to placebo, but this result was not statistically significant. One adverse event of interest was an SAE of liver chemistry elevations meeting Hy’s Law criteria in the GB001 60 mg group. The patient was asymptomatic during the event, which was reversible and resolved without sequelae. In a Phase 2 clinical trial conducted in Japan, GB001 showed a statistically significant improvement in time-

to-first asthma worsening compared to placebo. A single SAE, intrahepatic cholestasis, a liver disorder, deemed by the investigator likely to be related to study drug was observed in a Japanese patient who had received a 160 mg dose of GB001 in a Phase 1 clinical trial conducted by Teijin. The patient had GB001 exposure levels approximately three to five times higher than the other patients receiving the 160 mg dose. We engaged with the FDA and the EMA about the clinical development path in asthma, and based off those interactions, we believe that there is a viable clinical development path for GB001, or its backup molecule, in asthma. We do not currently plan to move forward with GB001, or its backup molecule, in further clinical trials without a partner. As previously announced, we do not plan to continue further development of GB001 in CRS. We retain worldwide rights to GB001, excluding Japan.

Mechanism of Action

DP2, also known as CRTh2, is a receptor for prostaglandin D2, or PGD2, a lipid mediator produced mainly by mast cells. DP2 is primarily responsible for mediating the pro-inflammatory effects of PGD2, including:

- the activation of T helper 2, or Th2, cells, ILC2 cells, basophils and eosinophils;
- the stimulation of type 2 cytokine production, including IL-4, IL-5 and IL-13, by Th2 cells; and
- the increased expression of adhesion molecules on eosinophils and basophils.

These pro-inflammatory effects contribute to airway constriction, swelling in the walls of the airways and mucous production at sites of allergic airway inflammation, all of which are hallmarks of the airway obstruction seen in asthma. The expression of DP2 is more common in patients with more severe disease, and, importantly, a significant proportion of severe asthma patients have eosinophilic inflammation.

Aberrant Th2 cell activation and resulting type 2 cytokine production have been shown to play a prominent role in various allergic and inflammatory disorders beyond eosinophilic asthma, including chronic rhinosinusitis, or CRS, chronic spontaneous urticaria, eosinophilic esophagitis and atopic dermatitis.

GB001 has been shown in preclinical studies to be a selective antagonist of the DP2 receptor. GB001 binds reversibly to human DP2 with an affinity, or Ki, of 1 to 2 nanomolar, significantly greater than its affinity for the other PGD2 receptors. No significant activity was demonstrated in a standard selectivity panel of 90 other receptors and enzymes.

In *in vitro* assays conducted by us, GB001 compared favorably to other DP2 antagonists, including high binding affinity, prolonged pharmacodynamics, long receptor residence time and slow receptor dissociation. Furthermore, we believe based on these data that GB001 may be highly insurmountable, meaning high concentrations of PGD2 would not be able to overcome receptor inhibition. Combined with our observed human plasma half-life of 10 to 15 hours, we believe these measurements support the oral, once-daily dosing regimen of GB001.

Overview of Asthma

Asthma is a complex, chronic, highly heterogeneous inflammatory condition of the airways characterized by airflow obstruction, bronchial hyperactivity and airway inflammation. Symptoms of asthma, which can be fatal, are also called asthma exacerbations or attacks and include episodes of wheezing, breathlessness, chest tightness and coughing.

Patients are deemed to have intermittent, mild, moderate or severe disease based on the frequency and severity of their symptoms. Asthma can also be sub-categorized by the composition of the white blood cells that are causing inflammation in and around the airway wall. We estimate that approximately 50% of severe asthma patients have a phenotype called eosinophilic asthma, which is marked by an increase of eosinophils in the mucosal sputum that coats the airways. Eosinophils are immune cells that have been shown to play a major role in inflammation and allergic response, and eosinophilic asthma is associated with more severe symptoms, late-onset disease and response to steroid treatment.

Clinical Development History of GB001

We acquired GB001 through our acquisition of Pulmagen Therapeutics (Asthma) Limited, or Pulmagen, a wholly-owned subsidiary of our AA BioPharma Inc. subsidiary, in January 2018, after its partner, Teijin, completed a positive Phase 2, proof-of-concept clinical trial in Japanese patients. We have worldwide rights, outside of Japan, to all of the data from the two Phase 2 clinical trials conducted by Pulmagen and Teijin described below. In addition, Gossamer has completed two Phase 2 trials with GB001 for the treatment of asthma and CRS. Over 800 subjects have received at least one dose of GB001 in completed clinical trials to date.

Summary of Pulmagen and Teijin Phase 1 Clinical Trials

In Phase 1 studies conducted by Pulmagen and Teijin, GB001 demonstrated safety and PD parameters consistent with the DP2 drug class. Most treatment emergent adverse events, or TEAEs, were mild or moderate and were considered not related to study drug. A single SAE deemed by the investigator likely to be related to study drug was observed in a Japanese patient who had received a 160 mg dose of GB001, which is eight times higher than the highest dose Teijin tested in its Phase 2 clinical trial conducted in Japan. The patient experienced intrahepatic cholestasis, which resolved after treatment discontinuation. At the time of the intrahepatic cholestasis, the patient had GB001 exposure levels approximately three to five times higher than other patients receiving the 160 mg dose. Other than this SAE, there were no laboratory testing, physical exam or electrocardiographic findings that were considered to be clinically significant and related to GB001.

Summary of Completed Pulmagen Phase 2 Clinical Trial

In December 2014, Pulmagen completed a Phase 2 clinical trial of GB001, the primary objectives of which were (1) to evaluate the safety and efficacy of 20 mg GB001 once daily compared to placebo and an active comparator, montelukast, over a 10-week treatment period and (2) to evaluate the effect of the co-administration of 10 mg montelukast once daily with GB001 treatment in a two-week extension. The primary endpoint was improvement in forced expiratory volume in one second, or FEV1, over 10 weeks. The study enrolled 248 patients with mild-to-moderate asthma that were uncontrolled on low- or medium-dose ICS, randomized 1:1:1 to placebo, 20 mg GB001 once daily and 10 mg montelukast once daily. Patients were put on a standard medium-dose of ICS with and without LABA in a four-week lead-in to the study, during which they were also removed from their LABA, if applicable.

GB001 was generally well tolerated with a TEAE incidence similar to placebo, but the study did not meet its primary endpoint. Notably, neither the active comparator, montelukast, nor GB001, showed statistically significant differences in FEV1 improvement as compared to placebo. We believe the lack of statistically significant differences between the active treatment arms and placebo was primarily related to study design and execution issues related to patient selection, including adherence to ICS therapy, eosinophilic phenotype thresholds and disease severity.

Summary of Completed Teijin Phase 2 Clinical Trial

In December 2016, Pulmagen and Teijin announced results from a Phase 2 clinical trial of GB001 conducted by Teijin in Japan. The trial was a double-blind, randomized, placebo-controlled, multi-center study, enrolling 158 patients with mild-to-moderate asthma who were using LABA and/or medium-dose ICS to control their disease. Patients on LABA discontinued its use upon entry to the trial, and all patients were brought to a standardized medium dose of ICS for a four-week lead-in period. Patients were then randomized 1:1:1 to one of two dose arms of GB001, 5 mg or 20 mg once daily, or to placebo in combination with a low dose of ICS for four weeks. Following this period of combination with low-dose ICS, use of ICS was discontinued, and patients continued taking GB001 or placebo for 12 weeks. The primary endpoint of the trial was change in morning peak expiratory flow, or AM PEF, a measure of lung function, from baseline to the last visit, marked as study completion or termination from the trial.

A statistically significant difference was seen in the AM PEF between placebo and both arms of GB001 ($p = 0.015$, 5 mg; $p = 0.027$, 20 mg). In addition, time-to-first asthma worsening reached statistical significance for the 20 mg dose arm versus placebo ($p < 0.001$). Asthma worsening in this trial was defined as a composite measure to help characterize overall uncontrolled asthma, including exacerbations.

GB001 was generally well tolerated in this trial, with adverse events consistent with placebo, including nasopharyngitis, gastrointestinal disorders and measures of blood and liver markers. No SAEs were observed in the GB001 treatment arms.

Summary of Completed Phase 2b Eosinophilic Asthma Clinical Trial (LEDA Study)

In October 2020, we announced topline results from the completed Phase 2b clinical trial (LEDA Study) of GB001 in moderate-to-severe eosinophilic asthma. The primary objective of this clinical trial was to evaluate the efficacy and safety of 20 mg, 40 mg, and 60 mg GB001 once daily relative to placebo when added to standard of care treatment. The LEDA study enrolled 480 patients with uncontrolled, moderate-to-severe eosinophilic asthma and assessed the effect of oral GB001 add-on therapy to standard of care over 24 weeks, comparing three dose groups of once-daily, oral GB001 (20 mg, n=120; 40 mg, n=118; and 60 mg, n=122) to placebo (n=120).

The primary outcome, asthma worsening, included five components and was chosen for its sensitivity in detecting deterioration in clinical outcome measures known to be correlated with exacerbations. Asthma worsening was a

composite outcome defined as the occurrence of any one of the following at any time by Week 24: deterioration of morning peak expiratory flow, pre-bronchodilator FEV1, or asthma control as measured by the Asthma Control Questionnaire 5, relative to baseline; an increase in rescue medication use relative to baseline; or the occurrence of a severe asthma exacerbation, defined as deterioration of asthma that led to the use of systemic corticosteroids for at least 3 days, hospitalization, or an Emergency Department visit. This endpoint has previously been used in the context of steroid withdrawal studies, including a prior Phase 2 trial of GB001.

The primary endpoint of the trial was not met, though consistent and meaningful numeric reductions in the odds of asthma worsening as compared to placebo were observed across all GB001 groups: 33% (p=0.1425), 32% (p=0.1482), and 35% (p=0.1086), for the GB001 20 mg, 40 mg, and 60 mg groups, respectively. In addition, statistically significant improvements in the key secondary endpoint of time to first asthma worsening as compared to placebo were observed for GB001 20 mg and 60 mg (28% and 30% risk reduction, p=0.0466 and p=0.0304, respectively), with GB001 40 mg also demonstrating a numeric improvement (23%, p=0.1222). Numeric reductions for each GB001 group as compared to placebo were seen across all individual components of the asthma worsening endpoint. In addition to asthma worsening, the expected Phase 3 registrational endpoint of annualized severe exacerbation rate, or AER, was evaluated as a secondary endpoint. While AER is typically formally evaluated in large Phase 3 studies with a one-year duration, reductions as compared to placebo were seen for each GB001 group (GB001 20 mg: 20%; 40 mg: 25%; 60 mg: 11%), although the reductions were not statistically significant. Numeric improvements in lung function, as measured by morning peak expiratory flow and pre-bronchodilator FEV1, and asthma control, as measured by the Asthma Control Questionnaire were also observed for all three GB001 groups compared to placebo.

The incidence of adverse events was generally comparable across treatment groups: 65.8% placebo, 65.8% GB001 20 mg, 69.5% GB001 40 mg, and 68.0% GB001 60 mg. Adverse events of interest (liver chemistry elevations leading to study drug discontinuation) occurred more frequently in GB001 60 mg (4.1%, n=5) than placebo (0.8%, n=1), GB001 20 mg (0.8%, n=1), or GB001 40 mg (1.7%, n=2). One adverse event of interest was a SAE of liver chemistry elevations meeting Hy's Law criteria in the GB001 60 mg group. The patient was asymptomatic during the event, which was reversible and resolved without sequelae.

Completed Phase 2 Chronic Rhinosinusitis Clinical Trial (TITAN Study)

The TITAN trial enrolled 97 patients with CRS with and without nasal polyps and assessed treatment with GB001 40 mg as compared to placebo over 16 weeks. Neither the primary nor the secondary endpoints of the trial were met. The safety and tolerability of GB001 40 mg was generally consistent with that observed in the LEDA Study. We do not plan to continue further development of GB001 in CRS.

Our Research Capabilities and Preclinical Programs

We currently have multiple programs in preclinical development. We are continuing to build our research capabilities, specifically focusing on our areas of expertise within immunology, inflammation and oncology, in order to advance new programs into the clinic, as well as to optimize our existing programs. We have six programs in preclinical development, and we expect at least one additional product candidate to enter clinical trials within the next 12 months.

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 from existing products and products in development for each of our product candidates. Seralutinib is a PDGFR, CSF1R and c-KIT inhibitor initially targeted for PAH patients. We expect competition in this patient set will include prostanoids, available in oral form as Orenitram (United Therapeutics Corporation, or United Therapeutics) and Uptravi (Janssen), by inhalation as Tyvaso (United Therapeutics), and by infusion as Remodulin (United Therapeutics). We also may face some competition from products used in 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). We believe that, if approved, seralutinib could be used alongside all three classes of approved therapies. PAH is also an active indication for investigational drugs, and we may face competition in the future from ralinepag (Arena Pharmaceuticals, Inc. and United Therapeutics), sotatercept (Acceleron Pharma, Inc.), RVT-1201 (Altavant Sciences, Inc.), PB1046 (PhaseBio Pharmaceuticals Inc.), MK-5475 (Merck) and GMA310 (Gmax Biopharm LLC). Additionally, although not approved for the treatment of PAH, we may face competition from formulations of imatinib, including those from Tenax Therapeutics, Aerovate Therapeutics and Aerami Therapeutics / Vectura Group.

GB004 is a HIF-1α stabilizer with the potential to restore epithelial barrier function in patients with IBD. Patients with mild to moderate UC can initially be maintained in remission using a 5-ASA. For those patients who do not respond to 5-ASA, or those with more severe and / or extensive disease at diagnosis, corticosteroids are generally the next line of treatment. Patients who have become nonresponsive or intolerant to corticosteroids may move to azathioprine and 6-mercaptopurine. The treatment of severe patients is dominated by anti-TNF biologics, though the paradigm is shifting because of the approval of agents in other classes, such as anti-integrin, IL-12 / IL-23, and JAK inhibitors. There is potential that the approval of biosimilar anti-TNF biologics moves the class further up in the treatment paradigm. Further disruption is expected in the coming years through the introduction of oral S1P1 inhibitors and additional oral JAK inhibitors.

GB1275 is a CD11b modulator for the treatment of cancer indications. To our knowledge, there are no other CD11b modulator programs in clinical development for oncology. Our initial targeted cancer indications for GB1275 include pancreatic, gastric, esophageal, prostate, triple negative breast cancer and colorectal. Treatment for patients in these indications has historically included chemotherapy, radiation, targeted therapy and surgery. In recent years immune checkpoint inhibitors have received approvals, including Keytruda (pembrolizumab / Merck) and Tecentriq (atezolizumab / Bristol-Myers Squibb), for the treatment of some of these difficult to treat cancer indications, including gastric and esophageal cancers (Keytruda) and triple negative breast cancer (Tecentriq). In addition to current standard of care, we may face competition from compounds with novel mechanisms of action that are currently in clinical development, including compounds targeting the CCR2, CCR5, CSF1R and CXCR2 pathways.

GB001, in development for the treatment of moderate-to-severe eosinophilic asthma, is an oral DP2 antagonist, a class of medicines with no currently approved agents. However, other DP2 antagonists are currently in development by Chiesi Farmaceutici S.p.A., Merck, Sunshine Lake Pharma Co., Ltd., Idorsia Pharmaceuticals Ltd., ZAI Lab Ltd. and CSPC ZhongQi Pharmaceutical Technology Co., Ltd. If approved, we will also face branded competition from existing biologics, including Xolair (omalizumab / anti-IgE, marketed by Genentech and Novartis) and Dupixent (dupilumab / anti-IL-4 / IL-13, marketed by Regeneron Pharmaceuticals, Inc. and Sanofi S.A.), for moderate-to-severe asthma, and Nucala (mepolizumab / anti-IL-5, marketed by GlaxoSmithKline), Cinqair (reslizumab / anti-IL-5, marketed by Teva Pharmaceutical Industries Ltd.), and Fasenra (benralizumab / anti-IL-5R, marketed by AstraZeneca Pharmaceuticals LP) for severe eosinophilic asthma. We will also face competition from generic montelukast, which is utilized in mild-to-moderate patients. Several other agents are advancing in clinical trials for moderate and / or severe asthma, including tezepelumab (anti-TSLP; Amgen Inc. / AstraZeneca), REGN3500 (anti-IL-33R; Regeneron), masitinib (anti-c-kit / PDGF; AB Science S.A.) and Dexpramipexole (dopamine receptor agonist, Knopp Biosciences LLC).

There may be other earlier stage clinical programs that, if approved, would compete with our product candidates. 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 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. 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 a milestone payment of $5.0 million to Pulmokine and are obligated to make future development and regulatory milestone payments of up to $58 million, commercial milestone payments of up to $45 million, and sales milestone payments of up to $190 million. 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.

The Pulmokine Agreement also includes a sublicense to patents concerning methods for detecting pulmonary arterial hypertension owned by The Rensselaer Center for Translational Research, Inc., or Rensselaer, and licensed to Pulmokine in an exclusive license agreement, or the Rensselaer License. Under the Rensselaer License, Pulmokine is required to use commercially reasonable efforts to develop and commercialize at least one licensed product covered by the Rensselaer patent rights, which obligation can be satisfied through our development efforts. If such obligation is not satisfied by Pulmokine or us, or the Rensselaer License is otherwise terminated for any reason, our sublicense under the Pulmokine Agreement will, at our option, either terminate or, subject to Rensselaer's approval and our acceptance of the provisions of the Rensselaer License, convert to a license directly between us and Rensselaer.

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.

Aerpio Pharmaceuticals

In June 2018, we entered into a license agreement, or the Aerpio Agreement, with Aerpio Pharmaceuticals, Inc., under which we were granted an exclusive worldwide license to certain intellectual property rights owned or controlled by Aerpio to develop and commercialize GB004 and certain other related compounds for all applications. We also have the right to sublicense our rights under the Aerpio 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, in at least two countries in the European Union, and in Japan, in each case for at least one of the initial indications of UC or CD. The Aerpio Agreement also includes a sublicense to a patent concerning methods for treating inflammatory bowel disease owned by The Regents of the University of Colorado, or UC Regents, and licensed to Aerpio in a nonexclusive license agreement, or the UC Regents License. If Aerpio breaches the UC Regents License and the UC Regents terminate the license, our sublicense under the Aerpio Agreement will also terminate.

Under the terms of the Aerpio Agreement, we made an upfront payment of $20 million to Aerpio in June 2018, which represented the purchase consideration for an asset acquisition. On May 11, 2020, we entered into an amendment to the license agreement with Aerpio pursuant to which we made an upfront payment of $15.0 million to Aerpio for a reduction in future milestone payments and royalties. Under the amended license agreement, we are obligated to make future approval milestone payments of up to $40.0 million and a sales milestone payment of $50.0 million. We are also obligated to pay tiered royalties on sales for each licensed product, at percentages ranging from a low- to mid-single-digits, subject to certain customary reductions. In addition, if we choose to sublicense or assign to any third parties our rights under the Aerpio Agreement with respect to any licensed product or if our GB004 operating subsidiary undergoes a change of control and the value of such transaction exceeds a specified value, we have an option to pay a specified percentage of all revenue to be

received in connection with such transaction, and if we exercise the option Aerpio will no longer be paid the development, regulatory, commercial or sales milestones or royalties on the sales of licensed products under the agreement. If we do not exercise our buy-down option with respect to a sublicense or assignment of our rights under the Aerpio Agreement or with respect to a change of control of our GB004 operating subsidiary, Aerpio will have an option to receive a specified percentage of all revenue received in connection with such transaction, and if Aerpio exercises the option Aerpio will no longer be paid the development, regulatory, commercial or sales milestones or royalties on sales of licensed products under the agreement.

Our royalty obligations and the Aerpio Agreement will expire on a licensed product-by-licensed product and country-by-country basis on the later of fifteen years from the date of first commercial sale or when there is no longer a valid patent claim covering such licensed product in such country. The agreement may be terminated either by Aerpio or by us in the event of an uncured material breach by the other party or in the event the other party becomes subject to specified bankruptcy, insolvency or similar circumstances. In the event we commence a legal action challenging the validity or enforceability of any licensed patents, Aerpio will have the right to terminate the agreement or elect to increase milestone and royalty payments by a specified percentage. We may terminate the agreement in the event of potential safety or efficacy concerns affecting a licensed product. Upon termination of the agreement for any reason all rights and licenses granted to us under the agreement will terminate, and in the event of certain termination events, we would grant Aerpio worldwide rights to the terminated program.

Manufacturing

We currently rely on multiple third-party manufacturers for the manufacture of our product candidates for preclinical and clinical testing. We intend to rely on third-party contract manufacturers for commercial manufacturing if our product candidates receive marketing approval. Typically, there are multiple sources for all of the materials required for the manufacture of our product candidates. Our manufacturing strategy enables us to more efficiently direct financial resources to the research, development and commercialization of product candidates rather than diverting resources to internally develop manufacturing facilities. As our product candidates advance 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, 2020, with respect to seralutinib, we have exclusively licensed one issued U.S. patent and a number of pending applications in other jurisdictions owned by Pulmokine directed to method of use claims, which, if issued, are not due to expire before 2037, excluding any additional term for patent term extension. We also have 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; five 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, the European Patent Convention and Japan, and pending applications in Australia, Canada, China, the European Patent Convention and Japan. These patents and patent applications are directed to seralutinib compound, formulation and method of use claims.

GB004

As of December 31, 2020, with respect to GB004, we have exclusively licensed from Aerpio ten issued U.S. patents directed to compound, pharmaceutical composition and method of use claims, eight of which are not due to expire before 2030, and one, directed to synthetic method claims, is not due to expire before 2035, excluding any additional term for patent term extension; two pending U.S. patent applications directed to compound and method of use claims, which, if issued, are not due to expire before 2030, excluding any additional term for patent term extension; and a number of patents and pending patent applications in other jurisdictions. The patents and pending patent applications directed to compound, pharmaceutical composition and method of use claims in other jurisdictions, and which are not due to expire before 2030, include issued

patents in Australia, Canada, China, the European Patent Convention, India, Japan, Mexico, New Zealand and South Korea, and pending patent applications in Brazil, the European Patent Convention, India, Mexico and South Korea. The patents and pending patent applications directed to synthetic method claims in other jurisdictions, and which are not due to expire before 2035, include pending patent applications in China, the European Patent Convention, India and Japan.

GB1275

As of December 31, 2020, we owned one issued U.S. patent directed to compound, pharmaceutical composition and method of use claims for GB1275, which, if issued, is not due to expire before 2036, excluding any additional term for patent term extension, and a number of corresponding patent applications pending in other jurisdictions, including Australia, Brazil, Canada, China, the European Patent Convention, Israel, Japan, Mexico, New Zealand, Singapore and South Korea, also directed to compound, pharmaceutical composition and method of use claims for GB1275.

GB001

As of December 31, 2020, with respect to GB001, we owned one issued U.S. patent directed to compound and pharmaceutical composition claims, which is not due to expire before 2026, excluding any additional term for patent term extension, and a number of patents in other jurisdictions, including issued patents in Australia, Canada, China, the European Patent Convention, India, Mexico, New Zealand, Russia, and Brazil directed to compound and pharmaceutical composition claims. As of December 31, 2020, we owned one U.S. patent directed to compound claims, which is not due to expire before 2037, excluding any additional term for patent term adjustment or extension, and a number of pending patent applications in other jurisdictions, including pending applications in Australia, Brazil, Canada, China, the European Patent Convention, India, South Korea, Mexico, New Zealand, Russia, and Taiwan directed to compound claims. As of December 31, 2020, with respect to a backup DP2 molecule, we owned three issued U.S. patent directed to compound and pharmaceutical composition claims, which are not due to expire before 2032, excluding any additional patent term extension, and a number of patents and pending patent applications in other jurisdictions, including issued patents in UK, France, Germany, China, Japan, Korea, Australia, Canada, New Zealand, Mexico and Israel, and pending patent applications in India and Brazil.

With respect to our product candidates and processes we intend to develop and commercialize in the normal course of business, we intend to pursue patent protection covering, when possible, compositions, methods of use, dosing and formulations. We may also pursue patent protection with respect to manufacturing and drug development processes and technologies. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies. We may not be able to obtain patent protections for our compositions, methods of use, dosing and formulations, manufacturing and drug development processes and technologies throughout the world. Issued patents can provide protection for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. In general, patents issued for applications filed in the United States can provide exclusionary rights for 20 years from the earliest effective filing date. In addition, in certain instances, the term of an issued U.S. patent that covers or claims an FDA approved product can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, which is called patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The term of patents outside of the United States varies in accordance with the laws of the foreign jurisdiction, but typically is also 20 years from the earliest effective filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of biopharmaceuticals has emerged in the United States. The relevant patent laws and their interpretation outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our technology or product candidates and could affect the value of such intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. We cannot guarantee that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may file in the future, nor can we be sure that any patents that may be granted to us in the future will be commercially useful in protecting our products, the methods of use or manufacture of those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. Patent and other intellectual property rights in the pharmaceutical and biotechnology space are evolving and involve many risks and uncertainties. For example, third parties may have blocking patents that could be used to prevent us from commercializing

our product candidates and practicing our proprietary technology, and our issued patents may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our product candidates. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents. For these reasons, we may face competition with respect to our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any patent protection for such product may expire or remain in force for only a short period following commercialization, thereby reducing the commercial advantage the patent provides.

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.

Certain of our product candidates are subject to regulation as combination products, which means that they are 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 our inhaled product candidate regulated as a combination product, 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 this product through the 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 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, 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

- 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 authorization from the FDA to administer an investigational new drug product to humans. The sponsor will also include a protocol detailing, among other things, the objectives of the first phase of the clinical trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, if the first phase 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 the trials may not begin or continue until the FDA notifies the sponsor that the hold has been lifted. Submission of an IND therefore may or may not result in FDA authorization 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 include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. They 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, and timely safety reports must be submitted to the FDA and the investigators for serious and unexpected adverse events. An 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.

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. Sponsors sometimes designate their Phase 1 clinical trials as Phase 1a or Phase 1b. Phase 1b clinical trials are typically aimed at confirming dosing, pharmacokinetics and safety in larger number of patients. Some Phase 1b studies evaluate biomarkers or surrogate markers that may be associated with efficacy in patients with specific types of diseases.

- *Phase 2*: This phase involves clinical trials 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*: Clinical trials are undertaken to further evaluate 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, if appropriate, 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.

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.

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 for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

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.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report 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.

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 discuss 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.

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, or QS, regulations applicable to medical devices.

NDA Review and Approval Process

The results of product development, 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 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 conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are 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.

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 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, such as an additional pivotal Phase 3 trial 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 Phase 4 testing, which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval, and may require testing and surveillance programs to monitor the safety of approved products which have been commercialized. 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. The FDA will not approve the NDA without an approved REMS, if required. 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. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

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 indication 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. Orphan exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval of the same drug as defined by the FDA or if our product candidate is determined to be contained within the competitor’s product for the same indication or disease.

In addition, if an orphan designated product receives marketing approval for an indication 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. seralutinib has received orphan drug designation for the treatment of patients with PAH, and GB1275 has received orphan drug designation for the treatment of pancreatic cancer.

Expedited Development and Review Programs

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA’s review and approval of new drugs and biological products that meet certain criteria. 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, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Unique to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and

accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug 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. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

In addition, a product 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 may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. 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 if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

The FDA Safety and Innovation Act established a category of drugs referred to as “breakthrough therapies” that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. The designation includes all of the fast track program features, which means that the sponsor may file sections of the NDA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

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

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 by us or our partners 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 marketing 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 marketing 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 another period of exclusivity 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 our product candidates 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 our product candidates 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) created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (which was increased to 70% commencing January 1, 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (8) 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 (9) established a Center for Medicare 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. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit affirmed the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace 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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020

through March 31, 2021, 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.

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. The likelihood of success of these and other measures proposed by the former Trump administration is unclear, particularly in light of the new Biden administration. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or Right to Try Act, was signed into law. The law, among other things, provides a federal framework for patients to access certain investigational new drug products that have completed a Phase I clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

U.S. Healthcare Fraud and Abuse Laws and Compliance Requirements

Federal and state 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 and the civil monetary penalties statute.

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.

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 other health care professionals beginning in 2022, 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 and local 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.

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. 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 & Security

In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), 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. In addition, certain state laws, such as the California Consumer Privacy Act, or the CCPA, and the California Privacy Rights Act, or the CPRA, govern the privacy and security of personal information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Foreign Regulation

In order to market any product outside of the United States, we would 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, 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.

To market a medicinal product in the European Economic Area, or EEA (which is comprised of the 28 Member States of the EU plus Norway, Iceland and Liechtenstein), we must obtain a Marketing Authorization, or MA. There are two types of marketing authorizations:

- the Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced therapy products, and medicinal products containing a new active substance indicated for the treatment certain diseases, such as AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU; and
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, 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 above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Data and marketing exclusivity

In the EEA, new products authorized for marketing, or reference products, qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. 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 marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial authorization of the reference product in the EU. The 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 marketing authorization 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.

Pediatric investigation plan

In the EEA, marketing authorization applications for new medicinal products not authorized have to include the results of studies 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 drug for which marketing authorization 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 marketing authorization is obtained in all Member States of the EU and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension.

Orphan drug designation

In the EEA, a medicinal product can be designated as an orphan drug if its sponsor can establish that the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the EU when the application is made, or that the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the European Community and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment. For either of these conditions, the applicant must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the drug will be of significant benefit to those affected by that condition.

In the EEA, an application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Marketing authorization for an orphan drug leads to a ten-year period of market exclusivity. During this market exclusivity period, the EMA or the member state competent authorities, cannot accept another application for a marketing authorization, or grant a marketing authorization, for a similar medicinal product for the same indication. The period of market exclusivity is extended by two years for medicines that have also complied with an agreed PIP.

This 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 drug designation, for example because the product is sufficiently profitable not to justify market exclusivity. Market exclusivity can be revoked only in very selected cases, such as consent from the marketing authorization holder, inability to supply sufficient quantities of the product, demonstration of "clinical superiority" by a similar medicinal product, or, after a review by the Committee for Orphan Medicinal Products, requested by a member state in the fifth year of the marketing exclusivity period (if the designation criteria are believed to no longer apply). Medicinal products designated as orphan drugs pursuant are eligible for incentives made available by the EU and its Member States to support research into, and the development and availability of, orphan drugs.

Clinical trials

Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCPs. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union 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.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization 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. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU Member State in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is currently expected to take effect in 2019, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with cGMP. Other national and European Union-wide regulatory requirements also apply.

Privacy and data protection laws

We are also subject to laws and regulations in non-U.S. countries covering data privacy and the protection of health-related and other personal data. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. Laws and regulations in these jurisdictions apply broadly to the collection, use, storage, disclosure, processing and security of personal data that identifies or may be used to identify an individual, such as names, contact information, and sensitive personal data such as health data. These laws and regulations are subject to frequent revisions and differing interpretations, and have generally become more stringent over time.

The General Data Protection Regulation, or GDPR, went into effect in May 2018. The GDPR imposes many requirements for controllers and processors of personal data of individuals within the EEA, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the 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. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. 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 EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the European Union. Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR (UK GDPR), which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and United Kingdom Trade and Cooperation Agreement, ending June 30, 2021 at the latest, whilst the parties discuss an adequacy decision. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from EU member states to the United Kingdom long term without additional measures. These changes may lead to additional costs and increase our overall risk exposure.

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 February 19, 2021, we had 195 full-time employees and one part-time employee. Of those 196 employees, 65, or 33%, have a Ph.D. or M.D., and 103, or 53%, 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 3013 Science Park Road, Suite 200, 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. The information in or accessible through the SEC and our website are not incorporated into, and are not considered part of, this filing.

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.
- Our business activities are expected to be adversely affected by the global COVID-19 pandemic.
- We depend heavily on the ability to successfully advance our product candidates 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 our product candidates.
- We are dependent on third parties to conduct our pre-clinical and clinical trials.
- We are dependent on third parties to manufacture our pre-clinical and clinical product candidates.
- We may not be successful in entering into or maintaining collaborations, licenses and other similar arrangements.
- If approved, the success of our product candidates 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 our product candidates.
- 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 certain of our product candidates, including seralutinib and GB004.
- Our stock price is volatile, and investors may incur substantial losses.
- We are 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 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 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 our product candidates and conducting preclinical studies and clinical trials. Seralutinib, GB004 and GB1275 are in active clinical development, while multiple other development programs remain in the preclinical or research stage. 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 our product candidates are not successfully developed and approved, we may never generate any revenue. Our net losses were $243.4 million and $180.3

million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $577.5 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. All of our product candidates, including our multiple preclinical product candidates, 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 any of our product candidates 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 our product candidates, obtaining regulatory approval for these product candidates 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 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 product development programs, commercialization efforts or other operations.

The development of biopharmaceutical product candidates is capital-intensive. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials of seralutinib, GB004 and GB1275, continue research and development, initiate clinical trials of our multiple other development programs, and seek regulatory approval for our current product candidates and any future product candidates we may develop. In addition, as our product candidates progress through development and toward commercialization, we will need to make milestone payments to the licensors and other third parties from whom we have in-licensed or acquired our product candidates, including seralutinib, GB004, GB1275 and multiple preclinical product candidates. 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 any of our product candidates, 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 our product candidates. 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 ongoing Phase 2 clinical trial in PAH for seralutinib, our ongoing Phase 2 clinical trial in UC for GB004 and our ongoing Phase 1/2 clinical trial in oncology indications for GB1275. 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. For example, in July 2020, we, and certain of our subsidiaries, as borrowers, amended our credit, guaranty and security agreement, or the Credit Facility, with MidCap Financial Trust, or MidCap, an agent and as a lender, and the additional lenders party thereto from time to time, or together with MidCap, the Lenders, pursuant to which the Lenders, including affiliates of MidCap and Silicon Valley Bank agreed to make term loans available to us 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 in May 2019. Under the Credit Facility, we have the ability to access the remaining $120.0 million in

two additional tranches (of $60.0 million each), subject to specified availability periods, the achievement of certain clinical development milestones, minimum cash requirements and other customary conditions. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates.

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 our product candidates which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing for our product candidates, including commercial manufacturing if any product candidate is approved;
- the costs, timing and outcome of regulatory review of our product candidates;
- 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 the licensors and other third parties from whom we have in-licensed our acquired our product candidates;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate 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; 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, our product candidates, 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. 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.

The terms of our Credit Facility place restrictions on our operating and financial flexibility.

On May 2, 2019, we entered into the Credit Facility, as further amended in September 2019 and July 2020. The outstanding principal balance under the credit facility was $30.0 million as of December 31, 2020.

The Credit Facility includes affirmative and negative covenants applicable to us. The affirmative covenants include, among others, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage, maintain property, pay taxes, satisfy certain requirements regarding accounts and comply with laws and regulations. The negative covenants include, among others, restrictions on transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, amending material agreements and organizational documents, selling assets and suffering a change in control, in each case subject to certain exceptions.

The Credit Facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 3.0% and would provide MidCap, as agent, with the right to exercise remedies against us, and the collateral securing the Credit Facility, including foreclosure against our properties securing the credit facilities, including our cash. These events of default include, among other things, our failure to pay any amounts due under the credit facility, a breach of covenants under the Credit Facility, our insolvency or the occurrence of insolvency events, the occurrence of a change in control, the occurrence of certain FDA and regulatory events, our failure to remain registered with the SEC and listed for trading on the Nasdaq Global Select Market, or Nasdaq, the occurrence of a material adverse change, the occurrence of a default under a material agreement reasonably expected to result in a material adverse change, the occurrence of certain defaults under certain other indebtedness in an amount greater than $2,500,000 and the occurrence of certain defaults under subordinated indebtedness and convertible indebtedness. The occurrence of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

Our ability to make scheduled payments on or to refinance our indebtedness depends on our future performance and ability to raise additional sources of cash, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate sufficient cash to service our debt, we may be required to adopt one or more alternatives, such as selling assets, restructuring our debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we desire to refinance our indebtedness, our ability to do so will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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, 2020, we have sold $200.0 million aggregate principal amount 5.00% convertible senior notes due 2027, and, excluding intercompany indebtedness, we, including our subsidiaries, had approximately $75.8 million of additional indebtedness and other liabilities, including trade payables, of which approximately $28.7 million was secured indebtedness under our Credit Facility. We may also incur additional indebtedness to meet future financing needs. Our indebtedness 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, our existing credit facility contains, and 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 product candidates.

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, such as our Credit Facility, 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, research programs or product candidates 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 Discovery, Development and Regulatory Approval of Our Product Candidates

Our business is subject to risks arising from epidemic diseases, such as the recent COVID-19 pandemic.

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, communities and business operations, as well as the U.S. and global economy and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. In response, we have implemented a work-from-home policy for certain of our employees, following the guidelines or directives issued by federal, state and local government agencies in the U.S. To date, we have been able to continue to supply our product candidates to our patients currently enrolled in our clinical trials, including our Phase 2 clinical trials of seralutinib and GB004 and Phase 1/2 clinical trial of GB1275, and do not currently anticipate any interruptions in supply. In addition, while we are continuing the clinical trials we have underway in sites across the globe, COVID-19 precautions have delayed, such as the pause in enrollment in our Phase 1b clinical trial for seralutinib in PAH, and may continue to delay completion of our current and future trials and may directly or indirectly impact the timeline for data readouts, initiation of, as well as monitoring, data collection and analysis and other related activities for, some of our current and future clinical trials. For example, our current expectations for how we will continue to enroll our Phase 2 clinical trials of seralutinib and GB004 are based on an assumption that clinical trial and healthcare activities begin to return to normal and clinical sites reopen or stay open in the first half of 2021. In particular with respect to seralutinib, some PAH clinical trial sites are currently closed or limited as PAH patients may be at a higher risk of COVID-19 complications than the general population. Therefore, our assumptions around enrollment timing may prove to be incorrect, in particular if COVID-19 continues to spread. As the COVID-19 pandemic continues to spread around the globe, we may experience disruptions that could severely impact our business, clinical trials and manufacturing and supply chains, including:

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff for our Phase 2 clinical trials of seralutinib and GB004;
- delays or difficulties in enrolling patients in our clinical trials, including our Phase 2 clinical trials of seralutinib and GB004, especially if sites do not reopen to screen and enroll PAH patients;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, including;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials and interruption in global shipping that may affect the transport of clinical trial materials;
- limitations on employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- interruptions or delays in the operations of the FDA, EMA or other regulatory authorities, including in receiving feedback or approvals from the FDA, EMA or other regulatory authorities with respect to future clinical trials or regulatory submissions;
- changes in local regulations as part of a response to COVID-19 which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- refusal of the FDA or EMA to accept data from clinical trials in affected geographies; and
- difficulties launching or commercializing products, including due to reduced access to doctors as a result of social distancing protocols.

In addition, the spread of COVID-19 has had and may continue to severely impact the trading price of shares of our common stock and could impact our ability to raise additional capital on a timely basis or at all. The COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 may impact our business, including our clinical trials, preclinical research, manufacturing and supply chains and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section.

We depend heavily on the success of* seralutinib*, GB004 and GB1275, which are in either Phase 1 or Phase 2 clinical development. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

Our four clinical-stage product candidates are in Phase 1 or Phase 2 clinical development. We commenced a Phase 2 clinical trial of seralutinib in PAH in 2020, a Phase 2 clinical trial of GB004 in UC in 2020 and a Phase 1/2 clinical trial of GB1275 in oncology indications in 2019, and we completed a Phase 2b clinical trial of GB001 in moderate-to-severe eosinophilic asthma and a Phase 2 clinical trial of GB001 in CRS in 2020. As previously announced, we do not plan to continue further development of GB001 in CRS, and we do not currently plan to move forward with GB001, or its backup compounds, in further clinical trials without a partner.

Our assumptions about why these product candidates are worthy of future development and potential approval in these, or any, indications are based on data primarily collected by other companies. We also have preclinical product candidates that will need to progress through IND-enabling studies prior to clinical development. None of our product candidates have advanced into a pivotal study for the indications for which we are studying. 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 our product candidates. The success of our product candidates will depend on several factors, including the following:

- successful enrollment in clinical trials and completion of clinical trials and preclinical studies with favorable results;
- acceptance of INDs by the FDA or similar regulatory filing by comparable foreign regulatory authorities for the conduct of clinical trials of our preclinical product candidates and our proposed design of future clinical trials;
- demonstrating safety and efficacy to the satisfaction of applicable regulatory authorities;
- receipt of marketing approvals from applicable regulatory authorities, including new drug applications, or 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 our products, if and when approved, whether alone or in collaboration with others;
- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for our product candidates;
- maintaining an acceptable safety profile of our products following approval; and
- maintaining and growing an organization of people who can develop our products and technology.

Certain of our product candidates, including seralutinib, are subject to regulation as combination products, which means that they are 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. Our product candidates that are considered to be drug-device combination products will 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, or QS, regulations applicable to medical devices. Combination products are also subject to the Medical Device Directives and Standards in Europe. Problems associated with the device component of the combination product candidate 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 approval prior to using the modified device component. If the FDA or any other regulatory body fails to approve use of those modified devices or take significant enforcement action against the manufacturer, we would not be able to market or may have to suspend marketing our products 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 our product candidates, which may never occur. We have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. Given our early 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 our product candidates, 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 our product candidates are worthy of future development and potential approval are based on data collected by other companies. Our product candidates may not have favorable results in later clinical trials, if any, 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, any product candidate can unexpectedly fail at any stage of preclinical or clinical development. The historical failure rate for product candidates in our industry is high.

The results from preclinical studies or clinical trials of a product candidate or a competitor's product candidate in the same class may not predict the results of later clinical trials of our product candidates, and interim 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. In particular, we do not know how GB001 will perform in future clinical trials, if any. In the Phase 2b LEDA study, GB001 showed a consistent numerical reduction of 32-35% across all three dose groups in proportion of patients presenting with asthma worsening, as compared to placebo, which was the primary endpoint of the clinical trial, but these results were not statistically significant. Further, GB001 did not meet its primary or secondary endpoints in the TITAN Phase 2 study of GB001 in chronic rhinosinusitis. In addition, GB001 did not meet the primary efficacy endpoint of improvement in FEV1 over 10 weeks in the first Phase 2 clinical trial conducted by Pulmagen Therapeutics (Asthma) Limited, or Pulmagen, and the second Phase 2 clinical trial conducted by Pulmagen and its partner, Teijin, was limited to only Japanese patients. In October 2019, Novartis announced that its oral DP2 antagonist, fevipiprant, failed to improve lung function in a pair of Phase 3 clinical trials of patients with moderate asthma, and in December 2019, Novartis announced that the pooled analysis from a pair of pivotal Phase 3 clinical trials of patients with moderate-to-severe asthma did not meet the clinically relevant threshold for reduction in rate of moderate-to-severe exacerbation and that the results did not support further development of fevipiprant in asthma. 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 clinical trials of seralutinib. Moreover, this 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. Furthermore, we cannot assure you that our preclinical programs will be able to progress from candidate identification to Phase 1 clinical development.

In addition, in May 2020 we reported promising topline results from our Phase 1b study of GB004 in patients with active mild-to-moderate UC, and we initiated a Phase 2 trial of GB004 in UC in October 2020. However, the Phase 1b study was not powered to show differences in clinical outcomes, and we may not observe positive efficacy data or safety results in our Phase 2 trial, including as a result of using a new oral tablet formulation versus the solution used in the Phase 1b study or different dosage strengths versus the doses used in the Phase 1b study.

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 our product candidates in those and other indications, 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 our product candidates, we must conduct extensive clinical studies to demonstrate the safety and efficacy of the product candidates in humans. We are currently conducting a Phase 2 clinical trial of seralutinib in PAH patients, a Phase 2 clinical trial of GB004 in UC and a Phase 1/2 clinical trial of GB1275 in certain oncology indications. In addition, before we can initiate clinical development for our preclinical product candidates, 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 application, and we may also be required to submit regulatory filings to foreign regulatory authorities to the extent we initiate clinical trials outside of the United States.

We do not know whether our planned trials will begin on time or be completed on schedule, if at all. The commencement 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;
- 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 from one or more institutional review boards, or IRBs;
- 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 product candidate 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 due to movement restrictions, heath reasons or otherwise resulting from the novel strain of coronavirus, COVID-19;

- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, 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 our product candidates or any of their 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 regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- interruptions to operations of clinical sites, manufacturers, suppliers, or other vendors from a health epidemic such as COVID-19;
- 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.

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 for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we currently and may continue to do for our product candidates, 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 relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process 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 a product candidate. We may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions. 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 our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates 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 our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as 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 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, which is our target indication for seralutinib, and we have encountered difficulties enrolling patients in our ongoing Phase 2 clinical trial and our previous Phase 1b study of seralutinib in PAH patients. We also may encounter difficulties in identifying and enrolling subjects with a stage of disease appropriate for our planned clinical trials 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. For certain of our product candidates, including seralutinib, the conditions which we currently plan to evaluate are orphan or rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials, once established, will further limit the pool of available trial participants. If patients are unwilling to participate in our trials for any reason, including the existence of concurrent clinical trials for similar patient populations, 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 our product candidates may be delayed. Our ability to activate clinical trial sites and decide to open enrollment for a given trial or commence a preclinical study may also be negatively affected by public health epidemics such as COVID-19. Our inability to enroll a sufficient number of subjects for 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 our product candidates 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 a product candidate, 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 our product candidates' 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 our product candidates 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. The 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 our product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may elect to abandon their development or limit their 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 the product candidate if approved. We may also be required to modify our study plans based on findings in our ongoing clinical trials. We are currently conducting a Phase 2 randomized, double-blind, placebo-controlled, multi-center trial of seralutinib in functional class II and III PAH patients. Although seralutinib was well-tolerated in completed Phase 1a SAD and MAD studies and our completed Phase 1b study, our Phase 2 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. We cannot be certain that seralutinib will not exhibit similar toxicities. Additionally, while we have completed Phase 1 SAD and MAD studies in healthy volunteers and a Phase 1b trial in UC patients with active disease for GB004, it is likely that there may be side effects associated with its use. GB001 was generally well tolerated in doses up to 40 mg with a treatment-emergent adverse event rate similar to placebo in completed Phase 2 clinical trials. However, in Phase 1 studies conducted by Pulmagen and Teijin, a single serious adverse event deemed by the investigator likely to be related to GB001 was observed in a Japanese patient who had received a 160 mg dose. The patient experienced intrahepatic cholestasis, which resolved after treatment discontinuation. In addition, in the Phase 2b LEDA study, a serious adverse event in the GB001 60 mg group was observed. The patient experienced liver chemistry elevations meeting Hy's Law criteria, which was reversible and resolved without sequelae. 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 our product candidates in larger, longer and more extensive clinical trials, or as the use of these product candidates becomes more widespread if they receive 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 one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approvals of such product;
- we may be required to recall a product or change the way such product 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;
- we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product 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 the product may decrease significantly or the product could become less competitive; and
- our reputation may suffer.

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

Although we have completed Phase 1 clinical trials for* seralutinib *and GB004 and Phase 2 clinical trials for GB001, we have not as an organization completed later-stage clinical trials or submitted an NDA, and we may be unable to do so for any of our product candidates.

We are early in our development efforts for our product candidates, and we will need to successfully complete later-stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market seralutinib, GB004, GB1275 or any future product candidates. Carrying out later-stage clinical trials and the submission of a successful NDA is a complicated process. As an organization, we have completed two Phase 2 clinical trials for GB001 and are conducting Phase 2 clinical trials for seralutinib and GB004 and a Phase 1/2 clinical trial for GB1275. We have not yet conducted any later-stage or pivotal clinical trials for our product candidates or begun clinical development for our multiple preclinical programs. We also have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an NDA or other comparable foreign regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates 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 how many additional clinical trials of seralutinib, GB004, GB1275 or any other product candidate will be required or how such trials should be designed. 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 any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs for and commercializing our product candidates.

Our product candidates are 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 our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates 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 our product candidates until we receive regulatory approval from the FDA. 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 has 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. We are not permitted to market any of our product candidates in the United States until we receive approval of an NDA from the FDA.

Prior to obtaining approval to commercialize a product candidate 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 such product candidates are safe and effective for their 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 our product candidates 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 our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate 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 our product candidates;
- 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 a product candidate'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 our product candidates 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 our product candidates;
- 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 our product candidates.

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 our product candidates, 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 our product candidates, 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, which may be required to ensure safe use of the drug after approval. The FDA or the comparable foreign regulatory authority also may approve a product candidate 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 that product candidate and would materially adversely impact our business and prospects.

Because we have multiple product candidates in our clinical pipeline and are considering a variety of target indications, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on specific product candidates, indications and development programs. We also plan to conduct several clinical trials for multiple product candidates in parallel over the next several years, which may make our decision as to which product candidates to focus on more difficult. As a result, we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential. For example, we have decided not to move forward with GB001, or its backup molecule, in further clinical trials without a partner, and, as previously announced, we do not plan to continue further development of GB001 in CRS. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

We may not be able to obtain or maintain orphan drug designations for certain of our product candidates, 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 Europe, 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 European Union, the European Medicines Agency's, or the EMA's, Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. We have received orphan drug designation in the United States and the European Union for seralutinib for patients with PAH and in the United States and the European Union for GB1275 for patients with pancreatic cancer, and we may seek orphan drug designation for certain of our other product candidates. There can be no assurance that the FDA or the EMA's Committee for Orphan Medicinal Products will grant orphan designation for any indication for which we apply or that we will be able to maintain such designation.

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 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 indication 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. The applicable exclusivity period is ten years in Europe, but such exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

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 our product candidates 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 our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA. For example, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. In addition, when studies are conducted only at sites outside of the United States, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which would likely require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates.

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; and
- diminished protection of intellectual property in some countries.

For example, effective January 31, 2020, the United Kingdom commenced an exit from the European Union, commonly referred to as "Brexit" and, following the expiration of the Brexit transitional period on December 31, 2020, operates under a distinct regulatory regime. European legislation, including on clinical trials (including the impending EU Clinical Trials Regulation, or EU CTR), is no longer directly applicable in the United Kingdom. Current United Kingdom rules on clinical trials are derived from existing European Union legislation (as implemented into United Kingdom law), however going forward there is a risk that United Kingdom rules will diverge from European Union laws. Although regulatory authorities in the United Kingdom have indicated in the Medicines and Medical Devices Bill that new United Kingdom rules will closely align with the European Union legislation, detailed proposals are yet to be published. In addition, already as a result of the United Kingdom ceasing to be part of the European Union, various benefits of membership no longer apply to the United Kingdom, such that, for example, United Kingdom sponsored trials that span several European countries now need to have an individual or organization in the European Union to act as a legal representative, or sponsor; it is unclear whether the United Kingdom will have access to European Union clinical trial databases such as the Clinical Trial Information System (the centralized EU Portal for clinical trial information storage); and additionally, new rules apply to the import of investigational medicinal products from the European Union and European Economic Area to the United Kingdom. As a result, Brexit may create additional administrative burdens including disruptions to, and uncertainty surrounding, our planned clinical trials and activities in the United Kingdom and the European Union, impacting relationships with our existing and prospective customers, partners, vendors and employees. Although the United Kingdom and European Union have now reached an agreement on their future trading relationship to be implemented in the EU-UK Trade and Cooperation Agreement from January 1, 2021, which includes zero tariffs on goods and provides for regulatory cooperation, the agreement does not cover all regulatory areas regarding supply of medicinal products, which will likely be subject to bilateral discussions going forward which could further change the relationship between the United Kingdom and the European Union in this regard. Changes impacting our ability to conduct business in the United Kingdom or other European Union countries, or changes to the regulatory regime applicable to our operations in those countries (such as with respect to the approval of our product candidates), may have a material adverse impact on our business, financial condition and prospects.

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, including initial topline data from our Phase 1b study of seralutinib and topline data from our Phase 1b study of GB004, 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 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 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 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 preliminary or interim data and final data could significantly harm our business prospects. For example, in December 2020 we reported initial topline data from our Phase 1b study of seralutinib in patients with PAH, and further analysis of such data or patients entering into an open-label extension study could result in material changes to the data and our conclusions about this product candidate.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product 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 a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition.

The topline data from our LEDA Phase 2b clinical trial for GB001 may not be predictive of future results, are subject to audit and verification procedures that could result in material changes in the final data, or may adversely affect the ability to advance GB001, or its backup molecule, into further clinical development or establish partnerships or strategic alternatives.

In October 2020, we announced topline data for our LEDA Phase 2b and TITAN Phase 2 clinical trials for GB001, which was based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data. We made certain 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 topline results that we reported 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 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 data should be viewed with caution until the final data are available. We recently engaged with the FDA and the EMA about the clinical development path in asthma, and based off those interactions, we believe that there is a viable clinical development path for GB001, or its backup molecule, in asthma. We do not currently plan to move forward with GB001, or its backup molecule, in further clinical trials without a partner. Regulatory agencies, including the FDA and the EMA, or potential partners 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 materially and adversely affect the feasibility of a further clinical development or the approvability or commercialization of GB001, or its backup molecule, and the value of the program or our company generally, even if we believe there is a viable clinical development path. Further, we may not be successful in establishing strategic partnerships or collaborations for GB001 based on the topline data, regulatory feedback or otherwise, and we may not realize the benefits of any established arrangements. In addition, the information we publicly disclosed regarding our LEDA Phase 2b clinical trial results for GB001 included what is typically extensive information; however, others may not agree with what we determined was the material or otherwise appropriate information to include in our disclosure, and any information we determined not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding the potential of GB001 or our business. If the topline data that we reported differ from actual results, or if others, including regulatory authorities or potential partners, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, GB001, or partner the program, 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 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 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 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 agency 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 and biologics or modifications to cleared or approved drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, 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 COVID-19, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to 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.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct many of our preclinical studies and clinical trials. 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 our product candidates.

We are dependent on third parties to conduct our clinical trials and preclinical studies, including our ongoing or potential future clinical trials for seralutinib, GB004 and GB1275 and preclinical studies for our multiple preclinical development programs. 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 all of our product candidates in clinical development. 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 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 concludes 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 we submit by the FDA. Any such delay or rejection could prevent us from commercializing our product candidates.

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. For example, we rely on CROs in China for certain preclinical studies, and the outbreak of COVID-19 has delayed certain preclinical work being conducted with CROs in China. 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 our product candidates for clinical and preclinical 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 our product candidates or products 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 our product candidates and related raw materials for clinical and preclinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. The facilities used by third-party manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP 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 our product candidates 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 our product candidates, 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 product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

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

- an inability to initiate or continue clinical trials of seralutinib, GB004, GB1275 or any future product candidates under development;
- delay in submitting regulatory applications, or receiving marketing approvals, for our product candidates;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product candidates or any other future product candidates.

In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. 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 our product according to our specifications;
- failure to manufacture our product 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.

Our product candidates 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 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 our product candidates. 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 such as the recent COVID-19 outbreak. 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 our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

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 our product candidates 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.

We may seek to enter into collaborations, licenses and other similar arrangements and may not be successful in doing so, and even if we are, we may not realize the benefits of such relationships.

We may seek to enter into 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 the product candidate or manufacturing constraints. For example, in November 2019, we entered into a clinical trial collaboration and supply agreement with Merck to evaluate the combination of GB1275 and pembrolizumab. We may not be successful in our efforts to establish or maintain such collaborations for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or 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, any future collaboration agreements may restrict us from entering into additional agreements with potential collaborators. We cannot be certain that, following a strategic transaction or license, we will achieve an economic benefit that justifies such transaction.

Even if we are successful in our efforts to establish such 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 a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

In addition, any potential future collaborations may be terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to our product candidates, could delay the development and commercialization of our product candidates and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Commercialization of Our Product Candidates

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, 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 our product candidates, when and if any of them are approved.

Following potential approval of any our product candidates, the FDA may impose significant restrictions on a product's 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 may also require a REMS as a condition of approval of our product candidates, 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 our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products 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 and GCP requirements for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with our products, 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 our products, withdrawal of the product 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 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 our products; 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 our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

In addition, if any of our product candidates is approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that

may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. 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.

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 our product candidates. 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 lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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. For example, the results of the 2020 U.S. Presidential election may impact our business and industry. Namely, the previous U.S. administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these executive actions, including the Executive Orders, will be implemented, or whether they will be replaced under the new Presidential administration. The policies and priorities of the new administration are unknown and could materially impact the regulation governing our product candidates. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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, which would adversely affect our business, prospects, financial condition and results of operations.

The commercial success of our product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.

Our product candidates may not be commercially successful. Even if any of our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or the medical community. The commercial success of any of our current or future product candidates 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 our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety compared to other more-established products;
- the indications for which our product candidates are approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products 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 our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;

- potential product liability claims;
- the timing of market introduction of our products 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 the product.

If any product candidate 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 that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products 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 our product candidates 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 our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

The successful commercialization of our product candidates, 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 our products could limit our ability to market those products 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 our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product 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 European Union or elsewhere will be available for any product that we may develop, 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 our products 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 our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product 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 our products and may not be able to obtain a satisfactory financial return on products that we may develop.

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 our products.

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 our products 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 our products. Accordingly, in markets outside the United States, the reimbursement for our products 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 our products. We expect to experience pricing pressures in connection with the sale of any of our products 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 products 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 our product candidates. Any product candidates that we successfully develop and commercialize 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 immunology, inflammation and oncology. 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 from existing products and products in development for each of our product candidates. Seralutinib is a PDGFR, CSF1R and c-KIT inhibitor initially targeted for PAH patients. We expect competition in this patient set will include prostanoids, available in oral form as Orenitram (United Therapeutics Corporation, or United Therapeutics) and Uptravi (Janssen), by inhalation as Tyvaso (United Therapeutics), and by infusion as Remodulin (United Therapeutics). We also may face some competition from products used in 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). We believe that, if approved, seralutinib could be used alongside all three classes of approved therapies. PAH is also an active indication for investigational drugs, and we may face competition in the future from ralinepag (Arena Pharmaceuticals, Inc. and United Therapeutics), sotatercept (Acceleron Pharma, Inc.), RVT-1201 (Altavant Sciences, Inc.), PB1046 (PhaseBio Pharmaceuticals Inc.), MK-5475 (Merck) and GMA310 (Gmax Biopharm LLC). Additionally, although not approved for the treatment of PAH, we may face competition from formulations of imatinib, including those from Tenax Therapeutics, Aerovate Therapeutics and Aerami Therapeutics / Vectura Group.

GB004 is a HIF-1α stabilizer with the potential to restore epithelial barrier function in patients with IBD. Patients with mild to moderate UC can initially be maintained in remission using a 5-ASA. For those patients who do not respond to 5-ASA, or those with more severe and / or extensive disease at diagnosis, corticosteroids are generally the next line of treatment. Patients who have become nonresponsive or intolerant to corticosteroids may move to azathioprine and 6-mercaptopurine. The treatment of severe patients is dominated by anti-TNF biologics, though the paradigm is shifting because of the approval of agents in other classes, such as anti-integrin, IL-12 / IL-23, and JAK inhibitors. There is potential that the approval of biosimilar anti-TNF biologics moves the class further up in the treatment paradigm. Further disruption is expected in the coming years through the introduction of oral S1P1 inhibitors and additional oral JAK inhibitors.

GB1275 is a CD11b modulator for the treatment of cancer indications. To our knowledge, there are no other CD11b modulator programs in clinical development for oncology. Our initial targeted cancer indications for GB1275 include pancreatic, gastric, esophageal, prostate, triple negative breast cancer and colorectal. Treatment for patients in these indications has historically included chemotherapy, radiation, targeted therapy and surgery. In recent years immune checkpoint inhibitors have received approvals, including Keytruda (pembrolizumab / Merck) and Tecentriq (atezolizumab / Bristol-Myers Squibb), for the treatment of some of these difficult to treat cancer indications, including gastric and esophageal cancers (Keytruda) and triple negative breast cancer (Tecentriq). In addition to current standard of care, we may face competition from compounds with novel mechanisms of action that are currently in clinical development, including compounds targeting the CCR2, CCR5, CSF1R and CXCR2 pathways.

GB001, in development for the treatment of moderate-to-severe eosinophilic asthma, is an oral DP2 antagonist, a class of medicines with no currently approved agents. However, other DP2 antagonists are currently in development by Chiesi Farmaceutici S.p.A., Merck, Sunshine Lake Pharma Co., Ltd., Idorsia Pharmaceuticals Ltd., ZAI Lab Ltd. and CSPC ZhongQi Pharmaceutical Technology Co., Ltd. If approved, we will also face branded competition from existing biologics, including Xolair (omalizumab / anti-IgE, marketed by Genentech and Novartis) and Dupixent (dupilumab / anti-IL-4 / IL-13, marketed by Regeneron Pharmaceuticals, Inc. and Sanofi S.A.), for moderate to severe asthma, and Nucala (mepolizumab / anti-IL-5, marketed by GlaxoSmithKline), Cinqair (reslizumab / anti-IL-5, marketed by Teva Pharmaceutical Industries Ltd.), and Fasenra (benralizumab / anti-IL-5R, marketed by AstraZeneca Pharmaceuticals LP) for severe eosinophilic asthma. We will also face competition from generic montelukast, which is utilized in mild-to-moderate patients. Several other agents are advancing in clinical trials for moderate and / or severe asthma, including tezepelumab (anti-TSLP; Amgen Inc. / AstraZeneca), REGN3500 (anti-IL-33R; Regeneron), masitinib (anti-c-kit / PDGF; AB Science S.A.) and Dexpramipexole (dopamine receptor agonist, Knopp Biosciences LLC).

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

If the market opportunities for our products 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 our product candidates 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 our product candidates, 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 across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the availability of alternative treatments and the safety, convenience, cost and efficacy of our product candidates 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 our products 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 our product candidates, because some of 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 our products, we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If any of our product candidates ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, 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 these products. 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 any products that we develop ourselves. 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 our products effectively. If we are not successful in commercializing our products, either on our own 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 growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our product candidates. To obtain separate regulatory approval in many other countries, we 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 our product candidates. If we obtain regulatory approval of our product candidates and ultimately commercialize our products in foreign markets, we 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;
- unexpected changes in tariffs, 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 such as COVID-19, 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 our product candidates, which may change from time to time;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products;
- the cost of manufacturing our product candidates, 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 the licensors and other third parties from whom we have in-licensed our acquired our product candidates, including payments due upon a change in control of our subsidiaries;
- 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 our product candidates 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. We are highly dependent upon our senior management, particularly our Chief Executive Officer, as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our product candidates. For example, effective November 16, 2020, Faheem Hasnain was appointed as our President and Chief Executive Officer, replacing Sheila Gujrathi, M.D. 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 expand and 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 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 of management 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 have recently substantially increased the size of our organization, and we may encounter difficulties in managing our growth and expanding our operations successfully.

We have substantially increased our organization from 11 employees in January 2018 to 195 full-time employees and one part-time employee as of February 19, 2021. As we continue development and pursue the potential commercialization of our product candidates, as well as function as a public company, we may need to continue to expand our financial, development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As 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 our product candidates and to compete effectively will depend, in part, on our ability to manage our recent substantial growth and any future growth effectively.

We are subject to various foreign, federal, and state 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 foreign, federal and state 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 other health care professionals beginning in 2022, 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. Compliance with these requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data, and the failure to comply with such requirements could have a material adverse effect on our business, financial condition or results of operations.

Privacy and data security have become significant issues in the U.S., E.U. and in many other jurisdictions where we may in the future conduct our operations. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and may increase our compliance costs and exposure to liability. As we receive, collect, process, use and store personal and confidential data, we are or may be subject to diverse laws and regulations relating to data privacy and security, including, in the U.S., HIPAA and CCPA (defined below), and, in the EU and the EEA, the General Data Protection Regulation, or the GDPR. Compliance with these privacy and data security requirements is rigorous and time-intensive and may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm, which could materially and adversely affect our business, financial condition and results of operations.

In the U.S., we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, impose, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information held by covered entities and their business associates. We may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade

Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

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. By way of example, California enacted the CCPA, effective January 1, 2020, which gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Further, the CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In addition, the CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or applicable state laws.

In the EEA, the GDPR imposes many requirements for controllers and processors of personal data, including, for example, high standards for obtaining consent from individuals to process their personal data, robust disclosures to individuals and a strong individual data rights regime, short timelines for data breach notifications, limitations on retention and secondary use of information, significant requirements pertaining to health data and pseudonymized (i.e., key-coded) data and obligations when we contract third-party processors in connection with the processing of the 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. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU and EEA Member States may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other regulatory investigations, reputational damage, orders to cease/ change our processing of our data, enforcement notices, and/ or assessment notices (for a compulsory audit). We may also face civil claims including representative actions and other class action type litigation (where individuals have suffered harm), potentially amounting to significant compensation or damages liabilities, as well as associated costs, diversion of internal resources, and reputational harm.

We are also subject to European Union rules with respect to cross-border transfers of personal data out of the EEA and the United Kingdom. Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA and the United Kingdom to the United States. Most recently, on July 16, 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-US Privacy Shield Framework ("Privacy Shield") under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. We currently rely on the standard contractual clauses to transfer personal data outside the EEA, including to the U.S. among other data transfer mechanisms pursuant to the GDPR, but excluding the EU-US Privacy Shield. These recent developments may require us to review and amend the legal mechanisms by which we make and/ or receive personal data transfers to/ in the United States. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses 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.

Additionally, following the United Kingdom's withdrawal from the European Union, from 1 January 2021, we are subject to the GDPR and also the UK GDPR which, together with the amended UK Data Protection Act 2018, retains

the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and UK Trade and Cooperation Agreement, ending 30 June 2021 at the latest, whilst the parties discuss an adequacy decision in favor of the United Kingdom. However, it is not clear whether (and when) an adequacy decision may be granted by the European Commission enabling data transfers from European Union member states to the United Kingdom long term without additional measures. These changes may lead to additional costs and increase our overall risk exposure, as well as requiring us to find alternative solutions for the compliant transfer of data into the United Kingdom.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. If we fail to comply with any such laws, rules or regulations, we may face government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity that could adversely affect our business, financial condition and results of operations.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates 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 our potential product candidates, 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; created a new Medicare Part D coverage gap discount 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 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. For example, the Tax Cuts and Jobs Act of 2017, or Tax Act, included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit affirmed the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when a decision will be made or how the Supreme Court will rule. In addition, there may be other efforts to challenge, repeal or replace the ACA. We are continuing to monitor any changes to the ACA that, in turn, may potentially impact our business in the future.

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 of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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.

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. The likelihood of success of these and other measures proposed by the former Trump administration is unclear, particularly in light of the new Biden administration.

We expect that the ACA, 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 our product candidates, 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 and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, 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 our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients with life-threatening diseases or conditions to access certain investigational new drug products that have completed a Phase 1 clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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

We face an inherent risk of product liability as a result of the clinical trials of our product candidates and will face an even greater risk if we commercialize our product candidates. For example, we may be sued if our product candidates allegedly cause injury or are 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 the product candidate, 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 our products. 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 our products;
- 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 our product candidates; 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 our product candidates. 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 our product candidates. 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 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 and any of our potential future collaborators are successful in commercializing our products, the FDA and foreign regulatory authorities would require that we 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 and any of our potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we 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 our products 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 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 and acquiring our current product candidates. 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 our product candidates, 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 our product candidates, 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 our product candidates, 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 our product candidates 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 other U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign countries 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, 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 our product candidates 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 our product candidates;
- 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 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 products or product candidates 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 from third parties, including* seralutinib *and GB004, or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business. Additionally, several of our license agreements include sublicenses from a third party, including for* seralutinib *and GB004, and we must rely on the direct licensor's compliance with its obligations under its original license agreement.

We are a party to a number of license agreements under which we are granted rights to intellectual property that are important to our business and we may enter into additional license agreements in the future. For example, 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. In June 2018, we entered into an exclusive license agreement with Aerpio Pharmaceuticals, Inc., or Aerpio, to obtain an exclusive license to certain intellectual property rights to develop, manufacture and commercialize GB004, which was further amended in May 2020.

These and our other existing license agreements impose, 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, several of our existing license agreements include sublicenses from a third party who is not the original licensor of the intellectual property at issue, including for seralutinib and GB004. Under these agreements, we must rely on our direct licensor to comply with its obligations under the primary license agreements under which such licensor obtained rights in the applicable intellectual property, where we may have no relationship with the original licensor of such rights. If our licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate our sublicense. 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 our product candidates incorporating the relevant intellectual property.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we cannot provide any assurances that third-party patents do not exist which might be enforced against our product candidates 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 affected product candidates, 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 our product candidates, 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 the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our agreements 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 agreements with Aerpio or Pulmokine with respect to any licensed product, we may be required to pay to Pulmokine or Aerpio, 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 our product candidates 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 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 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 our product candidates 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 our product candidates 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 partes 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 our product candidates 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 our product candidates. 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 current or future product candidates.

The patent protection and patent prosecution for some of our product candidates 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. 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.

As a licensee of third parties, we rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our license agreements. We have not had and do not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, 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 any of our product candidates, our ability to develop and commercialize those product candidates 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 our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of licensed and acquired technologies into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license or market and sell our product candidate.

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 acquired or 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 our product candidates 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 our product candidates 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 our product candidates

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 product candidates. 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 our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates 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 any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or 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 our product candidates 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 any of our product candidates 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 our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to our product candidates 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 our product candidates. 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 our product candidates 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 our product candidates, 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 one of our product candidates, 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 such product candidate. 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 current 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 our product candidates 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 our product candidates 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.

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 our product candidates.

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 our product candidates 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 our product candidates 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 product candidates, patents protecting our product candidates might expire before or shortly after such candidates are 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 our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, 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 our product candidates. 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 our product candidates, 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 our product candidates. 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 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 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 $7.52 and as high as $27.15 through February 19, 2021. 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 our product candidates, 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 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 the recent COVID-19 outbreak;
- 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 39.4% of our outstanding common stock as of February 19, 2021. 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 acquiror 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. In addition, the terms of our Credit Facility preclude us from paying dividends, subject to certain exceptions, as may any future debt agreements we enter into. 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.

The holders of 15,083,894 shares of our outstanding common stock, or approximately 20.0% of our total outstanding common stock as of February 19, 2021, are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders, or the registration of such shares, could have a material adverse effect on the trading price of our common stock.

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 provide 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 taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire (if at all). At December 31, 2020, the company had federal and state net operating loss, or NOL, carryforwards of approximately $310.7 million and $1.1 million, respectively. Such federal and state NOL carryforwards will begin to expire in 2034, unless previously utilized. At December 31, 2020, the Company has foreign NOL carryforwards of approximately $101.1 million. The foreign NOL can be carried forward indefinitely. At December 31, 2020, the Company also has orphan drug credit and federal research tax credit carryforwards of approximately $17.9 million and California research tax credits of $5.4 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.

Federal NOL carryforwards generated in periods after December 31, 2017, may be carried forward indefinitely but may only be used to offset 80% of our taxable income in taxable years beginning after December 31, 2020. Our NOL and credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service, or the IRS, and state tax authorities. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, our NOL and credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percentage points. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with our IPO or other equity offerings. Similar rules may apply under state tax laws. In connection with our IPO in February 2019, we experienced an ownership change for the purposes of Section 382 and 383 of the Code. The ownership change did not result in the forfeiture of any NOLs or credits generated prior to this date. Consequently, the Company's federal and state NOLs and tax credits generated through February 2019 will be subject to annual limitations. If a change in ownership occurs in the future, the NOL and credit carryforwards could be eliminated or restricted. If we earn taxable income, such 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 are 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 alleges 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. This lawsuit and any future lawsuits to which we may become a party are subject to inherent uncertainties and will likely be expensive and time-consuming to investigate, defend and resolve, and will 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 this and other suits, 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. See Item 3. "Legal Proceedings" below for additional information regarding the class action.

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 internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

The United States federal and various state and foreign governments have adopted or proposed requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, and federal and state consumer protection laws are being applied to enforce regulations related to the online collection, use, and dissemination of data. Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology 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 COVID-19 pandemic, 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. If such an event were to occur and cause interruptions in our operations or result in the unauthorized disclosure of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as GDPR), 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. Some of the federal, state and foreign government requirements 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 vendors, contractors, or organizations with which we have formed strategic relationships. Even though we may have contractual protections with such vendors, contractors, or other organizations, 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. For example, 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 also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws.

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 our product candidates. Our ability to obtain clinical supplies of our product candidates 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.

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 our products abroad once we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. 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.

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. Additionally, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. 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, 2020, 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 U.S. tax law 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 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. In particular, the recent presidential and congressional elections in the United States could result in significant changes in, and uncertainty with respect to, tax legislation, regulation and government policy directly or indirectly affecting our business. For example, the United States government may enact significant changes to the taxation of business entities including, among others, a permanent increase in the corporate income tax rate, an increase in the tax rate applicable to global intangible low-taxed income and elimination of certain exemptions, and the imposition of minimum taxes or surtaxes on certain types of income. No specific United States tax legislation has been proposed at this time and the likelihood of these changes being enacted or implemented is uncertain. We are currently unable to predict whether such changes will occur and, if so, 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 2. Properties.

Our corporate headquarters are located in San Diego, California, where we currently lease approximately 63,667 square feet of office, laboratory and vivarium space. We use our corporate headquarters primarily for corporate, research, development, clinical, regulatory, manufacturing and quality functions. Our primary lease for this facility expires in January 2025, and our lease with respect to 31,628 square feet of such space expires in December 2022. We are subletting approximately 12,685 square feet of office and laboratory space in San Diego, California, which sublease expires on December 31, 2021. Additionally, we lease approximately 19,845 square feet of office and laboratory space in Ann Arbor, Michigan which expires in December 2026. 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 discuss certain legal proceedings in Part II of this Annual Report on Form 10-K under the caption “Item 8. Financial Statements and Supplementary Data,” in Note 12 to our Condensed Consolidated Financial Statements, which is captioned “Commitments and Contingencies,” under the sub-caption “Litigation,” and refer you to that discussion, which is incorporated herein by reference to that Note 12, for important information concerning those legal proceedings, including the basis for such actions and, where known, the relief sought.

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 February 19, 2021, there were 75,527,707 shares of our common stock outstanding held by approximately 37 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

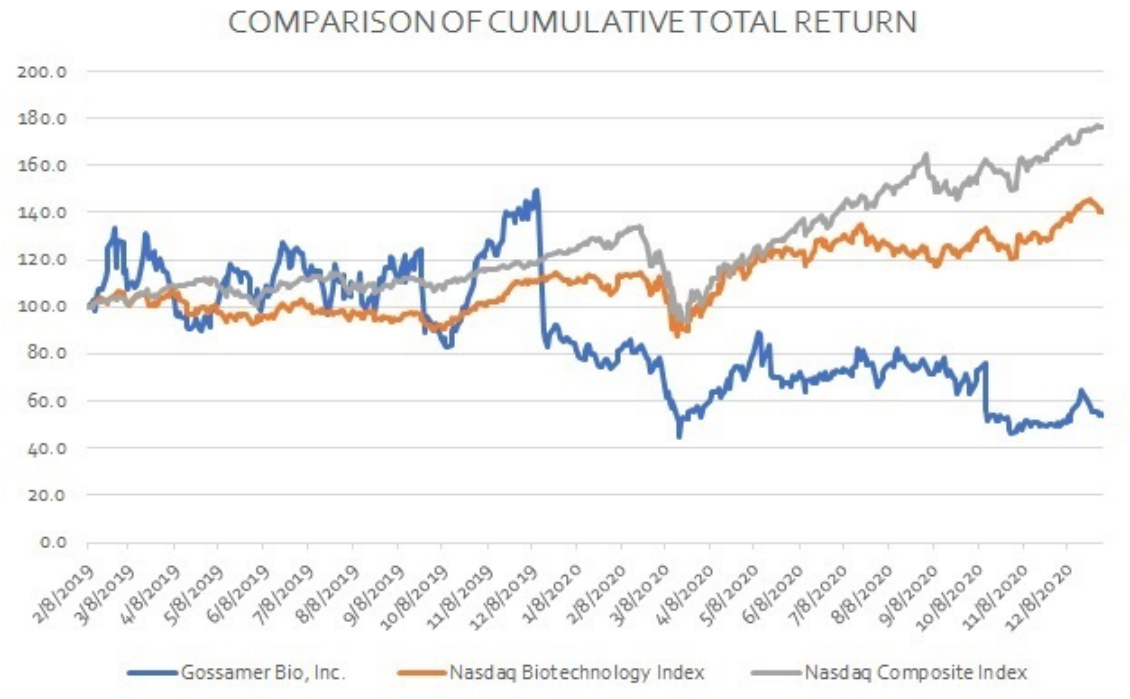
We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at 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. In addition, the terms of our Credit Facility restrict our ability to pay dividends, subject to certain exceptions.

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, 2020. 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

During the year ended December 31, 2020, we did not issue or sell any unregistered securities.

Use of Proceeds

On February 7, 2019, our registration statement on Form S-1 (File No. 333-228984) was declared effective by the SEC for our initial public offering. At the closing of the offering on February 12, 2019, we sold 19,837,500 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 2,587,500 additional shares, at an initial public offering price of $16.00 per share and received gross proceeds of $317.4 million, which resulted in net proceeds to us of approximately $291.3 million, after deducting underwriting discounts and commissions of approximately $22.2 million and offering-related transaction costs of approximately $3.9 million. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning ten percent or more of any class of equity securities, or to their associates, or to our affiliates. Merrill Lynch, Pierce, Fenner & Smith Incorporated, SVB Leerink LLC, Barclays Capital Inc. and Evercore Group L.L.C. acted as joint book-running managers for the offering.

As of December 31, 2020, we have used the proceeds from our IPO for general corporate purposes. There has been no material change in the planned use of proceeds from our initial public offering from that described in the final prospectus filed by us with the SEC on February 8, 2019.

Issuer Repurchases of Equity Securities

None.

Item 6. Selected Financial Data.

Not required.

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 discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology. Our goal is to be an industry leader in each of these therapeutic areas and enhance and extend the lives of patients suffering from such diseases. We currently have four clinical-stage product candidates, in addition to six preclinical programs. We are developing seralutinib for the treatment of PAH and commenced enrolling patients for a Phase 2 TORREY clinical trial in PAH patients in December 2020. We expect topline results from this trial in the first half of 2022, subject to developments in the ongoing COVID-19 pandemic. We are developing GB004 for the treatment of inflammatory bowel disease, including UC and CD. We commenced enrolling patients for a Phase 2 SHIFT-UC clinical trial in UC in October 2020. We expect topline results from this trial in the first half of 2022, subject to developments in the ongoing COVID-19 pandemic. We are developing GB1275 for the treatment of oncology indications. In the third quarter of 2019, we initiated a Phase 1/2 clinical trial for GB1275 in solid tumor indications as a monotherapy and in combination with either pembrolizumab or chemotherapy. We have reported data from that ongoing trial, and we expect to report further data from this trial in 2021. We announced topline Phase 2 asthma results for GB001 in the fourth quarter of 2020. GB001 did not achieve its primary endpoint of statistically significant reduction in the portion of patients experiencing asthma worsening, though consistent and meaningful numeric reductions in the odds of asthma worsening were observed across all three drug arms, as compared to placebo. GB001 did achieve statistically significant improvements in the key secondary endpoint of time to first asthma worsening in two of the three drug arms, as compared to placebo. We do not currently plan to move forward with GB001, or its backup molecule, in further clinical trials without a partner.

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 early clinical stage trials. We have funded our operations primarily through equity financings and debt issuance. We raised $942.0 million from October 2017 through December 31, 2020 through Series A and B convertible preferred stock financings, a convertible note financing, our IPO completed in February 2019, proceeds from our credit facility, and proceeds from our concurrent underwritten public offerings of 5.00% convertible Notes due 2027 (the "2027 Notes") and common stock in May 2020. In addition, we received $12.8 million in cash in connection with the January 2018 acquisition of AA Biopharma Inc., of which Pulmagen Therapeutics (Asthma) Limited is a wholly-owned subsidiary. As of December 31, 2020, we had $512.6 million in cash, cash equivalents and marketable securities.

On February 12, 2019, we closed our IPO and the underwriters in the IPO purchased 19,837,500 shares, including the full exercise of their option to purchase additional shares of common stock. The net proceeds were $291.3 million, after deducting underwriting discounts and commissions and estimated offering costs.

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, 2020 and 2019, our net loss was $243.4 million and $180.3 million, respectively. As of December 31, 2020, we had an accumulated deficit of $577.5 million. We expect our expenses and operating losses will increase substantially as we conduct our ongoing and planned clinical trials, continue our research and development activities and conduct preclinical studies, and seek regulatory approvals for our product candidates, as well as hire additional personnel, protect our intellectual property and incur additional costs associated with being a public company. In addition, as our product candidates progress through development and toward commercialization, we will need to make milestone payments to the licensors and other third parties from whom we have in-licensed or acquired our product candidates, including seralutinib, GB004 and GB1275. 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.

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years. If we

obtain regulatory approval for any of our product candidates, 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 our product candidate development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

COVID-19 Pandemic

The current COVID-19 worldwide pandemic has presented substantial public health and economic challenges and is affecting our employees, patients, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions are taking actions in an effort to slow the spread of COVID-19, including issuing varying forms of "stay-at-home" orders, and restricting business functions outside of one's home. In response, we have implemented a work-from-home policy for certain of our employees. To date, we have been able to continue to supply our product candidates to our patients currently enrolled in our clinical trials, including for seralutinib, GB004 and GB1275, and do not currently anticipate any interruptions in supply. In addition, while we are continuing the clinical trials we have underway in sites across the globe, COVID-19 precautions have delayed, such as the previous pause in enrollment in our Phase 1b clinical trial for seralutinib in PAH earlier this year, and may continue to delay completion of these and future trials and may directly or indirectly impact the timeline for data readouts, initiation of, as well as monitoring, data collection and analysis and other related activities for, some of our current and future clinical trials. For example, our current expectations for how we will continue to enroll our Phase 2 clinical trials of seralutinib and GB004 are based on an assumption that clinical trial and healthcare activities begin to return to normal and clinical sites remain open or reopen during the first half of 2021 in light of the continued spread of COVID-19. In particular with respect to seralutinib, some PAH clinical trial sites are currently closed or limited as PAH patients may be at a higher risk of COVID-19 complications than the general population, and some PAH clinical trials may close again if there is a surge of COVID-19 cases in the specific geographies of such trial site locations. Therefore, our assumptions around enrollment timing may prove to be incorrect, in particular if COVID-19 continues to spread. In light of recent developments relating to the COVID-19 pandemic, and consistent with the FDA's updated industry guidance for conducting clinical trials, clinical trials may be deprioritized in favor of treating patients who have contracted the virus or to prevent the spread of the virus. This may lead to clinical trial protocol deviations or to discontinuation of treatment for patients who are currently enrolled in our trials. Any delays in the completion of our clinical trials, data analysis or readouts and any disruption in our supply chain could have a material adverse effect on our business, results of operations and financial condition. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat it, as well as the economic impact on local, regional, national and international markets.

Components of Results of Operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products for the foreseeable future.

Operating expenses

Research and development

Research and development expenses have related primarily to preclinical and clinical development of our product candidates and discovery efforts. 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 plan to substantially increase our research and development expenses for the foreseeable future as we continue the development of our product candidates and conduct discovery and research activities for our preclinical programs. 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 our product candidates 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 which product candidates to pursue and how much funding to direct to each product candidate 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 each product candidate’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:

- the costs incurred as a result of the COVID-19 pandemic, including clinical trial delays;
- 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 our product candidates;
- the phase of development of our product candidates; and
- the efficacy and safety profile of our product candidates.

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.

IPR&D expenses consist of our upfront and milestone payments made to Pulmokine, Inc., in connection with the in-license of seralutinib, the value of our stock issued to former AA Biopharma Inc. shareholders, in connection with the acquisition of GB001, our upfront payments made to Aerpio Pharmaceuticals, Inc., or Aerpio, in connection with the in-license and subsequent amendment of the in-license of GB004, our upfront and milestone payments made to Adhaere Pharmaceuticals, Inc., or Adhaere, in connection with the acquisition of GB1275, and upfront and milestone payments made in connection with the acquisition or in-license of certain preclinical programs.

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 our general and administrative expenses will increase for the foreseeable future to support our expanded infrastructure and increased costs of operating as a public company. These increases will likely include increased expenses related to 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) sublease income, (3) interest expense related to our Credit Facility and our 2027 Notes, and (4) other miscellaneous income (expense).

Critical Accounting Policies and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. We base our estimates on historical experience, known trends and events, and various other factors that are 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 that are not readily apparent from other sources. Our 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.

Convertible Senior Notes

In accounting for the issuance of the 2027 Notes, we separated the 2027 Notes into liability and equity components. 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 is not remeasured as long as it continues to meet the condition for equity classification. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense over the term of the 2027 Notes.

We 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 are being 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.

Results of Operations for the Years Ended December 31, 2020 and 2019

The following table sets forth our selected statements of operations data for the years ended December 31, 2020 and 2019:

	Years Ended December 31,		2020 vs 2019 Change
	2020	2019	
	(in thousands)		
Operating expenses:			
Research and development	$ 160,854	$ 143,403	$ 17,451
In process research and development	23,380	$ 3,600	19,780
General and administrative	49,728	39,136	10,592
Total operating expenses	233,962	186,139	47,823
Loss from operations	(233,962)	(186,139)	(47,823)
Other income (expense)			
Interest income	3,442	5,563	(2,121)
Interest expense	(12,666)	(1,938)	(10,728)
Other income (expense)	(174)	2,207	(2,381)
Total other income (expense), net	(9,398)	5,832	(15,230)
Net loss	$ (243,360)	$ (180,307)	$ (63,053)

Operating expenses

Research and development

Research and development expenses were $160.9 million for the year ended December 31, 2020, compared to $143.4 million for the year ended December 31, 2019, for an increase of $17.5 million, which was primarily attributable to an increase of $4.4 million of costs associated with preclinical studies and clinical trials for GB004, an increase of $2.8 million of costs associated with preclinical and clinical trials for GB1275, an increase of $1.4 million of costs associated with preclinical studies and clinical trials for seralutinib, and an increase of $12.6 million of costs associated with preclinical studies for our other programs; offset by a decrease of $3.8 million of costs associated with preclinical research and clinical trials for GB001.

The following table shows our research and development expenses by program for the years ended December 31, 2020 and 2019:

	Years Ended December 31,	
	2020	2019
	(in thousands)	
GB001	$ 36,576	$ 40,404
Seralutinib	34,564	33,161
GB004	24,382	19,986
GB1275	16,714	13,870
Other Programs	48,618	35,982
Total research and development	$ 160,854	$ 143,403

In process research and development

IPR&D expenses were $23.4 million for the year ended December 31, 2020, compared to $3.6 million for the year ended December 31, 2019, for an increase of $19.8 million, which was primarily attributable to a $15.0 million payment to Aerpio in connection with the amendment to the in-license agreement of GB004 in 2020 and a milestone payment of $5.0 million in connection with the initiation of the first Phase 2 clinical trial of seralutinib in 2020.

General and administrative

General and administrative expenses were $49.7 million for the year ended December 31, 2020, compared to $39.1 million for the year ended December 31, 2019, for an increase of $10.6 million, which was primarily attributable to a $9.2 million increase in stock-based compensation costs and a $2.4 million increase in personnel-related costs.

Other income (expense), net

Other expense, net was $9.4 million for the year ended December 31, 2020, compared to other income, net of $5.8 million for the year ended December 31, 2019, for a decrease of $15.2 million, which was primarily related to a $10.7 million increase in interest expense, a $2.4 million decrease in investment income and a $2.1 million decrease in interest income earned on our cash, cash equivalents and marketable securities during the period.

Results of Operations for the Years Ended December 31, 2019 and 2018

The following table sets forth our selected statements of operations data for the years ended December 31, 2019 and 2018:

	Years Ended December 31,		2019 vs 2018 Change
	2019	2018	
	(in thousands)		
Operating expenses:			
Research and development	$ 143,403	$ 55,283	$ 88,120
In process research and development	3,600	$ 49,659	(46,059)
General and administrative	39,136	44,051	(4,915)
Total operating expenses	186,139	148,993	37,146
Loss from operations	(186,139)	(148,993)	(37,146)
Other income (expense)			
Interest income	5,563	1,720	3,843
Interest expense	(1,938)	(12)	(1,926)
Other income (expense)	2,207	316	1,891
Total other income (expense), net	5,832	2,024	3,808
Net loss	$ (180,307)	$ (146,969)	$ (33,338)

Operating expenses

Research and development

Research and development expenses were $143.4 million for the year ended December 31, 2019, compared to $55.3 million for the year ended December 31, 2018, for an increase of $88.1 million, which was primarily attributable to an increase of $17.1 million of costs associated with preclinical studies and clinical trials for seralutinib, an increase of $17.0 million of costs associated with preclinical and clinical trials for GB001, an increase of $13.2 million of costs associated with preclinical studies and clinical trials for GB004, an increase of $12.7 million of costs associated with preclinical studies and clinical trials for GB1275, an increase of $8.8 million of costs associated with preclinical research for our other programs, and an increase of $19.3 million of costs related to personnel and other associated costs.

The following table shows our research and development expenses by program for the years ended December 31, 2019 and 2018:

	Years Ended December 31,	
	2019	2018
	(in thousands)	
GB001	$ 40,404	$ 23,409
Seralutinib	33,161	16,028
GB004	19,986	6,739
GB1275	13,870	1,196
Other Programs	35,982	1,948
Total research and development	$ 143,403	$ 49,320

In process research and development

IPR&D expenses were $3.6 million for the year ended December 31, 2019, compared to $49.7 million for the year ended December 31, 2018, for a decrease of $46.1 million, which was primarily attributable to our $20.0 million upfront payment made to Aerpio in connection with the in-license of GB004 in 2018, $19.1 million of costs associated with the issuance of our stock in connection with our acquisition of GB001 and AA Biopharma in 2018, and a $7.5 million upfront payment in connection with our acquisition of GB1275 and Adhaere in 2018.

General and administrative

General and administrative expenses were $39.1 million for the year ended December 31, 2019, compared to approximately $44.1 million for the year ended December 31, 2018, for a decrease of $5.0 million, which was primarily attributable to a $19.7 million decrease in stock-based compensation costs, partially offset by a $5.7 million increase in personnel-related costs, a $4.3 million increase in professional and legal fees, a $2.5 million increase associated with insurance costs, and a $1.3 million increase in facility and office-related costs.

Other income, net

Other income, net was $5.8 million for the year ended December 31, 2019, compared to $2.0 million for the year ended December 31, 2018, attributable to a $3.8 million increase in investment income earned on our cash, cash equivalents and marketable securities during the period.

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, 2020 and 2019, we had an accumulated deficit of $577.5 million and $334.2 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. We enter into contracts in the normal course of business with clinical trial sites and clinical supply manufacturers and with vendors for preclinical studies, research supplies and other services and products for operating purposes. 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.

Under our license agreements with Pulmokine and Aerpio, as well as our other license and acquisition agreements, 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 those agreements. As of December 31, 2020, 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 our Credit Facility, 2027 Notes and existing operating leases.

From our inception through the year ended December 31, 2020, our operations have been financed primarily by gross proceeds of $942.0 million from the sale of our convertible preferred stock, convertible promissory note, proceeds from our IPO, proceeds from our Credit Facility, and proceeds from our concurrent underwritten public offerings of 2027 Notes and common stock. As of December 31, 2020, we had cash, cash equivalents and marketable securities of $512.6 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 February 12, 2019, we closed our IPO and the underwriters in the IPO purchased 19,837,500 shares, including the full exercise of their option to purchase additional shares of common stock. The net proceeds from the IPO were $291.3 million, after deducting underwriting discounts and commissions and estimated offering costs. In connection with the closing of the IPO, the outstanding shares of our convertible preferred stock were converted into shares of common stock at a ratio of 4.5-to-one.

On May 2, 2019, we entered into the Credit Facility, as amended on September 18, 2019 and July 2, 2020, pursuant to which the lenders party thereto agreed to make term loans available to us 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 which was funded at the closing date, with the ability to access the remaining $120.0 million in two additional tranches (each $60.0 million). The remaining two tranches are available no earlier than the satisfaction of the applicable funding conditions, including the applicable clinical development milestones, and no later than December 31, 2022. As of December 31, 2020, and through the date of this filing, no other tranches under the Credit Facility have been available.

On April 10, 2020, we filed a registration statement on Form S-3, or the 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.

In May 2020, we issued $200.0 million aggregate principal amount 5.00% convertible senior notes due 2027 in a registered public offering. 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 Shelf Registration Statement.

Additional information about the Credit Facility and our long-term borrowings is presented in Note 5 “Long-term Debt” to the Notes to Consolidated Financial Statements included in Part II, Item 8, of this Form 10-K, which is incorporated 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,		
	2020	2019	2018
	(in thousands)		
Net cash used in operating activities	$ (176,360)	$ (144,834)	$ (51,044)
Net cash provided by (used in) investing activities	215,342	(147,144)	(144,711)
Net cash provided by financing activities	312,540	321,578	300,859
Effect of exchange rate changes on cash, cash equivalents and restricted cash	$ 9	$ 70	$ —
Net increase in cash, cash equivalents and restricted cash	$ 351,531	$ 29,670	$ 105,104

Operating activities

During the year ended December 31, 2020, operating activities used approximately $176.4 million of cash, primarily resulting from a net loss of $243.4 million, partially reduced by stock-based compensation expense of $38.7 million, IPR&D expenses of $23.4 million and amortization of long-term debt discount and issuance costs of $3.9 million.

During the year ended December 31, 2019, operating activities used approximately $144.8 million of cash, primarily resulting from a net loss of $180.3 million, partially reduced by stock-based compensation expense of $20.8 million, and changes in operating assets and liabilities of $12.3 million. Net cash provided by changes in operating assets and liabilities consisted primarily of increases in accounts payable, accrued research and development expenses, and accrued expenses of $13.9 million, and an increase in other assets of $2.7 million due to long-term deposits for clinical development activities and property leases, partially offset by an increase in prepaid expenses and other current assets due to prepayments for clinical development activities, investments receivable, and receivables for stock option exercises of $4.4 million.

During the year ended December 31, 2018, operating activities used approximately $51.0 million of cash, primarily resulting from a net loss of $147.0 million, partially reduced by IPR&D expenses of $49.7 million, changes in operating assets and liabilities of $15.0 million and stock-based compensation expense of $30.9 million. Net cash provided by changes in operating assets and liabilities consisted primarily of increases in accounts payable, accrued research and development expenses, and accrued expenses of $18.6 million, partially offset by an increase in prepaid expenses due to prepayments for clinical development activities and security deposits of $2.8 million.

Investing activities

During the year ended December 31, 2020, investing activities provided approximately $215.3 million of cash, primarily resulting from the sales and maturities of marketable securities of $349.2 million, partially offset by the purchase of marketable securities of $109.0 million and upfront and milestone payments of $23.4 million made to third parties in connection with the in-license or acquisition of our clinical and preclinical programs.

During the year ended December 31, 2019, investing activities used approximately $147.1 million of cash, primarily resulting from the purchase of marketable securities of $499.1 million, partially offset by sales and maturities of investments of $358.5 million.

During the year ended December 31, 2018, investing activities used approximately $144.7 million of cash, primarily resulting from the upfront payment made to Aerpio of $20.0 million in connection with the in-license of GB004, upfront payments of $10.5 million in connection with the acquisition of our preclinical programs, the purchase of marketable securities of $123.5 million, and the purchase of property and equipment of $3.5 million, partially offset by $12.8 million of cash proceeds received from AA Biopharma in connection with our acquisition.

Financing activities

During the year ended December 31, 2020, financing activities provided $312.5 million of cash, primarily resulting from the concurrent registered underwritten public offerings of 2027 Notes and common stock for net proceeds of $193.6 million and $117.1 million, respectively.

During the year ended December 31, 2019, financing activities provided $321.6 million of cash, primarily resulting from the net proceeds from our IPO of $291.3 million, and proceeds from our Credit Facility of $30.0 million, offset by $1.8 million of debt issuance costs.

During the year ended December 31, 2018, financing activities provided $300.9 million of cash, primarily resulting from the net proceeds from issuance of our Series A and B convertible preferred stock of $303.0 million.

Funding requirements

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, and access to our Credit Facility, will be sufficient to fund our operations through at least the next 12 months. 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 product candidates 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, expansions, results, costs and timing of, our preclinical studies and clinical trials of our product candidates which we are pursuing or may choose to pursue in the future;
- the costs and timing of manufacturing for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- 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 preclinical and clinical activities increase;
- the timing and amount of the milestone or other payments we must make to the licensors and other third parties from whom we have in-licensed our acquired our product candidates;
- the costs and timing of establishing or securing sales and marketing capabilities if any product candidate 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 the COVID-19 pandemic.

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, our Credit Facility, 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 our product candidate development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates 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, 2020 our cash and cash equivalents consisted of cash and money market funds, and our marketable securities consisted of U.S. Treasury and agency securities, commercial paper, and corporate debt securities.

Due to the conservative nature of these instruments, 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.

Our outstanding debt under the Credit Facility bears interest at an annual rate equal to the sum of (i) one-month LIBOR (customarily defined, with a change to prime rate if LIBOR funding becomes unlawful or impractical), plus (ii) 7.00%, subject to a LIBOR floor of 2.00% and an interest rate ceiling of 16%. Given the floor and ceiling of the interest rate, a 10% change in market interest rates would increase annual interest expense and decrease cash flows by a maximum of $2.1 million.

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, 2020 and 2019, 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 $0.2 million in our consolidated balance sheets and consolidated statement of operations and other comprehensive loss.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the periods presented.

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, 2020 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, 2020 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, 2020. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm has issued an attestation report on the effectiveness of our internal control over financial reporting for the year ended December 31, 2020, which is included below.

Report of Independent Registered Public Accounting Firm

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

Opinion on Internal Control Over Financial Reporting

We have audited Gossamer Bio, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework, (the COSO criteria). In our opinion, Gossamer Bio, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements") and our report dated February 26, 2021 expressed an unqualified opinion thereon.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

San Diego, California
February 26, 2021

Item 9B. Other Information.

None.

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 2021 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, 2020, 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.

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 “Committees of the Board of Directors” 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 Accountants’ 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 Shareholders 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, 2020 and 2019, the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework, and our report dated February 26, 2021 expressed an unqualified opinion thereon.

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 PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Critical Audit Matters

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

Accrued Research and Development Expenses

Description of the Matter

As of December 31, 2020, 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 contractor's 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

We obtained an understanding and evaluated the design and tested the operating effectiveness of controls over the accounting for accrued research and development expenses. This included controls over management's assessment of the assumptions and accuracy of data underlying the accrued research and development expenses estimate.

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, confirmed amounts incurred to-date with third-party service providers, and performed lookback analyses. We also examined a sample of subsequent payments to evaluate the completeness of the accrued research and development expenses

Convertible Senior Notes

Description of the Matter

On May 21, 2020, the Company issued $200.0 million aggregate principal amount of 5.00% convertible senior notes due in 2027 in a public offering. As described in Note 2 of the consolidated financial statements, the Convertible Notes include conversion terms that require the Company to account for the debt and equity components of the Convertible Notes separately including allocating value to the debt component with the remaining value allocated to the equity component reflected as a debt discount to be amortized to interest expense over the terms of the notes.

Auditing management's conclusions related to the value allocated to the debt portion of the Convertible Note is complex and involves estimation to determine the effective yield that the Company would have received on the debt issuance had it not included the conversion feature.

How We Addressed the Matter in Our Audit

We obtained an understanding and evaluated the design and tested the operating effectiveness of controls over the Company's process to determine the allocation between debt and equity components, including the valuation model and assumptions.

To test the value assigned to each component, we performed audit procedures that included, among others, evaluating the Company's valuation methodology. We tested the completeness and accuracy of the calculation used to estimate the fair value of the debt component. In addition, we involved our valuation specialists to assist in testing the concluded effective yield used to determine the value allocated to the debt component by performing an independent credit analysis including comparison to market rates for similarly rated instruments.

/s/ Ernst & Young LLP

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

San Diego, California
February 26, 2021

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

	December 31,	
	2020	**2019**
ASSETS		
Current assets		
Cash and cash equivalents	$ 486,055	$ 135,026
Marketable securities	26,573	266,740
Restricted cash	565	63
Prepaid expenses and other current assets	9,129	7,488
Total current assets	522,322	409,317
Property and equipment, net	5,534	5,425
Operating lease right-of-use assets	10,550	10,303
Other assets	1,027	1,559
Total assets	**$ 539,433**	**$ 426,604**
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 7,508	$ 956
Accrued research and development expenses	10,431	19,258
Accrued expenses and other current liabilities	20,711	16,709
Total current liabilities	38,650	36,923
Long-term convertible senior notes	143,642	—
Long-term debt	28,744	28,459
Operating lease liabilities - long-term	7,713	8,737
Total liabilities	**218,749**	**74,119**
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value; 700,000,000 shares authorized as of December 31, 2020 and December 31, 2019; 75,524,254 shares issued and 73,874,904 shares outstanding as of December 31, 2020, and 66,284,003 shares issued and 61,635,477 shares outstanding as of December 31, 2019	8	7
Additional paid-in capital	897,607	686,390
Accumulated deficit	(577,530)	(334,170)
Accumulated other comprehensive income	599	258
Total stockholders' equity	320,684	352,485
Total liabilities and stockholders' equity	**$ 539,433**	**$ 426,604**

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)

	Years Ended December 31,		
	2020	**2019**	**2018**
Operating expenses:			
Research and development	$ 160,854	$ 143,403	$ 55,283
In process research and development	23,380	3,600	49,659
General and administrative	49,728	39,136	44,051
Total operating expenses	233,962	186,139	148,993
Loss from operations	**(233,962)**	**(186,139)**	**(148,993)**
Other income (expense)			
Interest income	3,442	5,563	1,720
Interest expense	(12,666)	(1,938)	(12)
Other income (expense)	(174)	2,207	316
Total other income (expense), net	(9,398)	5,832	2,024
Net loss	**$ (243,360)**	**$ (180,307)**	**$ (146,969)**
Other comprehensive income:			
Foreign currency translation, net of tax	441	(12)	—
Unrealized gain (loss) on marketable securities, net of tax	(100)	331	(61)
Other comprehensive income (loss)	341	319	(61)
Comprehensive loss	**(243,019)**	**(179,988)**	**(147,030)**
Net loss per share, basic and diluted	$ (3.55)	$ (3.29)	$ (22.59)
Weighted average common shares outstanding, basic and diluted	68,510,260	54,740,170	6,504,871

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

GOSSAMER BIO, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Series Seed convertible preferred stock		Series A convertible preferred stock		Series B convertible preferred stock		Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income (loss)	Total stockholders equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2017	—	$ —	—	$ —	—	$ —	9,160,888	$ —	$ 32	$ (6,894)	$ —	$ (6,862)
Issuance of Series A preferred stock for cash, net of $0.4 million in offering costs	—	—	42,215,077	73,491	—	—	—	—	—	—	—	—
Issuance of stock for acquisition	20,000,000	29,200	—	—	—	—	1,101,278	1	2,874	—	—	2,875
Issuance of Series A preferred stock to convert debt and accrued interest	—	—	3,499,209	6,124	—	—	—	—	—	—	—	—
Issuance of Series B preferred stock for cash, net of $0.5 million in offering costs	—	—	—	—	71,506,513	229,552	—	—	—	—	—	—
Vesting of restricted stock	—	—	—	—	—	—	2,369,696	1	—	—	—	1
Incremental vesting conditions placed on previously issued common shares	—	—	—	—	—	—	(4,580,444)	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	30,947	—	—	30,947
Net loss	—	—	—	—	—	—	—	—	—	(146,969)	—	(146,969)
Other comprehensive income (loss)	—	—	—	—	—	—	—	—	—	—	(61)	(61)
Balance as of December 31, 2018	20,000,000	$ 29,200	45,714,286	$ 79,615	71,506,513	$ 229,552	8,051,418	$ 2	$ 33,853	$ (153,863)	$ (61)	$ (120,069)
Issuance of common stock in connection with a public offering, net of underwriting discounts, commissions, and offering costs	—	—	—	—	—	—	19,837,500	2	291,309	—	—	291,311
Conversion of convertible preferred stock into common stock	(20,000,000)	(29,200)	(45,714,286)	(79,615)	(71,506,513)	(229,552)	30,493,460	3	338,364	—	—	338,367
Vesting of restricted stock	—	—	—	—	—	—	2,833,506	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	419,593	—	2,045	—	—	2,045
Stock-based compensation	—	—	—	—	—	—	—	—	20,819	—	—	20,819
Net loss	—	—	—	—	—	—	—	—	—	(180,307)	—	(180,307)
Other comprehensive income (loss)	—	—	—	—	—	—	—	—	—	—	319	319
Balance as of December 31, 2019	—	$ —	—	$ —	—	$ —	61,635,477	$ 7	$ 686,390	$ (334,170)	$ 258	$ 352,485
Issuance of common stock in connection with a public offering, net of underwriting discounts, commissions, and offering costs	—	—	—	—	—	—	9,433,963	1	117,093	—	—	117,094
Equity component of convertible note issuance	—	—	—	—	—	—	—	—	53,635	—	—	53,635
Debt issuance costs attributable to convertible feature	—	—	—	—	—	—	—	—	(109)	—	—	(109)
Vesting of restricted stock	—	—	—	—	—	—	2,557,375	—	—	—	—	—
Exercise of stock options	—	—	—	—	—	—	134,803	—	534	—	—	534
Stock-based compensation	—	—	—	—	—	—	—	—	38,748	—	—	38,748
Issuance of common stock pursuant to Employee Stock Purchase Plan	—	—	—	—	—	—	113,286	—	1,300	—	—	1,300
Other additional paid-in capital	—	—	—	—	—	—	—	—	16	—	—	16
Net loss	—	—	—	—	—	—	—	—	—	(243,360)	—	(243,360)
Other comprehensive income (loss)	—	—	—	—	—	—	—	—	—	—	341	341
Balance as of December 31, 2020	—	$ —	—	$ —	—	$ —	73,874,904	$ 8	$ 897,607	$ (577,530)	$ 599	$ 320,684

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

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

	Years Ended December 31,		
	2020	**2019**	**2018**
Cash flows from operating activities			
Net loss	$ (243,360)	$ (180,307)	$ (146,969)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,409	917	297
Stock-based compensation expense	38,748	20,819	30,947
In process research and development expenses	23,380	3,600	49,659
Amortization of operating lease right-of-use assets	2,859	2,172	—
Amortization of long-term debt discount and issuance costs	3,857	237	—
Amortization of premium on investments, net of accretion of discounts	98	(2,364)	—
Net realized gain on investments	(256)	(28)	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(1,641)	(4,393)	(2,827)
Other assets	532	2,714	(584)
Operating lease liabilities	(2,851)	(2,108)	—
Accounts payable	6,984	(1,399)	2,085
Accrued expenses	1,096	1,521	5,938
Accrued research and development expenses	(8,827)	8,605	10,527
Accrued compensation and benefits	1,612	5,180	—
Accrued interest expense	—	—	(117)
Net cash used in operating activities	(176,360)	(144,834)	(51,044)
Cash flows from investing activities			
Research and development asset acquisitions, net of cash acquired	(23,380)	(3,600)	(17,721)
Purchase of marketable securities	(108,968)	(499,079)	(123,500)
Maturities of marketable securities	265,678	328,000	—
Sales of marketable securities	83,515	30,501	—
Purchase of property and equipment	(1,503)	(2,966)	(3,490)
Net cash provided by (used in) investing activities	215,342	(147,144)	(144,711)
Cash flows from financing activities			
Proceeds from issuance of common stock in a public offering, net	117,110	291,311	—
Proceeds from issuance of convertible senior notes, net	193,596	—	—
Proceeds from the issuance of long-term debt, net of debt discount and issuance costs $1,778	—	28,222	—
Purchase of shares pursuant to Employee Stock Purchase Plan	1,300	—	—
Proceeds from the exercise of stock options	534	2,045	—
Proceeds from issuance of Series A convertible preferred stock, net	—	—	73,491
Proceeds from issuance of Series B convertible preferred stock, net	—	—	229,552
Repayment of notes payable to related parties	—	—	(40)
Payment of deferred offering costs	—	—	(2,144)
Net cash provided by financing activities	312,540	321,578	300,859
Effect of exchange rate changes on cash, cash equivalents and restricted cash	9	70	—
Net increase in cash, cash equivalents and restricted cash	351,531	29,670	105,104
Cash, cash equivalents and restricted cash, at the beginning of the period	135,089	105,419	315
Cash, cash equivalents and restricted cash, at the end of the period	**$ 486,620**	**$ 135,089**	**$ 105,419**
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 7,871	$ 1,475	$ 119
Supplemental disclosure of noncash investing and financing activities:			
Acquisition of in-process research and development through issuance of stock	$ —	$ —	$ 19,284
Issuance of Series A convertible preferred stock to convert debt and accrued interest	$ —	$ —	$ 6,124
Unpaid deferred offering costs - net	$ —	$ —	$ 1,545
Right-of-use assets obtained in exchange for lease liabilities	$ 3,106	$ 12,458	$ —
Conversion of convertible preferred stock to common stock	$ —	$ 338,367	$ —
Change in unrealized gain (loss) on marketable securities, net of tax	$ (100)	$ 331	$ (61)
Unpaid property and equipment	$ 15	$ 183	$ —

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

Gossamer Bio, Inc. Notes to Consolidated Financial Statements

Note 1—Organization and Basis of Presentation

Gossamer Bio, Inc. (including its subsidiaries, the "Company") is a clinical-stage biopharmaceutical company focused on discovering, acquiring, developing and commercializing therapeutics in the disease areas of immunology, inflammation and oncology. 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.

Initial Public Offering in February 2019

On February 12, 2019, the Company completed its initial public offering ("IPO") with the sale of 19,837,500 shares of common stock, including shares of common stock issued upon the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of $16.00 per share, resulting in net proceeds of $291.3 million after deducting underwriting discounts, commissions, and offering expenses.

Liquidity and Capital Resources

The Company has incurred significant operating losses since its inception. As of December 31, 2020 and 2019, the Company had an accumulated deficit of $577.5 million and $334.2 million, respectively.

From the Company's inception through the year ended December 31, 2020, the Company has funded its operations primarily through equity financings and debt issuance. The Company raised $942.0 million from October 2017 through December 31, 2020 through Series A and Series B convertible preferred stock financings, a convertible note financing, its IPO, its Credit Facility (as defined in Note 5 below), and concurrent underwritten public offerings of its 5.00% convertible senior notes due 2027 (the "2027 Notes") and common stock in May 2020. See Note 5 for additional information regarding the Credit Facility and the 2027 Notes. In addition, the Company received $12.8 million in cash in connection with the January 2018 acquisition of AA Biopharma Inc.

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 capital through equity offerings, debt financings and 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 twelve 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.

COVID-19

The COVID-19 pandemic has caused significant business disruption around the globe. The extent of the impact of COVID-19 on the Company's operational and financial performance will depend on certain developments, including the duration and spread of the pandemic and the impact on the Company's clinical trials, employees and vendors. At this point, the degree to which COVID-19 has impacted and may continue to impact the Company's financial condition or results of operations is uncertain. A prolonged pandemic could have a material and adverse impact on financial results and business operations of the Company, including the timing and ability of the Company to complete certain clinical trials and other efforts required to advance the development of its product candidates and raise additional capital. For example, the Company temporarily paused enrollment in its Phase 1b clinical trial in pulmonary arterial hypertension ("PAH") in 2020 as a result of the ongoing COVID-19 pandemic. In addition, due to the challenges of enrolling patients posed by the COVID-19 pandemic, the Company may experience delays in enrollment of patients in its Phase 2 clinical trials of GB004 in ulcerative colitis and of seralutinib, also known as GB002, in PAH, as well as delays in reporting data results from its ongoing trials.

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"). Certain prior period amounts have been reclassified to conform to the current period presentation.

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 expenses during the reporting period. The most significant estimates in the Company's consolidated financial statements relate to the allocation of the 2027 Notes into liability and equity components and accrued research and development expenses. 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 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 cash equivalents and 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 condensed consolidated balance sheets. 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 as interest income or expense. 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, 2020.

Restricted Cash

Restricted cash as of December 31, 2020, and 2019 represents cash held as collateral for the Company's facility leases. Restricted cash as of December 31, 2018 served as collateral for the Company's corporate credit card program.

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 office equipment and leasehold improvements, are carried at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the respective assets, generally three to seven years, using the straight-line method.

Convertible Senior Notes

In accounting for the issuance of the 2027 Notes, the Company separated the 2027 Notes into liability and equity components. 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 is not remeasured as long as it continues to meet the condition for equity classification. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is 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 are being 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.

Leases

In accordance with Accounting Standards Update ("ASU") No. 2016-02, *Leases* (Topic 842), as adopted on January 1, 2019, 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) and in process research and development expenses. 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 contractor's 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.

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") Standards Codification ("ASC") No. 740, *Income Taxes* ("ASC 740"), 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.

Deferred tax assets and liabilities reflect the future tax consequences of the differences between the financial reporting and tax bases of assets and liabilities using current enacted tax rates. Valuation allowances are recorded when the realizability of such deferred tax assets does not meet a more-likely-than-not threshold. For tax benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. The Company is subject to taxation in the United States and California, Ireland and Luxembourg. As of December 31, 2020, 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.

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). Foreign exchange transaction gains and losses are included in other income (expense) in the Company's consolidated statement of operations and comprehensive loss.

Recent Accounting Pronouncements—To Be Adopted

In August 2020, the FASB issued ASU 2020-06, Debt: Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06"), which simplifies the accounting for convertible instruments and contracts in an entity's own equity. This guidance is effective for annual reporting periods beginning after December 15, 2021, including interim periods within those years, with early adoption permitted only as of annual reporting periods beginning after December 15, 2020. The Company is currently assessing the impact this standard will have on its consolidated financial statements or related financial statement disclosures.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"), which changes the impairment model for most financial assets and certain other instruments. For trade receivables and other instruments, entities will be required to use a new forward-looking expected loss model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, the losses will be recognized as allowances rather than as reductions in the amortized cost of the securities. This guidance is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those years, with early adoption permitted only as of annual reporting periods beginning after December 15, 2018. The Company adopted ASU 2016-13 as of January 1, 2020. The adoption of this standard did not have a material impact on the Company's consolidated financial statements or related 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 Series Seed convertible preferred stock, Series A convertible preferred stock, and Series B convertible preferred stock, common stock options and 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.

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:

	December 31,		
	2020	2019	2018
Shares issuable upon conversion of Series Seed convertible preferred stock	—	—	4,444,444
Shares issuable upon conversion of Series A convertible preferred stock	—	—	10,158,710
Shares issuable upon conversion of Series B convertible preferred stock	—	—	15,890,306
2027 Notes	12,321,900	—	—
Shares issuable upon exercise of stock options	9,401,082	8,538,060	5,107,329
Non-vested shares under restricted stock grants	3,330,821	4,648,526	7,482,032

Note 3—Accrued Expenses and Other Current Liabilities

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

	Years Ended December 31,	
	2020	2019
Accrued compensation	$ 12,194	$ 9,282
Operating lease liabilities, current	3,633	2,354
Accrued consulting fees	1,919	1,337
Accrued interest, current	1,094	—
Accrued other	742	1,126
Accrued legal fees	619	837
Accrued accounting fees	285	173
Accrued in process research and development	225	1,600
Total accrued expenses	$ 20,711	$ 16,709

Note 4—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 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, 2020 and December 31, 2019 (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, 2020				
Money market funds	$ 411,104	$ 411,104	$ —	$ —
U.S. Treasury and agency securities	18,280	18,280	—	—
Corporate debt securities	26,573	—	26,573	—
As of December 31, 2019				
Money market funds	$ 82,125	$ 82,125	$ —	$ —
U.S. Treasury and agency securities	91,717	91,717	—	—
Commercial paper	37,411	—	37,411	—
Corporate debt securities	156,277	—	156,277	—

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, 2020 and December 31, 2019, the carrying amounts of the Company's financial instruments, which include cash, interest receivable, accounts payable and accrued expenses, approximate fair values because of their short maturities.

Interest receivable as of December 31, 2020 and December 31, 2019 was $0.2 million and $1.5 million, respectively, and is recorded as a component of prepaid expenses and other current assets on the condensed consolidated balance sheets.

The Company believes that its Credit Facility bears interest at a rate that approximates prevailing market rates for instruments with similar characteristics and, accordingly, the carrying value of the Credit Facility approximates fair value. The Company estimates the fair value of long-term debt utilizing an income approach. The Company uses a present value calculation to discount principal and interest payments and the final maturity payment on these liabilities using a discounted cash flow model based on observable inputs. The debt instrument is then discounted based on what the current market rates would be as of the reporting date. Based on the assumptions used to value these liabilities at fair value, the debt instrument is categorized as Level 2 in the fair value hierarchy.

As of December 31, 2020 the fair value of the Company's 2027 Notes was $198.5 million. 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 and debt instruments of corporations and commercial obligations, 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 as interest income or expense. 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 aggregate market value, cost basis, and gross unrealized gains and losses of available-for-sale investments by security type, classified in marketable securities and long-term investments as of December 31, 2020 are as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Fair Value
Marketable securities				
Corporate debt securities	$ 26,396	$ 177	$ —	$ 26,573
Total marketable securities	$ 26,396	$ 177	$ —	$ 26,573

As of December 31, 2020 and 2019, the Company classified $18.3 million and $18.7 million, respectively, of assets with original maturities of 90 days or less as 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, 2020, 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, 2020, were as follows (in thousands):

	Estimated Fair Value
Due within one year	$ 26,573
One to two years	—
Total	$ 26,573

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 and July 2, 2020 (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, including affiliates of MidCap and Silicon Valley Bank, 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. The Company, GB001, Inc., GB002, Inc., and GB004, Inc., each wholly-owned subsidiaries of the Company, are designated as co-borrowers to the Credit Facility, whereas GB003, Inc., GB005, Inc., GB006, Inc., GB007, Inc., GB008, Inc., and Gossamer Bio Services, Inc.,each wholly-owned subsidiaries of the Company, are designated as guarantors. The remaining two tranches are available no earlier than the satisfaction of the applicable funding conditions, including the applicable clinical development milestones, and no later than December 31, 2022. As of December 31, 2020, no other tranches under the Credit Facility have been available. The Credit Facility is secured by substantially all of the Company's and its domestic subsidiaries' personal property, including intellectual property.

Each term loan under the Credit Facility bears interest at an annual rate equal to the sum of (i) one-month LIBOR (customarily defined, with a change to prime rate if LIBOR funding becomes unlawful or impractical) plus (ii) 7.00%, subject to a LIBOR floor of 2.00%. The Company is required to make interest-only payments on the term loan for all payment dates prior to July 1, 2022. The term loans under the Credit Facility will begin amortizing on July 1, 2022, with equal monthly payments of principal plus interest being made by the Company to the Lenders in consecutive monthly installments following

such interest-only period until the Credit Facility matures on January 1, 2025. Upon final repayment of the term loans, the Company must pay an exit fee of 1.75% of the amount borrowed under the Credit Facility, less any partial exit fees previously paid. Upon partial prepayment of a portion of the term loans, the Company must pay a partial exit fee of 1.75% of the principal being prepaid. At the Company's option, the Company may prepay the outstanding principal balance of the term loan in whole or in part, subject to a prepayment fee of 3.00% of any amount prepaid if the prepayment occurs through and including the first anniversary of the second amendment effective date, 2.00% of the amount prepaid if the prepayment occurs after the first anniversary of the second amendment effective date through and including the second anniversary of the second amendment effective date, and 1.00% of any amount prepaid after the second anniversary of the second amendment effective date and prior to January 1, 2025.

The Credit Facility includes affirmative and negative covenants applicable to the Company and certain of its subsidiaries. The affirmative covenants include, among others, covenants requiring such entities to maintain their legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage, maintain property, pay taxes, satisfy certain requirements regarding accounts and comply with laws and regulations. The negative covenants include, among others, restrictions on such entities from transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying dividends or making other distributions, making investments, creating liens, amending material agreements and organizational documents, selling assets and suffering a change in control, in each case subject to certain exceptions. The Company and certain of its subsidiaries are also subject to an ongoing minimum cash financial covenant in which they must maintain unrestricted cash in an amount not less than 25% of the outstanding principal amount of the term loans. As of December 31, 2020, the Company was in compliance with these covenants.

The Credit Facility also includes events of default, the occurrence and continuation of which could cause interest to be charged at the rate that is otherwise applicable plus 3.00% and would provide MidCap, as agent, with the right to exercise remedies against the Company and/or certain of its subsidiaries, and the collateral securing the Credit Facility, including foreclosure against the properties securing the credit facilities, including cash. These events of default include, among other things, failure to pay any amounts due under the Credit Facility, a breach of covenants under the Credit Facility, insolvency or the occurrence of insolvency events, the occurrence of a change in control, the occurrence of certain U.S. Food and Drug Administration ("FDA") and regulatory events, failure to remain registered with the SEC and listed for trading on Nasdaq, the occurrence of a material adverse change, the occurrence of a default under a material agreement reasonably expected to result in a material adverse change, the occurrence of certain defaults under certain other indebtedness in an amount greater than $2.5 million and the occurrence of certain defaults under subordinated indebtedness and convertible indebtedness.

Long-term debt as of December 31, 2020 consisted of the following (in thousands):

	December 31, 2020
Term loan	$ 30,000
Debt discount and issuance costs	(1,256)
Long-term debt	$ 28,744

The scheduled future minimum principal payments are as follows (in thousands):

	December 31, 2020
2021	—
2022	5,806
2023	11,613
2024	11,613
2025	968
Total	$ 30,000

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 were registered pursuant to the Company's Shelf Registration Statement (as defined in Note 8 below). 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, including all indebtedness under the Credit Facility.

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 will not have the right to redeem the 2027 Notes prior to June 6, 2024. 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, 2020, 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, 2020, there were no events or market conditions that would allow holders to convert the 2027 Notes. At the time 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.

In accounting for the issuance of the 2027 Notes, the Company separated the 2027 Notes into liability and equity components. 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 $53.5 million and was determined by deducting the fair value of the liability component from the par

value of the 2027 Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. The debt discount is amortized to interest expense over the term of the 2027 Notes at an effective interest rate of 11.17% over the contractual terms of the 2027 Notes.

In accounting for the debt issuance costs of $0.4 million related to the 2027 Notes, the Company allocated the total amount 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 $0.3 million and will be amortized to interest expense using the effective interest method over the contractual terms of the 2027 Notes. Issuance costs attributable to the equity component were netted with the equity component in stockholders' equity.

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

	December 31, 2020	December 31, 2019
Principal amount	$ 200,000	$ —
Unamortized debt discount	(56,080)	—
Unamortized debt issuance cost	(278)	—
Net carrying amount	$ 143,642	$ —

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

	December 31, 2020	December 31, 2019
Debt discount related to the value of conversion option	$ 53,635	$ —
Debt issuance cost	(109)	—
Net carrying amount	$ 53,526	$ —

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

	Years Ended December 31,		
	December 31, 2020	December 31, 2019	December 31, 2018
Contractual interest expense	$ 6,139	$ —	$ —
Amortization of debt discount	3,555	—	—
Amortization of debt issuance cost	17	—	—
Total interest expense related to the 2027 Notes	$ 9,711	$ —	$ —

Note 6—License and Asset Acquisitions

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 statement of operations for the years ended December 31, 2020, 2019, and 2018.

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 resolved.

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. 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 $58.0 million, 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. The Company made an upfront payment of $5.5 million in October 2017. In December 2020, the Company accrued a milestone payment of $5.0 million in connection with the initiation of the first Phase 2 clinical trial of seralutinib.

AA Biopharma Inc. Acquisition (GB001)

On January 4, 2018, the Company acquired AA Biopharma Inc. pursuant to a merger agreement, and with the acquisition acquired the rights to GB001 and certain backup compounds. In connection with the merger agreement, the Company issued an aggregate of 20,000,000 shares of Series Seed convertible preferred stock and 1,101,278 shares of common stock to the AA Biopharma shareholders. The Company recorded IPR&D of $19.3 million in connection with the acquisition of AA Biopharma.

License from Aerpio Pharmaceuticals, Inc. (GB004)

On June 24, 2018, the Company entered into a license agreement with Aerpio Pharmaceuticals, Inc. (“Aerpio”) under which the Company was granted an exclusive worldwide license and sublicense to certain intellectual property rights owned or controlled by Aerpio to develop and commercialize GB004, and certain other related compounds for all applications. The Company made an upfront payment of $20.0 million in June 2018, which represented the purchase consideration for an asset acquisition. On May 11, 2020, the Company entered into an amendment to the license agreement with Aerpio pursuant to which the Company made an upfront payment of $15.0 million to Aerpio for a reduction in future milestone payments and royalties. Under the amended license agreement, the Company is obligated to make future approval milestone payments of up to $40.0 million and a sales milestone payment of $50.0 million. The Company also has the right to sublicense its rights under the license agreement, subject to certain conditions. The Company is also obligated to pay tiered royalties on sales for each licensed product, at percentages ranging from low- to mid-single digits, subject to certain customary reductions. Aerpio retains its twenty percent (20.00%) participation right on a disposition of GB004. As of December 31, 2020, no milestones had been accrued as the underlying contingencies had not yet been resolved.

Adhaere Pharmaceuticals, Inc. Acquisition (GB1275)

On September 21, 2018, the Company acquired Adhaere Pharmaceuticals, Inc. pursuant to a merger agreement for an upfront payment of $7.5 million in cash, and with the acquisition acquired the rights to GB1275 and certain backup compounds. The Company is obligated to make future regulatory, development and sales milestone payments of up to $62.0 million and pay tiered royalties on worldwide net sales, at percentages ranging from low to mid-single digits, subject to customary reductions. The Company recorded IPR&D of $7.5 million in connection with the acquisition of Adhaere. In May 2019, the Company made a milestone payment of $1.0 million in connection with the filing of the Investigational New Drug application for the GB1275 program. As of December 31, 2020, no other milestones had been accrued as the underlying contingencies had not yet been resolved.

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

	Years Ended December 31,		
	2020	2019	2018
Seralutinib	$ 5,000	$ —	$ —
GB004	15,000	—	20,000
GB1275	—	1,000	7,501
GB001	—	—	19,148
Other preclinical programs	3,380	2,600	3,010
Total in process research and development	$ 23,380	$ 3,600	$ 49,659

Note 7—Income Taxes

The amount of net loss before taxes for the years ended December 31, 2020, 2019, and 2018 is as follows:

	December 31,		
	2020	2019	2018
	(in thousands)		
U.S. loss before taxes	$ 186,888	$ 138,342	$ 116,920
Foreign loss before taxes	56,472	41,965	30,049
Loss before income taxes	$ 243,360	$ 180,307	$ 146,969

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, 2020, 2019 and 2018 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, 2020 was an increase of $38.9 million.

	December 31,		
	2020	2019	2018
	(in thousands)		
Deferred tax assets:			
Net operating losses	$ 77,946	$ 43,626	$ 14,442
Tax credits, net	17,372	9,196	1,131
Amortization	10,939	6,597	6,267
Stock-based compensation	4,448	1,388	—
Lease liability	2,383	2,329	—
Accrued compensation	2,137	1,476	834
Other	16	383	154
Total gross deferred tax assets	115,241	64,995	22,828
Deferred tax liabilities:			
Convertible senior notes	(10,592)	—	—
Right of use asset	(2,215)	(2,164)	—
Property, plant and equipment	(776)	(57)	(16)
Stock-based compensation	—	—	(1,057)
Total gross deferred tax liabilities	(13,583)	(2,221)	(1,073)
Valuation allowance	(101,658)	(62,774)	(21,755)
Net deferred tax asset	$ —	$ —	$ —

At December 31, 2020, the Company has federal and California NOL carryforwards of approximately $310.7 million and $1.1 million, respectively. The federal NOL carryforwards generated prior to January 1, 2018 begin to expire in 2034. The federal NOL generated after 2017 of $307.7 million can be carried forward indefinitely but may only be used to offset up to 80% of the Company's taxable income in taxable years beginning after December 31, 2020. The California NOL carryforwards begin to expire in 2036. At December 31, 2020, the Company has foreign NOL carryforwards of approximately $101.1 million that can be carried forward indefinitely.

At December 31, 2020, the Company also has orphan drug credit and federal research tax credit carryforwards of approximately $17.9 million and California research tax credits of $5.4 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.

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

	December 31,		
	2020	2019	2018
Federal statutory income tax rate	21.00 %	21.00 %	21.00 %
State income taxes, net of federal benefit	— %	— %	— %
Change in valuation allowance	(19.50 %)	(22.12 %)	(13.17 %)
Research and experimentation credits	2.76 %	3.81 %	0.77 %
Foreign rate differential	(1.64 %)	(1.84 %)	(1.74 %)
Stock-based compensation	(1.81 %)	— %	(2.6 %)
In process research and development	— %	— %	(3.92 %)
Other	(0.80 %)	(0.85 %)	(0.34 %)
Provision for income taxes	— %	— %	— %

The NOL carryforward may be subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986 (the "Code"), 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 Section 382 and 383, results from the transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percentage points over a three-year period. In connection with the Company's IPO in February 2019, the Company experienced an ownership change for the purposes of Section 382 and 383 of the Code. The ownership change did not result in the forfeiture of any NOLs or credits generated prior to this date. Consequently, the Company's federal and state NOLs and tax credits generated through February 2019 will be subject to annual limitations. If a change in ownership occurs in the future, the NOL and tax credits carryforwards could be eliminated or restricted. If eliminated, the related asset would be removed from the deferred tax asset schedule with a corresponding reduction in the valuation allowance. 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, Ireland, and Luxembourg. Due to the Company's unutilized NOLs and credits, 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. As of December 31, 2020, 2019, or 2018, there were no significant accruals for interest related to unrecognized tax benefits or tax penalties.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 ("Tax Act") was signed into law making significant changes to the Internal Revenue Code, including, but are not limited to (a) reducing the federal corporate income tax rate from 35% to 21%, effective January 1, 2018; (b) eliminating the federal corporate alternative minimum tax ("AMT") and changing how existing AMT credits can be realized; and (c) eliminating several business deductions and credits, including deductions for certain executive compensation in excess of $1 million.

As a result of the rate reduction, the Company reduced the deferred tax asset balance as of December 31, 2018 by $0.8 million. Due to the Company's full valuation allowance position, there was no net impact on the Company's income tax provision at December 31, 2018 as the reduction in the deferred tax asset balance was fully offset by a corresponding decrease in the valuation allowance.

A reconciliation of the beginning and ending amount of unrecognized tax benefits for 2020, 2019, and 2018, excluding interest and penalties, is as follows:

	December 31,		
	2020	2019	2018
	(in thousands)		
Balance at beginning of the year	$ 2,754	$ 408	$ —
Increase related to current year positions	2,306	2,346	408
Balance at the end of the year	$ 5,060	$ 2,754	$ 408

Included in the balance of unrecognized tax benefits at December 31, 2020 is $5.1 million that, if recognized, would not impact the Company's income tax benefit or effective tax rate as long as our deferred tax asset remains subject to a

full valuation allowance. The Company does not expect any significant increases or decreases to our unrecognized tax benefits within the next 12 months.

Note 8—Stockholders' Equity

In connection with the Company's IPO, the outstanding shares of the Company's Series Seed, Series A, and Series B convertible preferred stock automatically converted into 30,493,460 shares of 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 Board.

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.

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 and the Founders' Equity) 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.

In November 2017, in connection with the issuance of the Series A convertible preferred stock, certain employees entered into stock restriction agreements, whereby 1,305,421 shares are subject to repurchase by the Company upon the stockholder's termination of employment or service to the Company.

For the year ended December 31, 2020, 441,801 shares were forfeited due to termination of employment. 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, 2020, 2019 and 2018, 1,649,348 shares, 4,648,526 shares and 7,482,032 shares of common stock, respectively, were subject to repurchase by the Company. The unvested stock liability related to these awards is immaterial to all periods presented.

Note 9—Equity Incentive Plans

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, 2020, an aggregate of 1,609,830 shares of common stock were available for issuance under the 2019 Plan and 7,140,993 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 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 year ended December 31, 2020, 113,286 shares were issued pursuant to the ESPP. As of December 31, 2020, an aggregate of 1,249,554 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, 2020, 3,941,562 shares of common stock were subject to outstanding options under the 2017 Plan, and 268,719 shares of restricted stock awards granted under the 2017 plan were unvested.

Fair Value of Stock Option Awards

The fair value of each employee and non-employee stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company estimates its expected volatility based on the historical volatility of a publicly traded set of peer companies. 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.

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,		
	2020	2019	2018
Employee Stock Options			
Expected term (in years)	4.6 - 6.1	4.6 - 6.1	5.3 - 6.1
Risk-free interest rate	0.22% - 1.67%	1.38% - 2.58%	2.65% - 2.96%
Volatility	84.38% - 87.23%	70.25% - 86.92%	69.13% - 77.62%
Dividend yield	—	—	—
Employee Stock Purchase Plan			
Expected term (in years)	0.49 - 2.00	0.49 - 1.99	N/A
Risk-free interest rate	0.12% -0.95%	1.46% - 1.87%	N/A
Volatility	85.50% - 99.13%	72.08% - 78.70%	N/A
Dividend yield	—	—	N/A

Stock Options

The following table summarizes stock option activity for the years ended December 31, 2020, 2019 and 2018:

	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, 2017	—	$ —	0.0	$ —
Options granted	5,143,551	$ 7.49		
Options exercised	—	$ —		
Options forfeited/cancelled	(36,222)	$ 4.85		
Outstanding as of December 31, 2018	5,107,329	$ 7.51	9.7	$ 16,343
Options granted	4,194,624	$ 20.11		
Options exercised	(419,593)	$ 4.87		
Options forfeited/cancelled	(344,300)	$ 11.64		
Outstanding as of December 31, 2019	8,538,060	$ 13.67	9.0	$ 35,385
Options granted	2,712,372	$ 13.78		
Options exercised	(134,803)	$ 3.96		
Options forfeited/cancelled	(1,714,547)	$ 15.99		
Outstanding as of December 31, 2020	9,401,082	$ 13.42	8.1	$ 10,182
Options vested and exercisable as of December 31, 2020	3,749,170	$ 12.66	7.5	$ 6,293

The weighted-average grant date fair value per share for the stock options granted during the year ended December 31, 2020, 2019 and 2018 was $9.82, $13.17 and $4.87, respectively.

The aggregate fair value of stock options that vested during the years ended December 31, 2020, 2019 and 2018 was $29.9 million, $7.2 million and $0.1 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. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2020 and 2019 was $1.1 million and $6.9 million, respectively. There were no stock options exercised during the year ended December 31, 2018.

At December 31, 2020, the total unrecognized compensation related to unvested stock option awards granted was $48.1 million, which the Company expects to recognize over a weighted-average period of approximately 2.4 years.

Restricted Stock

The summary of the Company's restricted stock activity during the years ended December 31, 2020, 2019 and 2018 is as follows:

	Number of Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Nonvested at December 31, 2017	1,305,421	$ 0.09
Granted	8,673,584	5.53
Vested	(2,369,696)	7.58
Forfeited	(127,277)	0.09
Nonvested at December 31, 2018	7,482,032	$ 4.01
Granted	—	—
Vested	(2,833,506)	4.05
Forfeited	—	—
Nonvested at December 31, 2019	4,648,526	$ 3.98
Granted	2,003,900	10.96
Vested	(2,557,377)	4.00
Forfeited	(764,228)	8.30
Nonvested at December 31, 2020	3,330,821	$ 7.16

At December 31, 2020, the total unrecognized compensation related to unvested restricted stock awards granted was $18.8 million, which the Company expects to recognize over a weighted-average period of approximately 1.9 years.

Stock-Based Compensation Expense

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

	Year Ended December 31,		
	2020	2019	2018
Research and development	$ 18,997	$ 10,227	$ 679
General and administrative	19,751	10,592	30,268
Total stock-based compensation	$ 38,748	$ 20,819	$ 30,947

In connection with the departure of the Company's former President and Chief Executive Officer in November 2020, the Company recognized $5.5 million of incremental stock-based compensation expense during the year ended December 31, 2020, due to a modification of the executive's existing restricted stock award, which included 18 months of accelerated vesting of the executive's outstanding restricted stock in accordance with the terms of the executive's transition agreement.

As of December 31, 2020, total unrecognized compensation expense related to the ESPP was $1.4 million, which the Company expects to recognize over a weighted-average period of approximately 1 year.

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, 2020	December 31, 2019
Office equipment	3-7	$ 1,153	$ 1,097
Computer equipment	5	123	124
Software	3	116	87
Lab equipment	2-5	4,210	3,054
Leasehold improvements	6-7	2,540	2,229
Construction in process	N/A	15	48
Total property and equipment		8,157	6,639
Less: accumulated depreciation		2,623	1,214
Property and equipment, net		$ 5,534	$ 5,425

Depreciation expense for the years ended December 31, 2020, 2019 and 2018 was approximately $1.4 million, $0.9 million and $0.3 million, respectively, and was recorded in general and administrative expense in the consolidated statements of operations.

Note 11—Commitments and Contingencies

Leases

The Company subleases certain office and laboratory space under a non-cancelable operating lease expiring in January 2025 for the initial leased space and December 2022 for expansion space leased pursuant to an amendment to the lease agreement entered into in August 2018. The sublease agreement included options to extend for the entire premises through October 2028. The options to extend must be exercised prior to the termination of the original lease agreement. The period covered by the options was not included in the non-cancellable lease term as it was not determined to be reasonably certain to be executed. The lease agreement also includes a one-time termination option for the expansion space only whereby the Company can terminate the lease with advance written notice. The termination option was not determined to be reasonably certain to be executed. The lease is subject to charges for common area maintenance and other costs, and base rent is subject to an annual 3% increase each subsequent year. Costs determined to be variable and not based on an index or rate were not included in the measurement of the operating lease liabilities.

In November 2019, the Company entered into an additional non-cancelable lease agreement for certain office and laboratory space (the "permanent space") in San Diego, California, commencing on May 1, 2020 and expiring on December 31, 2021. The lease agreement includes a lease for temporary space commencing on January 1, 2020 and expiring on the commencement date of the lease of the permanent space. The monthly base rent for the permanent and temporary space is $63,425 and $28,745, respectively. The lease agreement included an option to extend the term of the permanent space for twelve months. The option to extend must be exercised nine months prior to the termination of the original lease agreement. The period covered by the option was not included in the non-cancellable lease term as it was not determined to be reasonably certain to be executed. The lease is subject to charges for common area maintenance and other costs, and base rent is subject to an annual 3% increase each subsequent year.

In June 2020, the Company entered into a sublease agreement for the permanent space with a third party. The sublease commenced on July 1, 2020 and expires on December 31, 2021. The sublessee pays the monthly base rent of $63,425, subject to an annual 3% increase, and is obligated to pay for common area maintenance and other costs. The sublessee received a 6 months base rent abatement. The Company determined that there was no impairment on the original right-of-use asset and will continue to account for the permanent space as it did before the commencement of the sublease. The Company recognized $0.2 million in sublease income for the year ended December 31, 2020.

On July 29, 2020, the Company entered into a lease assignment agreement, whereby it became the assignee to a lease for certain office and laboratory space in Ann Arbor, Michigan. The lease term expires on December 31, 2026 and the Company has the option to extend the term of the lease by up to five years. The period covered by the option was not included in the non-cancellable lease term as it was not determined to be reasonably certain to be executed. The monthly base rent for the space is $28,495. The lease is subject to charges for common area maintenance and other costs, and base rent is subject to an annual 2.5% increase on January 1 of each year.

Monthly rent expense is recognized on a straight-line basis over the term of the leases. The operating leases are included in the balance sheet at the present value of the lease payments at a weighted average discount rate of 7% 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. The weighted average remaining lease term was 3.4 years.

Lease costs were comprised of the following (in thousands):

	Year ended December 31, 2020
Operating lease cost	$ 3,615
Short-term lease cost	78
Total lease cost	$ 3,693

Cash paid for amounts included in the measurement of operating lease liabilities for the years ended December 31, 2020 and 2019 was $3.6 million and $3.0 million , respectively.

Gross future minimum annual rental commitments as of December 31, 2020, were as follows (in thousands):

	Undiscounted Rent Payments
Year ending December 31,	
2021	$ 4,273
2022	3,579
2023	2,063
2024	2,123
2025	387
	397
Total undiscounted rent payments	$ 12,822
Present value discount	(1,476)
Present value	$ 11,346
Current portion of operating lease liabilities (included as a component of accrued expenses and other current liabilities)	3,633
Noncurrent operating lease liabilities	7,713
Total operating lease liability	$ 11,346

For the years ended December 31, 2020, 2019 and 2018, the Company recorded approximately $4.0 million, $3.1 million and $1.5 million, respectively, in rent expense.

Litigation

Kuhne vs. Gossamer Bio, Inc., et. al.

On April 3, 2020, Scott Kuhne, individually and on behalf of all others similarly situated, filed a putative class action lawsuit against the Company, certain of its executive officers and directors, and the underwriters of its IPO in the United States District Court for the Southern District of California (Case No. 3:20-cv-00649-DMS-DEB). The first amended complaint was filed on August 31, 2020, and the second amended complaint was filed on November 20, 2020. The second amended complaint was filed on behalf of all investors who purchased the Company's securities pursuant to or traceable to the Company's February 8, 2019 IPO. The second amended complaint alleges that the Company, certain of its executive officers and directors, and the underwriters of its IPO made false and/or misleading statements and failed to disclose material adverse facts about its business, operations and prospects in violation of Sections 11 and 15 of the Securities Act of 1933, as amended. The plaintiff seeks damages, interest, costs, attorneys' fees, and other unspecified equitable relief. The Company moved to dismiss the second amended complaint on January 19, 2021, and Plaintiff filed an opposition to the motion on February 18, 2021. The Company's deadline to file a reply in support of the motion to dismiss is March 22, 2021. The Company intends to vigorously defend this matter. Given the uncertainty of litigation, the preliminary stage of the case, and the legal standards that must be met for, among other things, class certification and success on the merits, the Company cannot estimate the reasonably possible loss or range of loss that may result from this action.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation.	8-K	2/12/2019	3.1	
3.2	Amended and Restated Bylaws.	10-Q	5/12/2020	3.2	
4.1	Form of Common Stock Certificate.	S-1/A	1/23/2019	4.1	
4.2	Amended and Restated Investors' Rights Agreement, dated July 20, 2018, by and among the Registrant and certain of its stockholders.	S-1	12/21/2018	4.2	
4.3	Description of Securities Registered under Section 12 of the Exchange Act.				X
4.4	Indenture, dated as of May 21, 2020, by and between the Registrant and Wilmington Trust, National Association.	8-K	5/21/2020	4.1	
4.5	First Supplemental Indenture, dated May 21, 2020, by and between the Registrant and Wilmington Trust, National Association.	8-K	5/21/2020	4.2	
4.6	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	
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.	S-1/A	1/23/2019	10.7	
10.8#	Gossamer Bio, Inc. Restricted Stock Unit Agreement under the 2019 Equity Incentive Plan.	10-Q	5/12/2020	10.1	
10.9#	Employment Letter, dated January 4, 2018, by and between Sheila Gujrathi, M.D. and the Registrant.	S-1	12/21/2018	10.8	
10.10#	Transition Agreement, dated November 17, 2020, by and between Sheila Gujrathi, M.D. and the Registrant.				X
10.11#	Letter Agreement, dated November 16, 2020, by and between Faheem Hasnain and the Registrant.				X
10.12#	Employment Letter, dated December 4, 2018, by and between Bryan Giraudo and the Registrant.	S-1	12/21/2018	10.10	
10.13#	Employment Letter, dated December 4, 2018, by and between Christian Waage and the Registrant.	S-1	12/21/2018	10.11	
10.14#	Employment Letter, dated December 4, 2018, by and between Luisa Salter-Cid, Ph.D. and the Registrant.	S-1	12/21/2018	10.13	
10.15#	Form of Indemnification Agreement.	S-1	12/21/2018	10.14	
10.16	Sublease Agreement, dated December 29, 2017, by and between The Medicines Company and the Registrant.	S-1	12/21/2018	10.15	
10.17	First Amendment to Sublease Agreement, dated August 24, 2018, by and between The Medicines Company and the Registrant.	S-1	12/21/2018	10.16	
10.18†	Exclusive License Agreement, dated October 2, 2017, by and between GB002, Inc., the Registrant and Pulmokine, Inc.	S-1	12/21/2018	10.17	
10.19†	License Agreement, dated June 24, 2018, by and between Aerpio Pharmaceuticals, Inc. and GB004, Inc.	S-1	12/21/2018	10.18	
10.20†	Amendment No. 1 to License Agreement, dated May 11, 2020, by and between GB004, Inc. and Aerpio Pharmaceuticals, Inc.	10-Q	8/11/2020	10.2	
10.21	Credit, Guaranty and Security Agreement, dated May 2, 2019, by and among GB001, Inc., as Borrower, Gossamer Bio, Inc., as Guarantor, MidCap Financial Trust, as Agent and Lender, and the additional lenders from time to time party thereto.	8-K	5/3/2019	10.1	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.22	First Amendment to Credit, Guaranty and Security Agreement, dated September 18, 2019, by and among GB001, Inc., as borrower, the Registrant, as guarantor, the other guarantors from time to time party thereto and MidCap Financial Trust, as Agent and as Lender, and the additional lenders from time to time party thereto.	10-Q	11/12/2019	10.1	
10.23	Second Amendment to Credit, Guaranty and Security Agreement, dated July 2, 2020, by and among the Registrant, GB001, Inc., GB002, Inc. and GB004, Inc., as co-borrowers, the other guarantors from time to time party thereto and MidCap Financial Trust, as Agent and as a Lender and the additional lenders from time to time party thereto.	8-K	7/2/2020	10.1	
21.1	List of Subsidiaries of the Registrant.	10-K	3/24/2020	21.1	
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm.				X
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
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 February 26, 2021

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)	February 26, 2021
/s/ Bryan Giraudo Bryan Giraudo	Chief Financial Officer (principal financial and accounting officer)	February 26, 2021
/s/ Joshua H. Bilenker Joshua H. Bilenker, M.D.	Director	February 26, 2021
/s/ Kristina Burow Kristina Burow	Director	February 26, 2021
/s/ Russell Cox Russell Cox	Director	February 26, 2021
/s/ Thomas Daniel, M.D. Thomas Daniel, M.D.	Director	February 26, 2021
/s/ Renée Galá Renée Galá	Director	February 26, 2021

DESCRIPTION OF GOSSAMER BIO, INC. SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Gossamer Bio, Inc. has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock, par value $0.0001 per share (the "common stock").

DESCRIPTION OF COMMON STOCK

The following description of our common stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our amended and restated certificate of incorporation, as amended ("certificate of incorporation") and our amended and restated bylaws ("bylaws"), each of which are filed as exhibits to our Annual Report on Form 10-K ("Annual Report") and are incorporated by reference herein. The terms "Gossamer" "we," "our," and "us" refer solely to Gossamer Bio Inc. and not its subsidiaries.

Our authorized capital stock includes 770,000,000 shares, consisting of 700,000,000 shares of common stock and 70,000,000 shares of preferred stock, par value $0.0001 per share (the "preferred stock").

Voting Rights

Holder of our common stock are entitled to one vote for each share held on all matters to be voted upon by our stockholders, including the election of directors, and do not have cumulative voting rights. Accordingly, the holders of a majority of the outstanding shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they so choose, other than any directors that holders of any preferred stock we may issue may be entitled to elect. Subject to the supermajority votes for some matters, other matters shall be decided by the affirmative vote of our stockholders having a majority in voting power of the votes cast by the stockholders present or represented and voting on such matter. Our certificate of incorporation and bylaws also provide that our directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon. In addition, the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock entitled to vote thereon is required to amend or repeal, or to adopt any provision inconsistent with, several of the provisions of our certificate of incorporation.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared by the board of directors out of legally available funds.

Liquidation

Upon any liquidation, dissolution or winding up of our business, the holders of our common stock are entitled to share equally in all assets available for distribution after payment of all liabilities, subject to the liquidation preference of shares of preferred stock, if any, then outstanding.

Rights and Preferences

Holders of our common stock have no preemptive or conversion rights or other subscription rights and there are no redemption or sinking funds provisions applicable to the common stock. The rights, preferences and privileges of holders of common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable

All outstanding shares of common stock are duly authorized, validly issued, fully paid and non-assessable.

Anti-Takeover Effects of Delaware Law and Our Certificate of Incorporation and Bylaws

Some provisions of Delaware law, our certificate of incorporation and our bylaws contain provisions that could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 70,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our bylaws provide that a special meeting of stockholders may be called only by our chairman of the board of directors, chief executive officer or president, or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our certificate of incorporation and bylaws eliminate the right of stockholders to act by written consent without a meeting.

Staggered Board of Directors

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two thirds of the total voting power of all of our outstanding voting stock then entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (1) any derivative action or proceeding brought on our behalf; (2) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, creditors or other constituents; (3) any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws; (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (5) any action asserting a claim governed by the internal affairs doctrine. The provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. In any case, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, our 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 of 1933, as amended. 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. Our certificate of incorporation and bylaws also provide that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to these choice of forum provisions.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock, would require approval by holders of at least two thirds of the total voting power of all of our outstanding voting stock.

The provisions of Delaware law, our certificate of incorporation and our bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board of directors and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Listing

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar’s address is 250 Royall Street, Canton, Massachusetts 02021.

Exhibit 10.10

TRANSITION AGREEMENT

This Transition Agreement (the "***Agreement***") is entered into by and among Sheila Gujrathi, M.D. ("***Executive***"), Gossamer Bio Services, Inc. (the "***Gossamer Services***"), and Gossamer Bio, Inc. ("***Parent***," and together with Gossamer Services, collectively the "***Company***"), effective as of the Effective Date (as defined below).

Recitals

WHEREAS, Executive is a party to that certain offer letter dated as of January 4, 2018, with the Company (the "***Offer Letter***");

WHEREAS, Executive's employment with the Company will terminate effective as of November 16, 2020 (the "***Termination Date***"); and

WHEREAS, Executive acknowledges that, but for her agreement to execute this Agreement, she would not be eligible for the Termination Benefits (as defined below).

NOW THEREFORE, in consideration of, and subject to, the Termination Benefits payable to Executive described in Section 3 below, the adequacy of which is hereby acknowledged by Executive, and which Executive acknowledges that she would not otherwise be entitled to receive, Executive and the Company hereby agree as follows:

Agreement

1. Effective Date. This Agreement shall not become effective unless both of the following events have occurred: (a) execution of this Agreement by Executive, and (b) expiration of the revocation period applicable under Section 4(e) below without Executive having given notice of revocation. The date on which this Agreement becomes effective shall be referred to in this Agreement as the "*Effective Date*." Unless the Effective Date occurs on or before the date that is sixty (60) days following the Termination Date, this Agreement shall be null and void. The parties agree that any material or immaterial changes to this Agreement shall not extend the deadline for the occurrence of the Effective Date.

2. Termination of Employment.

(a) The Termination Date will be the termination date of Executive's employment with the Company and any of its affiliates for all purposes, including active participation in and coverage under all benefit plans and programs sponsored by or through the Company and its affiliates except as provided in this Agreement. Executive hereby confirms her termination from all positions she holds with the Company and any of its affiliates, including her position as Chief Executive Officer and as a member of the boards of directors of Parent, Gossamer Services and their affiliates, effective as of the Termination Date. In accordance with applicable law, on the Termination Date, the Company will issue to Executive her final paycheck, reflecting (i) her earned but unpaid base salary through the Termination Date, and (ii) all accrued, unused vacation or paid time off due Executive through the Termination Date.

(b) The Company will reimburse Executive for any and all reasonable and necessary business expenses incurred by Executive in connection with the performance of her job

duties prior to the Termination Date, which expenses shall be submitted to the Company with supporting receipts and/or documentation no later than thirty (30) days after the Termination Date.

(c) Subject to Section 3(d) below, Executive's entitlement to health benefits from the Company, and eligibility to participate in the Company's health benefit plans, shall cease on the last day of the calendar month during which the Termination Date occurs, except to the extent Executive elects to and is eligible to receive continued healthcare coverage pursuant to the provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("*COBRA*"), for herself and any covered dependents. Executive's entitlement to other benefits from the Company, and eligibility to participate in the Company's other benefit plans and programs, shall cease on the Termination Date.

(d) Executive shall continue to serve as a consultant to the Company following the Termination Date pursuant to the terms and conditions of the Consulting Agreement attached hereto as Exhibit A (the "*Consulting Agreement*").

3. Termination Benefits. In consideration for Executive's agreement to be bound by the terms of this Agreement, including but not limited to the release of claims in Section 4, but subject to Executive's compliance with Section 5, including Section 5(d) regarding the return of Company property, the Company agrees to provide Executive with the following termination benefits (the "*Termination Benefits*"):

(a) Continued payment of Executive's base salary at the rate in effect on the Termination Date for a period of twelve (12) months following the Termination Date, in accordance with the Company's then-current payroll policies and practices. The Termination Benefits under this clause (a) shall commence with the first payroll period following the Effective Date (the "***Payment Date***"), and the first payment shall include all accrued amounts from the Termination Date, provided that if the period during which Executive may deliver the release required hereunder spans two (2) calendar years, the Payment Date shall be no earlier than January 1, 2021 and in all events all payments under this clause (a) will be paid to Executive prior to December 31, 2021;

(b) Payment of an incentive bonus amount of $276,676, payable on the Payment Date, but in no event more than sixty (60) days following the Termination Date;

(c) Executive holds shares of Parent's common stock consisting of a portion of the Restricted Shares, the Anti-Dilution Shares and the Additional Shares (each as defined in the Offer Letter) (the "***Existing Equity***") originally issued to Executive pursuant to certain stock issuance or restricted stock purchase agreements, and, in the case of a portion of the Existing Equity, subjected to vesting as set forth in the Offer Letter (collectively, the "***Restricted Stock Agreements***"). As of the Termination Date, a portion of the shares of the Existing Equity remain unvested and subject to forfeiture restrictions under the Restricted Stock Agreements (the "***Restricted Stock***"). Effective as of the Effective Date, the vesting of such number of shares of Restricted Stock as would have vested during the eighteen (18) month period following the Termination Date in accordance with the Restricted Stock Agreements shall vest on an accelerated basis (the "***Accelerated Equity***"). Other than the Accelerated Equity, Executive hereby agrees and acknowledges that, notwithstanding any provisions in any other agreement between Executive and the Company to the contrary, including the Restricted Stock Agreements and any other equity award agreements between the Company and Executive and all equity plans maintained by Parent, on the Termination Date, all other equity awards held by Executive (including any unvested Restricted Stock not eligible to vest on the Effective Date pursuant to the preceding sentences) and all stock options or

restricted stock units (whether vested or unvested) held by Executive and outstanding as of the Termination Date shall be cancelled, surrendered and forfeited by Executive for no consideration immediately upon the Termination Date;

(d) Provided Executive timely elects and remains eligible for coverage pursuant to COBRA, payment or reimbursement to Executive of an amount equal to the full monthly premium for COBRA continuation coverage under the Company's medical plans as in effect on the Termination Date with respect to the level of coverage in effect for Executive and her eligible dependents as of the Termination Date, on a monthly basis on the first business day of the calendar month next following the calendar month in which the applicable COBRA premiums were paid, with respect to the period from the Termination Date until the earlier of (i) twelve (12) months following such date and (ii) the date Executive becomes eligible for coverage under a subsequent employer's medical plan.

The Termination Benefits shall be the exclusive severance benefits to which Executive is entitled, unless Executive has breached the provisions of this Agreement, in which case Section 5(e) shall apply. Executive understands that Executive will not be entitled to the Termination Benefits under this Agreement if the Effective Date does not occur on or before the date that is sixty (60) days following the Termination Date, or in the event Executive breaches the terms of this Agreement. Executive acknowledges that, other than the compensation set forth in Section 2 above paid to her as provided therein and the Termination Benefits set forth in this Section 3, she has or will have received all wages, accrued but unused vacation or paid time off, and other benefits due her as a result of her employment or service with and termination from the Company.

4. Release.

(a) On behalf of herself, her heirs, executors, administrators, successors and assigns, Executive hereby fully and forever generally releases and discharges Company, its current, former and future parents, subsidiaries, affiliated companies, related entities, employee benefit plans and their fiduciaries, predecessors, successors, officers, directors, shareholders, agents, employees and assigns (collectively, the "***Company Releasees***") from any and all claims, causes of action, and liabilities up through the date of her execution of the Agreement (except with respect to Termination Benefits under this Agreement and any other rights that she has accrued under the employee benefit plans and equity award plans of the Company). The claims subject to this Agreement include, but are not limited to, those relating to Executive's employment with Company and/or any predecessor to Company and the termination of such employment. All such claims (including related attorneys' fees and costs) are barred without regard to whether those claims are based on any alleged breach of a duty arising in statute, contract or tort. This expressly includes waiver and release of any rights and claims arising under any and all laws, rules, regulations and ordinances, including, but not limited to: Title VII of the Civil Rights Act of 1964; the Older Workers Benefit Protection Act; the Americans With Disabilities Act; the Age Discrimination in Employment Act; the Fair Labor Standards Act; the National Labor Relations Act; the Family and Medical Leave Act; the Employee Retirement Income Security Act of 1974, as amended ("***ERISA***"); the Workers Adjustment and Retraining Notification Act; the California Fair Employment and Housing Act (if applicable); the provisions of the California Labor Code (if applicable); the Equal Pay Act of 1963; and any similar law of any other state or governmental entity.

(b) The parties agree to apply California law in interpreting the Agreement. Accordingly, Executive further waives any rights under Section 1542 of the Civil Code of the State of California or any similar state statute. Section 1542 states:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY, AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

(c) This Agreement does not extend to, and has no effect upon, (i) any benefits that have previously accrued, and to which Executive has become vested or otherwise entitled to, under any agreement, employee benefit plan, program or policy sponsored or maintained by the Company; (ii) Executive's right to indemnification and/or contribution, advancement or payment of related expenses by the Company under any written indemnification or other agreement between the parties; (iii) Executive's right to continued coverage by the Company's director's and officer's insurance, other insurance policies of the Company, COBRA or any similar state law; (iv) any claims for breach of this Agreement; (v) any claims arising after the date Executive signs this Agreement; (vi) Executive's right to communicate or cooperate with any government agency; and (vii) any other claims which, by law, may not be released.

(d) In understanding the terms of the Agreement and her rights, Executive has been advised to consult with an attorney of her choice prior to executing the Agreement. Executive understands that nothing in the Agreement will prohibit her from exercising legal rights that are, as a matter of law, not subject to waiver, such as: (i) her rights under applicable workers' compensation laws; (ii) her right, if any, to seek state disability or unemployment benefits; (iii) her right to indemnity under California Labor Code section 2802 or other applicable state-law right to indemnity; and (iv) her right to file a charge or complaint with a government agency such as but not limited to the Equal Employment Opportunity Commission, the National Labor Relations Board, the Department of Labor, the California Department of Fair Employment and Housing, or other applicable state agency. Moreover, Executive will continue to be indemnified for my actions taken while employed by the Company to the same extent as other then-current or former directors and officers of the Company under the Company's Certificate of Incorporation and Bylaws and the Indemnification Agreement between her and the Company, if any, and she will continue to be covered by the Company's directors and officers liability insurance policy as in effect from time to time to the same extent as are other then-current or former directors and officers of the Company, each subject to the requirements of the laws of the State of Delaware.

(e) Executive agrees that she has had at least twenty-one (21) calendar days in which to consider whether to execute the Agreement, no one hurried Executive into executing the Agreement during that period and no one coerced Executive into executing the Agreement. Executive understands that the offer of the Termination Benefits and this Agreement will expire on the twenty-second (22nd) calendar day after the Termination Date if Executive has not accepted it by that time. Executive further understands that the Company's obligations under the Agreement will not become effective or enforceable until the eighth (8th) calendar day after the date Executive signs the Agreement provided that Executive has timely delivered it to the Company, and that in the seven (7) day period following the date Executive delivers a signed copy of the Agreement to the Company, Executive understands that Executive may revoke her acceptance of the Agreement. Executive understands that the Termination Benefits will become available to her at such time after the Effective Date as provided in this Agreement.

(f) Executive represents and warrants that she is the sole owner of all claims relating to her employment or service with the Company and/or with any predecessor of the Company and that she has not assigned or transferred any claims relating to her employment or service to any other person or entity. Executive understands and agrees that the Agreement will not be construed at any time as an admission of liability or wrongdoing by either the Company or Executive.

5. Restrictive Covenants.

(a) PIIA. Executive hereby expressly reaffirms her obligations under the Company's Proprietary Information and Inventions Assignment Agreement between Executive and the Company, which is attached hereto as Exhibit B and incorporated herein by reference ("***PIIA***"), and agrees that such obligations shall survive the Termination Date. Notwithstanding any other provision in the PIIA or any other agreement between Executive and the Company, Company Confidential Information shall not include any information that (i) is or becomes generally used in the industry or publicly available through lawful means and absent any wrongful conduct by Executive or others; (ii) any information that was known by Executive or lawfully in Executive's possession prior to Executive's employment with the Company; and (iii) is independently developed or lawfully disclosed to Executive by a third party that is unrelated to the Company and is not bound by obligations of confidentiality to the Company with respect to such information.

(b) For one (1) year following the Termination Date, Executive will not, either directly or through others, solicit or attempt to solicit any employee, independent contractor or consultant of the Company to terminate his or her relationship with the Company in order to become an employee, consultant or independent contractor to or for any other person or entity, or otherwise encourage or solicit any employee of the Company to leave the Company for any reason or to devote less than all of any such employee's efforts to the affairs of the Company.

(c) Executive agrees that Executive will not make any negative or disparaging statements or comments, either as fact or as opinion, about Company, its employees, officers, directors, shareholders, vendors, products or services, business, technologies, market position or performance. The Company agrees that it shall not, and shall cause its directors, executive officers, employees and representatives not to, make any negative or disparaging statements or comments, either as fact or as opinion, about Executive. Nothing in this paragraph will prohibit Executive or the Company from providing truthful information in response to a subpoena or other legal process.

(d) By signing below, Executive represents and warrants that she has returned to the Company all Company documents (and all copies thereof) and other Company property that Executive had in her possession at any time, including but not limited to Company files, notes, drawings, records, business plans and forecasts, financial information, specification, computer-recorded information, tangible property (including, but not limited to, computers, laptops, pagers, etc.), credit cards, entry cards, identification badges and keys and any materials of any kind which contain or embody any proprietary or confidential information of Company (and all reproductions thereof). Executive understands that, even if Executive does not sign this Agreement, she is still bound by any and all confidential/proprietary/trade secret information, non-disclosure and inventions assignment agreement(s) signed by Executive in connection with her employment with Company, or with a predecessor or successor of Company pursuant to the terms of such agreement(s). Executive's compliance with this Section 5(d) shall be a condition to her receipt of the Termination Benefits.

(e) In addition to all other rights and remedies available to the Company under law or in equity, the Company shall be entitled to withhold all Termination Benefits from Executive in the event of her breach of this Section 5 prior to such payment.

(f) Nothing herein shall be construed to prohibit Executive from communicating directly with, cooperating with, or providing information to, any government regulator, including, but not limited to, the U.S. Securities and Exchange Commission, the U.S. Commodity Futures Trading

Commission, or the U.S. Department of Justice. Executive acknowledges that the Company has provided Executive with the following notice of immunity rights in compliance with the requirements of the Defend Trade Secrets Act: (i) Executive shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of proprietary information that is made in confidence to a Federal, State, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law, (ii) Executive shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of proprietary information that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal, and (iii) if Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, Executive may disclose the proprietary information to Executive's attorney and use the proprietary information in the court proceeding, if Executive files any document containing the proprietary information under seal, and does not disclose the proprietary information, except pursuant to court order.

(g) For purposes of this Section 5, the term "***Company***" means not only Parent and Gossamer Services, but also as any company, partnership or entity which, directly or indirectly, controls, is controlled by or is under common control with such entities.

6. Cooperation. As a condition of her receipt of the Termination Benefits, Executive agrees that, upon reasonable notice (after taking into account, to the extent reasonably practicable, her other personal and business commitments) and without the necessity of Company obtaining a subpoena or court order, she will provide reasonable cooperation to Company in connection with any suit, action or proceeding (or any appeal from any suit, action or proceeding), or the decision to commence on behalf of the Company any suit, action or proceeding, any investigation and/or any defense of any claims asserted against the Company or any of the Company's current or former directors, officers, employees, partners, stockholders, agents or representatives of any of the foregoing, and any ongoing or future investigation or dispute or claim of any kind involving the Company that relates to events occurring during my employment as to which she may have relevant information and any other matter for which she was responsible or had knowledge of through the Termination Date. Such cooperation may include, but will not be limited to, providing background information within my knowledge; aiding in the drafting of declarations; executing declarations or similar documents; testifying or otherwise appearing at investigation interviews, depositions, arbitrations or court hearings; and preparing for the above-described or similar activities. Upon the reasonable request of Company, Executive agrees to cooperate with the transition of her job responsibilities following the Termination Date and cooperate in providing information on matters on which she was involved while an employee.

7. Section 409A.

(a) The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from Section 409A ("***Section 409A***") of the Internal Revenue Code of 1986, as amended (the "***Code***"), and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith. For purposes of Section 409A, Executive's right to receive any installment payments pursuant to this Agreement will be treated as a right to receive a series of separate and distinct payments.

(b) The parties acknowledge that the Termination Date will constitute the date of Executive's "separation from service" within the meaning of Section 409A. If, as of the date of her "separation from service" from the Company, Executive is a "specified employee" (within the meaning of Section 409A), then the payment of the Termination Benefits shall be subject to the following provisions:

(i) Each installment of the severance payments that, in accordance with the dates and terms set forth in this Agreement, will in all circumstances, regardless of when the "separation from service" occurs, be paid within the short-term deferral period (as defined in Section 409A) shall be treated as a "short-term deferral" within the meaning of Treasury Regulation Section 1.409A-l(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in this Agreement; and

(ii) Each installment of the severance payments that is not described in clause (iii)(A) above and that would, absent this clause (ii), be paid within the six-month period following Executive's "separation from service" from the Company shall not be paid until the date that is six (6) months and one (1) day after such "separation from service" (or, if earlier, Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six (6) months and one (1) day following Executive's "separation from service" and any subsequent installments, if any, being paid in accordance with the dates and terms set forth in this Agreement; *provided*, *however*, that the preceding provisions of this clause (ii) shall not apply to any installment of severance payments if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-l(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-l(b)(9)(iii) must be paid no later than the last day of Executive's second taxable year following the taxable year in which the "separation from service" occurs.

(iii) The determination of whether and when Executive's "separation from service" from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section l.409A-1(h). Solely for purposes of this paragraph (iv), "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

(c) All reimbursements and in-kind benefits provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during Executive's lifetime (or during a shorter period of time specified in this Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of any eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

(d) Notwithstanding any other provision of this Agreement, the Company makes no representation or warranty and shall have no liability to Executive or to any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A but do not satisfy an exemption from, or the conditions of, that section. If either Executive or the Company reasonably determines that any payment to Executive will violate Section 409A, Executive and the Company agree to use reasonable best efforts to restructure the payment in a manner that is either exempt from or compliant with Section 409A to the extent that the restructuring is consistent with the original economic intent of the parties. Executive and the Company agree to execute any and all amendments to this Agreement (or any other applicable agreement) that are consistent with the original economic intent of the parties and promote compliance with the distribution provisions of Section 409A in an effort to avoid or minimize, to the extent allowable by law, the tax (and any interest or penalties thereon)

associated with Section 409A. If it is determined that a payment to Executive was (or may be) made in violation of Section 409A, the Company will cooperate, to the extent commercially reasonable, with any effort by Executive to mitigate the tax consequences of such violation, including cooperation with Executive's participation in any IRS voluntary compliance program or other correction procedure under Section 409A that may be available to Executive; *provided*, that such correction is consistent with the commercial intent of the parties hereunder; *provided*, *further*, that in no event shall the Company be obligated to incur any material cost in connection with its obligations under this sentence.

8. Section 280G. Notwithstanding anything to the contrary contained in this Agreement, to the extent that any of the payments and benefits provided for under this Agreement or any other agreement or arrangement between the Company and Executive (collectively, the "***Payments***") (a) constitute a "parachute payment" within the meaning of Section 280G of the Code and (b) but for this paragraph, would be subject to the excise tax imposed by Section 4999 of the Code, then the Payments shall be reduced to the extent necessary so that no portion of such Payments retained by Executive shall be subject to excise tax under Section 4999 of the Code; *provided*, *however*, such reduction shall only occur if after taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999, such reduction results in Executive's receipt on an after-tax basis, of the greatest amount of benefits under this Agreement, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code; *provided*, *further*, that this sentence shall not apply if, immediately before the change in ownership or control on which such Payment is contingent or otherwise relates, no stock in the Company is readily tradeable on an established securities market or otherwise (as determined in accordance with Treasury Reg. Section 1.280G-1 Q&A 6). In the event of a determination that such reduction is to take place, reduction shall occur in the following order: first, reduction of cash payments, which shall occur in reverse chronological order such that the cash payment owed on the latest date following the occurrence of the event triggering such excise tax will be the first cash payment to be reduced; second, cancellation of accelerated vesting of equity awards, which shall occur in the reverse order of the date of grant for such stock awards (i.e., the vesting of the most recently granted stock awards will be reduced first); and third, reduction of employee benefits, which shall occur in reverse chronological order such that the benefit owed on the latest date following the occurrence of the event triggering such excise tax will be the first benefit to be reduced. If two or more equity awards are granted on the same date, each award will be reduced on a pro-rata basis. Notwithstanding the foregoing, if any Payments would not be subject to such excise tax if the stockholder approval requirements of Section 280G(b)(5) of the Code are satisfied, subject to Executive's waiver of the rights to such Payments in accordance with Section 280G of the Code with respect to any portion of the Payments that would otherwise be subject to excise tax imposed by Section 4999 of the Code (before giving effect to any reduction in Payments contemplated in the two preceding sentences), the Company shall use its reasonable best efforts to cause such payments to be submitted for such approval prior to the event giving rise to such payments. To the extent the Company submits any payment or benefit payable to Executive under this Agreement or otherwise to the Company's stockholders for approval in accordance with Treasury Reg. Section 1.280G-1 Q&A 7, the foregoing provisions shall not apply following such submission and such payments and benefits will be treated in accordance with the results of such vote, except that any reduction in, or waiver of, such payments or benefits required by such vote will be applied without any application of discretion by Executive and in the order prescribed in the preceding paragraph. In no event shall Executive have any discretion with respect to the ordering of payment reductions. Unless Executive and the Company otherwise agree in writing, any determination required under this paragraph shall be made in writing by the Company's independent public accountants (the "***Accountants***"), whose determination shall be subject to the consent of Executive, which shall not be unreasonably withheld. For purposes of making the calculations required by this paragraph, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may

rely in reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and Executive shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this paragraph. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this paragraph. If the limitation set forth in this paragraph is applied to reduce an amount payable to Executive, and the Internal Revenue Service successfully asserts that, despite the reduction, Executive has nonetheless received payments which are in excess of the maximum amount that could have been paid to Executive without being subjected to any excise tax, then, unless it would be unlawful for the Company to make such a loan or similar extension of credit to Executive, Executive may repay such excess amount to the Company as though such amount constitutes a loan to Executive made at the date of payment of such excess amount, bearing interest at 120% of the applicable federal rate (as determined under Section 1274(d) of the Code in respect of such loan). The parties acknowledge and agree that Executive's termination of employment, and the Termination Benefits payable pursuant to this Agreement, were not undertaken in contemplation or expectation of a change in ownership or control of the Company.

9. Arbitration. To aid in the rapid and economical resolution of any disputes that may arise in the course of the employment relationship, Executive and the Company agree that any and all disputes, claims, or demands in any way arising out of or relating to the terms of this Agreement, Company equity held by Executive, Executive's employment relationship with the Company, or the termination of Executive's employment or service relationship with the Company, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration in San Diego, California, conducted before a single neutral arbitrator selected and administered in accordance with the employment arbitration rules & procedures or then applicable equivalent rules of JAMS (the "***JAMS Rules***") and the Federal Arbitration Act, 9 U.S.C. Sec. 1, et seq. A copy of the JAMS rules may be found on the JAMS website at www.jamsadr.com and will be provided to Executive by the Company upon request. BY AGREEING TO THIS ARBITRATION PROCEDURE, EXECUTIVE AND THE COMPANY WAIVE THE RIGHT TO RESOLVE ANY SUCH DISPUTE, CLAIM OR DEMAND THROUGH A TRIAL BY JURY OR JUDGE OR BY ADMINISTRATIVE PROCEEDING IN ANY JURISDICTION. Executive will have the right to be represented by legal counsel at any arbitration proceeding, at Executive's expense. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall administer and conduct any arbitration in accordance with California law and shall apply substantive and procedural California law to any such dispute, claim or demand, without reference to any conflict-of-law provisions of any jurisdiction. To the extent that the JAMS Rules conflict with California law, California law shall take precedence. The parties agree that the prevailing party in any arbitration shall be entitled to injunctive relief in any court of competent jurisdiction to enforce the arbitration award. Nothing in this Agreement is intended to prevent either Executive or the Company from obtaining injunctive relief (or any other provisional remedy) in any court of competent jurisdiction pursuant to California Code of Civil Procedure Section 1281.8 to prevent irreparable harm (including, without limitation, pending the conclusion of any arbitration). The Company shall pay the arbitrator's fees, arbitration expenses and any other costs unique to the arbitration proceeding (recognizing that each side shall bear its own deposition, witness, expert and attorney's fees and other expenses to the same extent as if the matter were being heard in court); *provided*, *however*, that the arbitrator shall award attorney's fees and costs to the prevailing party, except as prohibited by law.

10. Notices. All notices or other communications required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been duly given when delivered personally or one (1) business day after being sent by a nationally recognized overnight delivery service, charges prepaid. Notices also may be given electronically via PDF and shall be effective on the date transmitted if confirmed within forty-eight (48) hours thereafter by a signed original sent in the manner provided in the preceding sentence. Notice to Executive shall be sent to her most recent residence and personal email address on file with the Company. Notice to the Company shall be sent to its physical address set forth on the first page hereto and addressed to the Chairperson of the Board at the email address provided by the Company for such person.

11. Entire Agreement. This Agreement, the Consulting Agreement and the PIIA, together with the Restricted Stock Agreements to the extent related to the Accelerated Equity (other than any Prior Agreements (as defined in the Offer Letter)) and the other documents referenced herein and therein, constitute the entire agreement and understanding between the parties as to the subject matter herein and supersede all prior or contemporaneous agreements whether written or oral, including, without limitation, the Offer Letter. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision hereof, which will remain in full force and effect. The terms in this Agreement may only be modified in writing and signed by Executive and a member of the Board of Directors of Parent. In the event of any conflict between any of the terms in this Agreement and the terms of any other agreement between Executive and the Company, the terms of this Agreement will control.

12. Severability. Should any provision of the Agreement be determined by an arbitrator, court of competent jurisdiction or government agency to be wholly or partially invalid or unenforceable, the legality, validity and enforceability of the remaining parts, terms or provisions are intended to remain in full force and effect. Specifically, should a court, arbitrator or agency conclude that a particular claim may not be released as a matter of law, it is the intention of the parties that the general release and the waiver of unknown claims above will otherwise remain effective to release any and all other claims. Executive acknowledges that she has obtained sufficient information to intelligently exercise her own judgment regarding the terms of the Agreement before executing the Agreement.

13. Governing Law and Venue. This Agreement will be governed by and construed in accordance with the laws of the United States of America and the State of California applicable to contracts made and to be performed wholly within such State, and without regard to the conflicts of laws principles thereof. Any suit brought hereon shall be brought in the state or federal courts sitting in San Diego County, California, the parties hereby waiving any claim or defense that such forum is not convenient or proper. Each party hereby agrees that any such court shall have in personam jurisdiction over it and consents to service of process in any manner authorized by California law.

14. Non-transferability of Interest. None of the rights of Executive to receive any form of compensation payable pursuant to this Agreement shall be assignable or transferable except through a testamentary disposition or by the laws of descent and distribution upon the death of Executive. Any attempted assignment, transfer, conveyance, or other disposition (other than as aforesaid) of any interest in the rights of Executive to receive any form of compensation to be made by the Company pursuant to this Agreement shall be void.

15. Construction. The language in all parts of this Agreement shall in all cases be construed simply, according to its fair meaning, and not strictly for or against any of the parties hereto. Without limitation, there shall be no presumption against any party on the ground that such party was responsible

for drafting this Agreement or any part thereof. Where the context so requires, the use of the masculine gender shall include the feminine and/or neuter genders and the singular shall include the plural, and vice versa, and the word "person" shall include any corporation, firm, partnership or other form of association.

16. Withholding and Other Deductions. All compensation payable to Executive hereunder shall be subject to such deductions as the Company is from time to time required to make pursuant to law, governmental regulation or order.

17. Knowing and Voluntary. Executive represents and agrees that, prior to signing this Agreement, Executive has had the opportunity to discuss the terms of this Agreement with legal counsel of her choosing. Executive further represents and agrees that she is entering into this Agreement knowingly and voluntarily. Executive affirms that no promise was made to cause her to enter into this Agreement, other than what is promised in this Agreement. Executive further confirms that she has not relied upon any other statement or representation by anyone other than what is in this Agreement as a basis for her agreement. Executive acknowledges and agrees that neither the Company nor the Company's counsel has provided any legal or tax advice to Executive and that Executive is free to, and is hereby advised to, consult with a legal or tax advisor of her choosing.

18. Counterparts. This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one instrument. Execution and delivery of this Agreement by facsimile or other electronic signature is legal, valid and binding for all purposes.

[Signature page follows]

EXECUTIVE'S ACCEPTANCE OF AGREEMENT

BEFORE SIGNING HER NAME TO THIS AGREEMENT, EXECUTIVE STATES THE FOLLOWING: EXECUTIVE HAS READ THE AGREEMENT, SHE UNDERSTANDS IT AND SHE KNOWS THAT SHE IS GIVING UP IMPORTANT RIGHTS. SHE HAS OBTAINED SUFFICIENT INFORMATION TO INTELLIGENTLY EXERCISE HER OWN JUDGMENT. SHE HAS BEEN ADVISED THAT SHE SHOULD CONSULT WITH AN ATTORNEY BEFORE SIGNING IT, AND SHE HAS SIGNED THE AGREEMENT KNOWINGLY AND VOLUNTARILY.

Executed this 17 day of November, 2020.

/s/ Sheila Gujrathi
Sheila Gujrathi, M.D.

Agreed and Accepted:

Gossamer Bio Services, Inc.

/s/ Christian Waage
By: Christian Waage
Title: Secretary
Date: November 17, 2020

Gossamer Bio, Inc.

/s/ Christian Waage
By: Christian Waage
Title: Secretary
Date: November 17, 2020

Exhibit A

Consulting Agreement

Exhibit B

Proprietary Information and Inventions Assignment Agreement

Exhibit 10.11

Gossamer Bio, Inc.
Gossamer Bio Services, Inc.

November 16, 2020

Faheem Hasnain
c/o Gossamer Bio, Inc.
3013 Science Park Road
San Diego, CA 92121

Dear Mr. Hasnain:

The purpose of this letter agreement (this "Agreement") is to memorialize the terms and conditions of your employment as President and Chief Executive Officer of Gossamer Bio, Inc. ("Parent") and continued service as Chairman of the Board of Directors (the "Board") of Parent. Effective as of November 16, 2020 (the "Effective Date"), you will be employed by Gossamer Bio Services, Inc. ("Gossamer Services", a wholly-owned subsidiary of Parent, and together with Parent, collectively the "Company"), on a full-time basis, as its President and Chief Executive Officer and to serve as an officer with those same positions of Parent, working out of the Company's headquarters located in San Diego, California. You shall have all the duties, responsibilities and authority commensurate with these positions, subject to the supervision of, and reporting directly to, the Board. This Agreement supersedes and replaces that certain letter agreement dated June 3, 2019, between you and the Company (the "Original Letter"). The Original Letter, in turn, superseded and replaced that certain offer letter dated January 4, 2018 between you and the Company (the "Offer Letter").

1. Duties.

(a) Employment Duties. During the term of your employment as President and Chief Executive Officer under this Agreement (the "Employment Period"), you agree to perform the duties and responsibilities of your positions, and such other duties and responsibilities as shall from time to time be mutually agreed upon between you and the Board. You agree to abide by the rules, regulations, instructions, personnel practices and policies of the Company, as adopted and amended from time to time by the Company.

(b) Service as Chairman of the Board. You shall continue to serve as Chairman of the Board until the earlier of your resignation, removal from the Board or death, or your successor as Chairman of the Board is duly appointed by the Board; *provided, however*, nothing contained herein shall adversely affect your rights to be elected to the Board by the stockholders of Parent pursuant to Parent's bylaws and applicable law. The termination of the Employment Period will not affect your service as Chairman of the Board or otherwise as a member of the Board. For the avoidance of doubt, all references in this Agreement to your "service with the company" or "employment with the Company", shall include your employment or service with the Company and any of its affiliates and subsidiaries, as applicable.

(c) Outside Activities. You agree that, during the Employment Period, you will devote substantially all of your business time and your best efforts, business judgment, skill and knowledge exclusively to the advancement of the business and interests of the Company and to the discharge of your duties and responsibilities for it; *provided*, *however*, it is agreed that you may (i) serve on outside boards on which you serve as of the Effective Date or as otherwise approved by the Board following the Effective Date, (ii) serve on the boards of directors of non-profit organizations on which you serve as of the Effective Date or as otherwise approved by the Board following the Effective Date, (iii) participate in charitable, civic, educational, professional, community or industry affairs, and (iv) manage your personal investments to the extent such activities do not individually or in the aggregate interfere with your duties and responsibilities to the Company or create an actual or potential conflict of interest with the Company's business.

(d) Company Support During Board Service. Following the termination of the Employment Period, during the term of your services as Chairman of the Board, the Company will provide you with work space at the Company's offices and such technical and administrative support as you require (by Lisa Evans). You will also retain your Company email address for so long as you continue to serve as Chairman of the Board, notwithstanding any termination of your employment.

2. Terms of Employment.

(a) At-Will Employment. This Agreement shall not be construed as an agreement, either express or implied, to employ you for any stated term, and shall in no way alter the Company's policy of employment at-will, under which both the Company and you remain free to end the employment relationship for any reason, at any time, with or without Cause (as defined below) or notice. Although your job duties, title, compensation and benefits, as well as the Company's personnel policies and procedures, may change from time to time, the "at-will" nature of your employment may only be changed by a written agreement signed by you and a member of the Board, which expressly states the intention to modify the at-will nature of your employment. Similarly, nothing in this Agreement shall be construed as an agreement, either express or implied, to pay you any compensation or grant you any benefit beyond the end of your employment with the Company, except as otherwise explicitly set forth herein.

(b) Compensation During Employment Period. During the Employment Period:

(i) You will receive an annual base salary of $572,000, payable in accordance with the normal payroll practices of the Company in effect from time to time. Your performance will be reviewed by the Compensation Committee of the Board on an annual basis in conjunction with an annual salary review.

(ii) You will be eligible to receive an annual cash incentive bonus with a target amount equal to 55% of your then-current annual base salary (the "Target Bonus"). Your bonus will be subject to the terms of the applicable bonus plan developed and approved by the Board or the Compensation Committee of the Board in consultation with you. Any bonus awarded will be paid on or before March 15 of the calendar year immediately following the year for which the bonus was awarded, subject to your employment at the end of the calendar year for which the bonus is due, except as otherwise expressly provided for herein. Your annual bonus will be pro-rated for any partial year of service as President and Chief Executive Officer.

(iii) You will be eligible to participate in any and all benefit programs that the Company establishes and makes available to its employees from time to, time, provided that you are eligible under (and subject to all provisions of) the plan documents that govern those programs. Benefits are subject to change at any time in the Company's sole discretion. You will be entitled to paid time off in accordance with the policies of the Company.

(iv) The Company will reimburse you for all reasonable business expenses incurred by you in the performance of your duties, subject to the Company's expense reimbursement policies applicable to senior executives in effect from time to time.

3. Director Compensation.

(a) Cessation of Director Compensation During Employment Period. During the Employment Period, you will not be compensated for your service as Chairman of the Board in accordance with the Company's policy for non-employee members of the Board (the "Director Compensation Policy"), including the cash compensation and equity awards to be provided thereunder. Following the termination of the Employment Period, for so long as you remain on the Board, you will again be compensated under the Director Compensation Policy in accordance with its terms in effect at such time. You and the Company acknowledge and agree that the compensation payable to you under Section 2 of this Agreement and any equity awards granted to you during the Employment Period are solely for your services as an employee and not for your service as a member of the Board.

(b) COBRA Coverage Following Termination. In addition, to the extent you do not receive the Severance Benefits or the Change in Control Severance Benefits in connection with your termination of employment, for the period beginning on the date of your termination of employment and ending on June 30, 2022 (or, if earlier, (i) the date on which your service with the Company terminates or (ii) the date you become eligible to receive the equivalent or increased healthcare coverage by means of subsequent employment or self-employment) (the "Coverage Period"), the Company shall arrange to provide you and/or your eligible dependents who were covered under the Company's health insurance plans as of the last day of the Employment Period with comparable health (including medical and dental) insurance benefits to those provided to you and your dependents immediately prior to the last day of the Employment Period, which continuation coverage shall be provided, to the extent possible, under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA") or Cal-COBRA, if applicable). During the Coverage Period, the Company shall pay (A) the premiums for such coverage less (B) the amount you would have had to pay to receive group health coverage for yourself and your dependents based on the cost sharing levels in effect for executive employees of the Company during the Coverage Period. If the Company is not reasonably able to continue health insurance benefits coverage under the Company's insurance plans or if such coverage would violate applicable law or result in adverse tax consequences for you or the Company, the Company shall instead pay to you the foregoing monthly amount as a taxable monthly payment for the Coverage Period (or any remaining portion thereof). You shall notify the Company immediately if you become eligible to receive the equivalent or increased healthcare coverage by means of subsequent employment or self-employment.

4. Equity.

(a) Existing Equity. As of the Effective Date, you and/or your family trust hold shares of Parent's common stock ("Common Stock"), originally issued pursuant to certain stock issuance agreements or restricted stock purchase agreements (the "Existing Equity"), and, in the case of a portion of the Existing Equity, subjected to vesting as set forth in the Offer Letter (collectively, the "Restricted Stock Agreements"). As of the Effective Date, a portion of the shares of the Existing Equity remains unvested and subject to repurchase or forfeiture restrictions under the Restricted Stock Agreements (the "Restricted Shares"). You have also been granted stock options to purchase shares of Parent Common Stock in your capacity as an employee and as a member of the Board pursuant to the stock option agreements pursuant to which such stock options were issued (the "Stock Option Agreements"). The Restricted Stock Agreements and the Stock Option Agreement are referred to collectively herein as the "Equity Agreements."

(b) Equity Awards During Employment Period. You may be awarded one or more equity awards for your employment service under this Agreement to be determined and granted to you by the Compensation Committee of the Board as soon as reasonably practicable following the Effective Date.

(c) Continued Vesting; No Break in Service. There will be no break in service under the Equity Agreements as a result of the transition occurring on the Effective Date, and you will retain all right, title and interest you have in any Restricted Shares and the Stock Options granted to you by the Company prior to the Effective Date. All equity awards previously granted to you in connection with your service as an employee or as a member of the Board, and any equity awards granted to you during the Employment Period, will continue to vest based on your employment and/or your service on the Board (including any such Board service after any termination of your employment), and will be eligible for accelerated vesting as provided in Section 5(c) below. You and the Company hereby agree that, notwithstanding any provisions in the Equity Agreements or any other agreement between you and the Company to the contrary, (i) all of your Restricted Shares and Stock Options shall continue to vest, and the exercisability of such Stock Options shall continue, in accordance with the vesting schedules provided in the Equity Agreements, subject to and based on your continued service as an employee or a member of the Board, and (ii) the accelerated vesting provisions applicable to such Restricted Shares and Stock Options shall be as provided in this Agreement, including without limitation, any defined terms related thereto. The Equity Agreements are hereby amended to be consistent with the foregoing, including all references therein to your "termination of employment" therein which are hereby amended to be references to your "Termination of Service" as defined in the Equity Plan.

5. Termination Payments.

(a) Termination of Employment Period. Upon the termination of the Employment Period for any reason, you will receive your accrued but unpaid base salary and all accrued but unused paid time off through the last day of your employment, in accordance with the Company's then-current payroll policies and practices (the "Termination Payment"). The Company shall promptly reimburse you for all reasonable and properly incurred out-of-pocket business expenses that are submitted by you in accordance with the Company's policies. Except as provided in this Agreement, your entitlement to benefits from the Company, and eligibility to participate in the Company's benefit plans, shall cease on the last day of your employment, except to the extent provided in this Agreement or you elect to and are eligible to receive

continued healthcare coverage pursuant to COBRA, for yourself and any covered dependents, in accordance with the provisions of COBRA.

(b) Severance.

(i) Without otherwise limiting the "at-will" nature of your employment, in the event at any time during the Employment Period your employment is terminated at any time by the Company (or any of its subsidiaries or affiliates, as applicable, or any of their respective successors or assigns) without Cause (excluding by reason of your death and Disability (as defined below)) or by you for Good Reason (as defined below), in each case prior to a Change in Control (as defined below) or more than twelve (12) months following a Change in Control, then, in addition to the Termination Payment and any Acceleration Benefits set forth in Section 5(c) below, the Company shall provide the following payments and benefits ("Severance Benefits"): (i) continued payment of your base salary at the then-current rate per pay period for a period of twelve (12) months following your termination date, in accordance with the Company's then-current payroll policies and practices, (ii) payment of your Target Bonus pro-rated for the portion of the then-current calendar year during which you were employed by the Company, on the Payment Date (as defined below) (but in all events within sixty (60) days following the last day of your employment), and (iii) provided you timely elect and remain eligible for coverage pursuant to COBRA, payment or reimbursement to you of an amount equal to the full monthly premium for COBRA continuation coverage under the Company's medical plans as in effect on the date of your termination with respect to the level of coverage in effect for you and your eligible dependents as of the date of your termination, on a monthly basis on the first business day of the calendar month next following the calendar month in which the applicable COBRA premiums were paid, with respect to the period from the date of your termination until the earlier of (x) twelve (12) months following such date and (y) the date you become eligible for coverage under a subsequent employer's medical plan.

(ii) In the event at any time during the Employment Period your employment is terminated at any time by the Company (or any of its subsidiaries or affiliates, as applicable, or any of their respective successors or assigns) without Cause (excluding by reason of your death and Disability) or by you for Good Reason, in each case on or within twelve (12) months after a Change in Control, then, in addition to the Termination Payment and any Acceleration Benefits set forth in Section 5(c) below, the Company shall provide the following payments and benefits ("Change in Control Severance Benefits"): (i) continued payment of your base salary at the then-current rate per pay period for a period of eighteen (18) months following your termination date, in accordance with the Company's then-current payroll policies and practices, (ii) payment of your Target Bonus for the calendar year during which your date of termination occurs, on the Payment Date (but in all events within sixty (60) days following the last day of your employment), and (iii) provided you timely elect and remain eligible for coverage pursuant to COBRA, payment or reimbursement to you of an amount equal to the full monthly premium for COBRA continuation coverage under the Company's medical plans as in effect on the date of your termination with respect to the level of coverage in effect for you and your eligible dependents as of the date of your termination, on a monthly basis on the first business day of the calendar month next following the calendar month in which the applicable COBRA premiums were paid, with respect to the period from the date of your termination until the earlier of (x) eighteen (18) months following such date and (y) the date you become eligible for coverage under a subsequent employer's medical plan. Notwithstanding anything to the contrary and for

the avoidance of doubt, any Change in Control Severance Benefits paid to you shall be instead of, and not in addition to, any Severance Benefits that may be paid to you.

(iii) The Termination Benefits payable under this Section 5(b) shall be paid or commence on the first payroll period following the date the Release becomes effective (the "Payment Date") and the first payment shall include all accrued amounts from the date of termination, provided that if the period during which you may deliver the Release required hereunder spans two (2) calendar years, the Payment Date shall be no earlier than January 1 of the second calendar year.

(c) Acceleration Provisions.

(i) In the event (A) during the Employment Period, your employment is terminated by the Company (or any of its subsidiaries or affiliates, as applicable, or any of their respective successors or assigns) without Cause or you resign for Good Reason, or (B) at any time your service on the Board is terminated without Cause or you resign from the Board for Good Reason (in the case of clauses (A) and (B), excluding by reason of your death and Disability), in each case under clauses (A) and (B) prior to a Change in Control, then the vesting of any Restricted Shares and Stock Options and any other equity awards issued to you during the Employment Period and then held by you shall be accelerated for twelve (12) months of additional vesting from the date of such termination; *provided*, *however*, that this clause (i) shall not apply if your employment is terminated under the circumstances described in clause (A) but you continue to serve as Chairman or Executive Chairman of the Board and the circumstances in clause (B) do not apply.

(ii) In the event (A) during the Employment Period, your employment is terminated by the Company (or any of its subsidiaries or affiliates, as applicable, or any of their respective successors or assigns) without Cause or you resign for Good Reason, or (B) at any time your service on the Board is terminated without Cause or you resign from the Board for Good Reason (in the case of clauses (A) and (B), excluding by reason of your death and Disability), in each case under clauses (A) and (B) on or within twelve (12) months after a Change in Control, then you shall be entitled to full vesting of any unvested portion of the Restricted Shares and Stock Options and any other equity awards issued to you during the Employment Period and then held by you, which shall no longer be subject to any restrictions or forfeiture on the date of such termination; *provided*, *however*, that this clause (ii) shall not apply if your employment is terminated under the circumstances described in clause (A) but you continue to serve as Chairman or Executive Chairman of the Board and the circumstances in clause (B) do not apply.

(iii) In the event (A) of your death, (B) during the Employment Period, your employment is terminated by reason of your Disability, or (C) at any time, your service on the Board is terminated by reason of your Disability, then the Company shall provide that the greater of (i) fifty percent (50%) of the unvested portion of the Restricted Shares and Stock Options and any other equity awards issued to you during the Employment Period and then held by you immediately prior to such termination and (ii) the portion of such Restricted Shares and Stock Options and any other equity awards issued to you during the Employment Period and then held by you that would have otherwise vested in the twelve (12) month period following the date of such termination, shall vest and shall no longer be subject to any restrictions or forfeiture on the date of such termination.

(iv) In the event that the Director Compensation Policy or any of the agreements governing your equity awards granted to you for your service on the Board on or after June 3, 2019 provide for more favorable vesting than provided in this Section 5(c), such more favorable vesting shall continue to apply.

(v) The benefits described in this Section 5(c) are referred to herein as the "Acceleration Benefits."

(d) Release. Notwithstanding anything to the contrary in the foregoing, you will not be entitled to receive any Severance Benefits, Change in Control Severance Benefits or the Acceleration Benefits (to the extent applicable, the "Termination Benefits") unless, within sixty (60) days following the date of termination, you, or in the event of your death or Disability, your legal representatives, have executed a general release of all known and unknown claims and covenant not to sue in the form attached hereto as Exhibit A (with such changes to such form to help ensure enforceability under applicable law) (the "Release") and any revocation period thereunder has lapsed without exercise by you (or your legal representatives) of such revocation right.

(e) Defined Terms.

(i) For purposes of this Agreement, "Change in Control" shall have the meaning set forth in the Gossamer Bio, Inc. 2019 Incentive Award Plan, as in effect on the Effective Date (the "Equity Plan").

(ii) As used herein, "Cause" means: (A) a willful and material act of dishonesty by you in connection with the performance of your duties as a member of the Board or, during the Employment Period, as President and Chief Executive Officer; (B) your conviction of, or plea of guilty or nolo contendere to, a felony (other than a traffic offense that does not result in a fatality), or any crime involving fraud or embezzlement that the Board reasonably determines has had or is reasonably likely to have a materially detrimental effect on the Company's reputation or business; (C) your gross misconduct in the performance of your duties as a member of the Board or, during the Employment Period, as President and Chief Executive Officer; (D) your willful and material unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party to whom you owe an obligation of nondisclosure as a result of your relationship with the Company; (E) your willful and material breach of any obligations under any written agreement or written covenant with the Company; or (F) your continued willful and substantial failure to perform your duties as a member of the Board or, during the Employment Period, your material employment duties that are lawfully assigned to you in good faith by the Board (other than as a result of your death or Disability) after written notice. Cause shall not exist unless, in any case, you have first received a written notice from the Board that sets forth the factual basis for the Board's determination as to any behavior or occurrence claimed as Cause and you fail to cure such claimed behavior or occurrence, if curable, to the reasonable satisfaction of a majority of the Board within ten (10) business days after receiving such written notice, in which case your termination date will be the expiration date of the cure period, if any. For purposes of this definition of Cause, (i) no act or failure to act on your part shall be considered "willful" unless it is done or omitted to be done by you in bad faith and without reasonable belief that the act or failure to act was in the best interest of the Company, and

(ii) while you are serving on the Board, you shall take no part in any determination as to whether "Cause" exists hereunder.

(iii) As used herein, "Good Reason" means the occurrence of one or more of the following, without your written consent: (A) during the Employment Period, (1) a material reduction in your base salary or target annual bonus; (2) a material diminution of your title, duties, responsibilities or reporting lines; or (3) a material change in the principal geographic location at which you must perform services, more than fifty (50) miles from the Company's head office; *provided*, *however*, that, prior to a Change in Control, an event occurring under this clause (A) in connection with your cessation of service as President and Chief Executive Officer will not constitute Good Reason under this clause (A) if you remain serving as Chairman of the Board or Executive Chairman following such transition and neither clause (B) nor clause (C) of this definition of Good Reason is not triggered as a result of such transition; or (B) at any time, your involuntary removal from the Board or the failure of the stockholders to reelect you to the Board, other than for Cause; or (C) at any time, a material breach by the Company of this Agreement. Any such event shall not constitute Good Reason unless and until you have provided the Company with written notice thereof no later than sixty (60) days following the initial occurrence of such event and the Company shall have failed to remedy such event (if capable of being remedied) within thirty (30) days of receipt of such notice, and you must terminate your employment or service on the Board within sixty (60) days after the expiration of such thirty (30)-day remedial period.

(iv) As used herein, "Disability" shall have the meaning set forth in the Equity Plan.

(f) Section 409A. The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from Section 409A of the Internal Revenue Code and the regulations and guidance promulgated thereunder (collectively, "Section 409A") and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith.

(i) Any severance payments to you under Section 5(b) of this Agreement shall begin only after the date of your "separation from service" within the meaning of Section 409A and determined as set forth below, which occurs on or after date of the termination of your employment, and shall be subject to the following provisions:

(A) The intent of the parties is that payments and benefits under this Agreement comply with, or be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement shall be interpreted to be in compliance therewith. For purposes of Section 409A, your right to receive any installment payments pursuant to this Agreement will be treated as a right to receive a series of separate and distinct payments. Neither the Company nor you shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.

(B) If, as of the date of your "separation from service" from the Company, you are not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in this Agreement.

(C) If, as of the date of your "separation from service" from the Company, you are a "specified employee" (within the meaning of Section 409A), then:

(1) Each installment of the severance payments that, in accordance with the dates and terms set forth in this Agreement, will in all circumstances, regardless of when the "separation from service" occurs, be paid within the short-term deferral period (as defined in Section 409A) shall be treated as a "short-term deferral" within the meaning of Treasury Regulation Section 1.409A-l(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in this Agreement; and

(2) Each installment of the severance payments that is not described in clause (C)(1) above and that would, absent this clause (2), be paid within the six-month period following your "separation from service" from the Company shall not be paid until the date that is six (6) months and one (1) day after such "separation from service" (or, if earlier, your death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six (6) months and one (1) day following your "separation from service" and any subsequent installments, if any, being paid in accordance with the dates and terms set forth in this Agreement; *provided*, *however*, that the preceding provisions of this clause (2) shall not apply to any installment of severance payments if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-l(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-l(b)(9)(iii) must be paid no later than the last day of your second taxable year following the taxable year in which the "separation from service" occurs.

(D) The determination of whether and when your "separation from service" from the Company has occurred shall be made in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section l.409A-1(h). Solely for purposes of this paragraph (D), "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

(E) All reimbursements and in-kind benefits provided under the Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (1) any reimbursement is for expenses incurred during your lifetime (or during a shorter period of time specified in this Agreement), (2) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (3) the reimbursement of any eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred, and (4) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

(F) Notwithstanding any other provision of this Agreement, the Company makes no representation or warranty and shall have no liability to you or to any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A but do not satisfy an exemption from, or the conditions of, that section. If either you or the Company reasonably determines that any payment to you will violate Section 409A, you and the Company agree to use reasonable best efforts to restructure the

payment in a manner that is either exempt from or compliant with Section 409A to the extent that the restructuring is consistent with the original economic intent of the parties. You and the Company agree to execute any and all amendments to this Agreement (or any other applicable agreement) that are consistent with the original economic intent of the parties and promote compliance with the distribution provisions of Section 409A in an effort to avoid or minimize, to the extent allowable by law, the tax (and any interest or penalties thereon) associated with Section 409A. If it is determined that a payment to you was (or may be) made in violation of Section 409A, the Company will cooperate, to the extent commercially reasonable, with any effort by you to mitigate the tax consequences of such violation, including cooperation with your participation in any IRS voluntary compliance program or other correction procedure under Section 409A that may be available to you; *provided*, that such correction is consistent with the commercial intent of the parties hereunder; *provided*, *further*, that in no event shall the Company be obligated to incur any material cost in connection with its obligations under this sentence.

(G) Notwithstanding the foregoing, if a Change in Control would give rise to a payment or settlement event with respect to any payment or benefit that constitutes "nonqualified deferred compensation," the transaction or event constituting the Change in Control must also constitute a "change in control event" (as defined in Treasury Regulation §1.409A-3(i)(5)) in order to give rise to the payment or settlement event for such payment or benefit, to the extent required by Section 409A.

6. Section 280G of the Code.

(a) Best Pay Provision. Notwithstanding anything to the contrary contained in this Agreement, to the extent that any of the payments and benefits provided for under this Agreement or any other agreement or arrangement between the Company and you (collectively, the "Payments") (i) constitute a "parachute payment" within the meaning of Section 280G of the Code and (ii) but for this Section 6, would be subject to the excise tax imposed by Section 4999 of the Code, then the Payments shall be reduced to the extent necessary so that no portion of such Payments retained by you shall be subject to excise tax under Section 4999 of the Code; *provided*, *however*, such reduction shall only occur if after taking into account the applicable federal, state and local income taxes and the excise tax imposed by Section 4999 of the Code, such reduction results in your receipt on an after-tax basis, of the greatest amount of benefits under this Agreement, notwithstanding that all or some portion of such benefits may be taxable under Section 4999 of the Code; *provided*, *further*, that this sentence shall not apply if, immediately before the change in ownership or control on which such Payment is contingent or otherwise relates, no stock in the Company is readily tradeable on an established securities market or otherwise (as determined in accordance with Treasury Reg. Section 1.280G-1 Q&A 6). In the event of a determination that such reduction is to take place, reduction shall occur in the following order: first, reduction of cash payments, which shall occur in reverse chronological order such that the cash payment owed on the latest date following the occurrence of the event triggering such excise tax will be the first cash payment to be reduced; second, cancellation of accelerated vesting of equity awards, which shall occur in the reverse order of the date of grant for such stock awards (i.e., the vesting of the most recently granted stock awards will be reduced first); and third, reduction of employee benefits, which shall occur in reverse chronological order such that the benefit owed on the latest date following the occurrence of the event triggering such excise tax will be the first benefit to be reduced. If two or more equity awards are granted on the same date, each award will be reduced on a pro-rata basis.

(b) Calculations. Unless you and the Company otherwise agree in writing, any determination required under this Section 6 shall be made in writing by the Company's independent public accountants immediately preceding the change in ownership or control on which such Payments are contingent or otherwise relate (the "Accountants"), whose determination shall be conclusive and binding upon you and the Company for all purposes. For purposes of making the calculations required by this Section 6, the Accountants may make reasonable assumptions and approximations concerning applicable taxes and may rely in reasonable, good faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Company and you shall furnish to the Accountants such information and documents as the Accountants may reasonably request in order to make a determination under this Section 6. The Company shall bear all costs the Accountants may reasonably incur in connection with any calculations contemplated by this Section 6. If the limitation set forth in this Section 6 is applied to reduce an amount payable to you, and the Internal Revenue Service successfully asserts that, despite the reduction, you have nonetheless received payments which are in excess of the maximum amount that could have been paid to you without being subjected to any excise tax, then, unless it would be unlawful for the Company to make such a loan or similar extension of credit to you, you may repay such excess amount to the Company as though such amount constitutes a loan to you made at the date of payment of such excess amount, bearing interest at 120% of the applicable federal rate (as determined under Section 1274(d) of the Code in respect of such loan).

7. Restrictive Covenants.

(a) No Other Agreements. You represent that you are not bound by any employment contract, restrictive covenant or other restriction preventing you from entering into employment with or carrying out your responsibilities for the Company or which is in any way inconsistent with the terms of this Agreement.

(b) PIIA. You have previously executed the Company's Proprietary Information and Inventions Assignment Agreement, which is attached hereto as Exhibit B ("PIIA"), and agree that you shall continue to be bound by the terms and conditions of the PIIA. Notwithstanding any other provision in the PIIA or any other agreement between you and the Company, Company Confidential Information shall not include any information that (i) is or becomes generally used in the industry or publicly available through lawful means and absent any wrongful conduct by you or others; (ii) any information that was known by you or lawfully in your possession prior to your employment with the Company; and (iii) is independently developed or lawfully disclosed to you by a third party that is unrelated to the Company and is not bound by obligations of confidentiality to the Company with respect to such information.

(c) Defend Trade Secrets Act Notice of Immunity Rights. You acknowledge that the Company has provided you with the following notice of immunity rights in compliance with the requirements of the Defend Trade Secrets Act: (i) you shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of Confidential Information (as defined in the PIIA) that is made in confidence to a Federal, State, or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law; (ii) you shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of Confidential Information that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; and (iii) if you file a lawsuit for retaliation by the Company for reporting a suspected violation of law,

you may disclose the Confidential Information to your attorney and use the Confidential Information in the court proceeding, if you file any document containing the Confidential Information under seal, and do not disclose the Confidential Information, except pursuant to court order.

8. Governing Law. This Agreement will be governed by the laws of the State of California, without reference to conflicts of laws principles which would result in the application of the law of any other jurisdiction.

9. Notices. All notices or other communications required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been duly given when delivered personally or one (1) business day after being sent by a nationally recognized overnight delivery service, charges prepaid. Notices also may be given electronically via PDF and shall be effective on the date transmitted if confirmed within 48 hours thereafter by a signed original sent in the manner provided in the preceding sentence. Notice to you shall be sent to your most recent residence and personal email address on file with the Company. Notice to the Company shall be sent to its physical address set forth on the first page hereto and addressed to the General Counsel of Parent, with a copy to the Chairman of the Compensation Committee of the Board, at the email address provided by the Company for such person.

10. Entire Agreement; Miscellaneous. This Agreement, together with any documents relating to the Company equity held by you, any stock grant notices or stock agreements referenced herein and the PIIA, including the Equity Agreements, constitutes the entire agreement and understanding between the parties as to the subject matter herein and supersedes all prior or contemporaneous agreements whether written or oral, including, without limitation, the Original Letter. The terms of this Agreement may only be modified in a specific writing signed by you and an authorized representative of the Company. The invalidity or unenforceability of any provision or provisions of this Agreement will not affect the validity or enforceability of any other provision hereof, which will remain in full force and effect. The terms in this Agreement may only be modified in writing and signed by you and a member of the Board. In the event of any conflict between any of the terms in this Agreement and the terms of any other agreement between you and the Company, the terms of this Agreement will control. This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one instrument. Execution and delivery of this Agreement by facsimile or other electronic signature is legal, valid and binding for all purposes. This Agreement is intended to bind and inure to the benefit of and be enforceable by you and the Company, and their respective successors, assigns, heirs, executors and administrators, except that you may not assign any of your duties hereunder and you may not assign any of your rights hereunder, without the written consent of the Company, which shall not be withheld unreasonably.

11. Arbitration. To aid in the rapid and economical resolution of any disputes that may arise in the course of the employment relationship, you and the Company agree that any and all disputes, claims, or demands in any way arising out of or relating to the terms of this Agreement, Company equity held by you (including, but not limited to, the Existing Equity), your employment or service relationship with the Company, or the termination of your relationship with the Company, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration in San Diego, California, conducted before a single neutral arbitrator selected and administered in accordance with the employment arbitration rules & procedures or then applicable equivalent rules of JAMS (the "JAMS Rules") and the Federal Arbitration Act, 9

U.S.C. Sec. 1, et seq. A copy of the JAMS rules may be found on the JAMS website at www.jamsadr.com and will be provided to you by the Company upon request. BY AGREEING TO THIS ARBITRATION PROCEDURE, YOU AND THE COMPANY WAIVE THE RIGHT TO RESOLVE ANY SUCH DISPUTE, CLAIM OR DEMAND THROUGH A TRIAL BY JURY OR JUDGE OR BY ADMINISTRATIVE PROCEEDING IN ANY JURISDICTION. You will have the right to be represented by legal counsel at any arbitration proceeding, at your expense. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall administer and conduct any arbitration in accordance with California law and shall apply substantive and procedural California law to any such dispute, claim or demand, without reference to any conflict-of-law provisions of any jurisdiction. To the extent that the JAMS Rules conflict with California law, California law shall take precedence. The parties agree that the prevailing party in any arbitration shall be entitled to injunctive relief in any court of competent jurisdiction to enforce the arbitration award. Nothing in this Agreement is intended to prevent either you or the Company from obtaining injunctive relief (or any other provisional remedy) in any court of competent jurisdiction pursuant to California Code of Civil Procedure Section 1281.8 to prevent irreparable harm (including, without limitation, pending the conclusion of any arbitration). The Company shall pay the arbitrator's fees, arbitration expenses and any other costs unique to the arbitration proceeding (recognizing that each side shall bear its own deposition, witness, expert and attorney's fees and other expenses to the same extent as if the matter were being heard in court).

12. Withholding and Other Deductions. All compensation payable to you hereunder shall be subject to such deductions as the Company is from time to time required to make pursuant to law, governmental regulation or order.

[Signature Page Follows] Please acknowledge your acceptance of the foregoing terms and conditions by returning a signed copy of this Agreement.

Very truly yours,

Gossamer Bio Services, Inc.

By: /s/ Christian Waage

Gossamer Bio, Inc.

By: /s/ Christian Waage

Accepted and agreed:

I have read and understood this Agreement and hereby acknowledge, accept and agree to the terms as set forth above.

/s/ Faheem Hasnain
Faheem Hasnain

Exhibit A

Form of Release

In consideration of the Termination Benefits (as defined in the Agreement) provided and to be provided to me by Gossamer Bio, Inc., Gossamer Bio Services, Inc., or any affiliate or successor thereof (the "Company") pursuant to that certain letter agreement with Company dated November 16, 2020 (the "Agreement"), and in connection with the termination of my employment or service with the Company, the Company and I agree to the following, including a general release as specified below (the "Release").

1. On behalf of myself, my heirs, executors, administrators, successors and assigns, I hereby fully and forever generally release and discharge Company, its current, former and future parents, subsidiaries, affiliated companies, related entities, employee benefit plans and their fiduciaries, predecessors, successors, officers, directors, shareholders, agents, employees and assigns (collectively, the "Company Releasees") from any and all claims, causes of action, and liabilities up through the date of my execution of the Release (except with respect to Termination Benefits under the Agreement and any other rights that I have accrued under the benefit plans and equity award plans of the Company). The claims subject to this release include, but are not limited to, those relating to my employment or service with Company and/or any predecessor to the Company and the termination of such employment or service. All such claims (including related attorneys' fees and costs) are barred without regard to whether those claims are based on any alleged breach of a duty arising in statute, contract or tort. This expressly includes waiver and release of any rights and claims arising under any and all laws, rules, regulations and ordinances, including, but not limited to: Title VII of the Civil Rights Act of 1964; the Older Workers Benefit Protection Act; the Americans With Disabilities Act; the Age Discrimination in Employment Act; the Fair Labor Standards Act; the National Labor Relations Act; the Family and Medical Leave Act; the Employee Retirement Income Security Act of 1974, as amended ("ERISA"); the Workers Adjustment and Retraining Notification Act; the California Fair Employment and Housing Act (if applicable); the provisions of the California Labor Code (if applicable); the Equal Pay Act of 1963; and any similar law of any other state or governmental entity.

2. The parties agree to apply California law in interpreting the Release. Accordingly, I further waive any rights under Section 1542 of the Civil Code of the State of California or any similar state statute. Section 1542 states:

> **"A general release does not extend to claims which the creditor or releasing party does not know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party."**

This Release does not extend to, and has no effect upon, (a) any benefits that have previously accrued, and to which I have become vested or otherwise entitled to, under any agreement, benefit plan, program or policy sponsored or maintained by the Company; (b) my right to indemnification and/or contribution, advancement or payment of related expenses by the Company under any written indemnification or other agreement between the parties; (c) my right to continued coverage by the Company's director's and officer's insurance, other insurance

policies of the Company, COBRA or any similar state law; (d) any claims for breach of this Release or the Agreement; (d) any claims that may not be released by private agreement; and (f) any claims arising after the date I sign the Release.

3. In understanding the terms of the Release and my rights, I have been advised to consult with an attorney of my choice prior to executing the Release. I understand that nothing in the Release will prohibit me from exercising legal rights that are, as a matter of law, not subject to waiver, such as: (a) my rights under applicable workers' compensation laws; (b) my right, if any, to seek state disability or unemployment benefits; (c) my right to indemnity under California Labor Code Section 2802 or other applicable state-law right to indemnity; (d) my right to file a charge or complaint with a government agency such as but not limited to the Equal Employment Opportunity Commission, the National Labor Relations Board, the Department of Labor, the California Department of Fair Employment and Housing, or other applicable state agency; and (e) my right to communicate or cooperate with any governmental agency and to receive awards from or by a government agency for providing information. Moreover, I will continue to be indemnified for my actions taken while employed by or providing services to the Company to the same extent as other then-current or former directors and officers of the Company under the Company's Certificate of Incorporation and Bylaws and the Indemnification Agreement between me and the Company, if any, and I will continue to be covered by the Company's directors and officers liability insurance policy as in effect from time to time to the same extent as are other then-current or former directors and officers of the Company, each subject to the requirements of the laws of the State of Delaware.

4. I understand and agree that Company will not provide me with the Termination Benefits unless I execute the Release. I also understand that I have received or will receive, regardless of the execution of the Release, all wages owed to me together with any accrued but unused paid time off, less applicable withholdings and deductions, earned through my termination date.

5. In my existing and continuing obligations to Company, I have returned to Company all Company documents (and all copies thereof) and other Company property that I have had in my possession at any time, including but not limited to Company files, notes, drawings, records, business plans and forecasts, financial information, specification, computer-recorded information, tangible property (including, but not limited to, computers, laptops, pagers, etc.), credit cards, entry cards, identification badges and keys and any materials of any kind which contain or embody any proprietary or confidential information of Company (and all reproductions thereof). I understand that, even if I did not sign the Release, I am still bound by any and all confidential/proprietary/trade secret information, non-disclosure and inventions assignment agreement(s) signed by me in connection with my employment with Company, or with a predecessor or successor of Company pursuant to the terms of such agreement(s).

6. I represent and warrant that I am the sole owner of all claims relating to my employment or service with Company and/or with any predecessor of Company and that I have not assigned or transferred any claims relating to my employment or service to any other person or entity.

7. I agree to keep the Termination Benefits and the provisions of the Release confidential and not to reveal its contents to anyone except my lawyer, my accountant, my spouse or other immediate family member and/or my financial consultant, or as required by legal process

or applicable law or otherwise responding accurately and fully to any question, inquiry or request for information or documents, including, without limitation, in any criminal, civil, or regulatory proceeding or investigation, or as necessary in any action for enforcement or claimed breach of this Release or any other legal dispute with the Company. Nothing in this Agreement shall prohibit me from reporting or disclosing information under the terms of the Company's Reporting Suspected Violations of Law Policy or such similar policy as the Company may have in effect from time to time.

8. I understand and agree that the Release will not be construed at any time as an admission of liability or wrongdoing by either the Company Releasees or me.

9. I agree that I will not make any negative or disparaging statements or comments, either as fact or as opinion, about the Company, its employees, officers, directors, shareholders, vendors, products or services, business, technologies, market position or performance. The Company agrees that it shall not, and shall cause its directors, executive officers, employees and representatives not to, make any negative or disparaging statements or comments, either as fact or as opinion, about you. Nothing in this paragraph will prohibit me or the Company from providing truthful information in response to a subpoena or other legal process.

10. Any controversy or claim arising out of or relating this Release, its enforcement or interpretation, or because of an alleged breach, default or misrepresentation in connection with any of its provisions, will be submitted to arbitration consistent with the terms of the Agreement.

11. As a condition of my receipt of the Termination Benefits, I agree that, upon reasonable notice (after taking into account, to the extent reasonably practicable, my other personal and business commitments) and without the necessity of Company obtaining a subpoena or court order, I will provide reasonable cooperation to Company in connection with any suit, action or proceeding (or any appeal from any suit, action or proceeding), or the decision to commence on behalf of the Company any suit, action or proceeding, any investigation and/or any defense of any claims asserted against the Company or any of the Company's current or former directors, officers, employees, partners, stockholders, agents or representatives of any of the foregoing, and any ongoing or future investigation or dispute or claim of any kind involving the Company that relates to events occurring during my employment or service as to which I may have relevant information and any other matter for which I was responsible or had knowledge of through date of my termination of employment or service. Such cooperation may include, but will not be limited to, providing background information within my knowledge; aiding in the drafting of declarations; executing declarations or similar documents; testifying or otherwise appearing at investigation interviews, depositions, arbitrations or court hearings; and preparing for the above-described or similar activities. Upon the reasonable request of Company, I agree to cooperate with the transition of my job responsibilities on any termination of service and cooperate in providing information on matters on which I was involved while an employee or member of the Board.

12. As provided in the Older Workers Benefit Protection Act, I am hereby advised and agree that:

(a) I have had at least twenty-one (21) calendar days in which to consider whether to execute the Release, no one hurried me into executing the Release during that period and no one coerced me into executing the Release. If I signed this Release prior to the expiration

of the twenty-one (21) day period, I did so voluntarily and waive the balance of the twenty-one (21) day period. I understand that the offer of the Termination Benefits and the Release will expire on the twenty-second (22nd) calendar day after my termination date if I have not accepted it by that time.

(b) I am hereby advised to consult with a lawyer before signing this Agreement.

(c) This Release provides for consideration in addition to any amount I am otherwise entitled to receive without signing this Release.

(d) This Release does not release any claims arising out of events occurring after I sign this Release

(e) I may revoke this Agreement within the seven (7) day period following the date on which I signed this Release. I understand that if I revoke this release, the Company will not be obligated to provide the Termination Benefits. I further understand that Company's obligations under the Release will not become effective or enforceable until the eighth (8th) calendar day after the date I sign the Release provided that I have timely delivered it to Company (the "Release Effective Date") and have not timely revoked it. I understand that the Termination Benefits will become available to me at such time after the Release Effective Date.

13. In executing the Release, I acknowledge that I have not relied upon any statement made by Company, or any of its representatives or employees, with regard to the Release unless the representation is specifically included herein. Furthermore, the Release contains our entire understanding regarding eligibility for Termination Benefits and supersedes any or all prior representations and agreements regarding the subject matter of the Release. However, the Release does not modify, amend or supersede written Company agreements that are consistent with enforceable provisions of the Release such as the Agreement, my confidential information and invention assignment agreement, and any stock, stock option and/or stock purchase agreements between Company and me. Once effective and enforceable, this Release can be changed only by another written agreement signed by me and an authorized representative of Company.

14. Should any provision of the Release be determined by an arbitrator, court of competent jurisdiction or government agency to be wholly or partially invalid or unenforceable, the legality, validity and enforceability of the remaining parts, terms or provisions are intended to remain in full force and effect. Specifically, should a court, arbitrator or agency conclude that a particular claim may not be released as a matter of law, it is the intention of the parties that the general release and the waiver of unknown claims above will otherwise remain effective to release any and all other claims. I acknowledge that I have obtained sufficient information to intelligently exercise my own judgment regarding the terms of the Release before executing the Release.

15. The Termination Benefits provided and to be provided to me by the Company consist of the applicable benefits and payments in accordance with the Agreement.

16. The Release may be executed in any number of counterparts, all of which taken together shall constitute one instrument. Execution and delivery of the Release by facsimile or other electronic signature is legal, valid and binding for all purposes.

17. The Release will be governed by and enforced under California law, without regard to its conflict of law rules that would result in the application of the laws of any other jurisdiction.

[Signature page follows]

ACCEPTANCE OF RELEASE

BEFORE SIGNING MY NAME TO THE RELEASE, I STATE THE FOLLOWING: I HAVE READ THE RELEASE, I UNDERSTAND IT AND I KNOW THAT I AM GIVING UP IMPORTANT RIGHTS. I HAVE OBTAINED SUFFICIENT INFORMATION TO INTELLIGENTLY EXERCISE MY OWN JUDGMENT. I HAVE BEEN ADVISED THAT I SHOULD CONSULT WITH AN ATTORNEY BEFORE SIGNING IT, AND I HAVE SIGNED THE RELEASE KNOWINGLY AND VOLUNTARILY.

EFFECTIVE UPON EXECUTION BY THE UNDERSIGNED AND THE COMPANY.

Executed this ____ day of _____, 20__

_____

Agreed and Accepted:

Gossamer Bio Services, Inc.

_____
By:
Title:
Date:

Gossamer Bio, Inc.

_____
By:
Title:
Date:

Exhibit B

Proprietary Information and Inventions Assignment Agreement

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-237639) of Gossamer Bio, Inc., and
(2) Registration Statement (Form S-8 No. 333-229586) pertaining to the 2017 Equity Incentive Plan, 2019 Incentive Award Plan, and 2019 Employee Stock Purchase Plan of Gossamer Bio, Inc.;

of our reports dated February 26, 2021, with respect to the consolidated financial statements of Gossamer Bio, Inc., and the effectiveness of internal control over financial reporting of Gossamer Bio, Inc. included in this Annual Report (Form 10-K) of Gossamer Bio, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

San Diego, California
February 26, 2021

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Faheem Hasnain, certify that:

1. I have reviewed this annual report on Form 10-K of Gossamer Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2021

/s/ Faheem Hasnain

Faheem Hasnain
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Bryan Giraudo, certify that:

1. I have reviewed this annual report on Form 10-K of Gossamer Bio, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2021

/s/ Bryan Giraudo

Bryan Giraudo
Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Gossamer Bio, Inc. (the "Company") hereby certifies, to his knowledge, that:

(i) the accompanying Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Faheem Hasnain

Faheem Hasnain
President and Chief Executive Officer

Date: February 26, 2021

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Gossamer Bio, Inc. (the "Company") hereby certifies, to his knowledge, that:

(i) the accompanying Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Bryan Giraudo

Bryan Giraudo
Chief Financial Officer

Date: February 26, 2021

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.